



Kaleida Health

# Kaleida Health Research Associate Orientation Manual



## **Research Associate Orientation Manual**

**Attestation\***

**Infection Control Policy**

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**Corporate Compliance and HIPAA**

**Language Assistance Services**

**Request for Laboratory Support**

\*Signed Attestation must be returned to Danni Zhang, Clinical Regulatory Administrator, at

[dxzhang@kaleidahealth.org](mailto:dxzhang@kaleidahealth.org)



# KALEIDA HEALTH

## Attestation Form

### Orientation for Research Associate

I hereby certify that I have listened to and/or read and understand the Kaleida Health Orientation information. I understand that I am required to comply with all Kaleida Health policies, rules and regulations. I understand that if this attestation is found to be false or untrue, the provision of any false or misleading information on this form may subject me to disciplinary action up to and including dismissal or termination of my privileges.

I agree to conduct myself in a professional manner at all times while on the Kaleida Health campus and will support the hospital's mission and vision of providing excellence in health care.

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Name (Please Print)

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Signature

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Date

RETURN COMPLETED ATTESTATION TO:

Danni Zhang, Clinical Regulatory Administrator  
dxzhang@kaleidahealth.org

## INFECTION PREVENTION

The Infection Prevention program at Kaleida Health is a shared responsibility of all system members. For each person who works at Kaleida Health, there is an expectation that they will do whatever they can to prevent the transmission of infections from one patient to another, from a patient to a health care worker, and between and among colleagues. Several important pieces of information are presented in this booklet; however, you have the responsibility to explore further to make sure you take all the necessary steps to fulfill your obligation.

**INFECTION PREVENTION** - The Infection Prevention Policies can be found on KaleidaScope. Ask your manager to show you how to locate and review the index. You will find policies covering employee health, tuberculosis control, exposure control and department specific Infection Prevention policies. There is also an Infection Prevention website link on the home page of KaleidaScope. Multiple resources can be found within the website including a link to the policies, newsletters, names and contact information of Infection Preventionists, and transmission based precautions information.

**EMPLOYEE HEALTH** - Each employee must have an initial health assessment, which includes review of immunizations against rubella, measles and mumps, and a purified protein derivative (PPD) tuberculosis skin test. If the required immunization documentation is not present, you will be offered immunizations through Employee Health. New York State requires that all employees and volunteers at the hospital/health care facilities have a reassessment of their health status (after their pre-placement physical) no less than annually to ensure a health impairment would neither pose a risk to patients nor interfere with the performance of his/her duties. Kaleida Health will provide an Annual Health Assessment each year through Employee Health at no charge to personnel or volunteers. .

**HAND HYGIENE** – (refer to [policy IC.05](#) Hand Hygiene) is defined as using an alcohol based hand rub (ABHR) and rubbing all surfaces of the hands until dry; or washing hands with soap and water scrubbing all surfaces of the hands with friction for 20 seconds. If hands and other skin surfaces are visibly soiled, hand hygiene with soap and water is required. Hand hygiene must be performed before entering a patient room, before touching a patient, before clean/aseptic procedures, after body/fluid exposures/risk, after touching a patient, and after touching a patient surroundings.

### Basic Hand Hygiene (soap and water)

Procedure	Rationale
1. If faucets are foot controlled, use control to get a gentle flow of water. Water should not be too hot. If hand (wrist) faucets are used, leave water running the entire procedure.	<ul style="list-style-type: none"> <li>• To prevent splashing.</li> <li>• To prevent skin irritation.</li> </ul>
2. Wet hands thoroughly, holding them downward over the sink.	<ul style="list-style-type: none"> <li>• To enable water to run towards the fingertips.</li> </ul>

Procedure	Rationale
3. Apply adequate soap. Hospital approved soap is available on all clinical units.	<ul style="list-style-type: none"> <li>• To decrease contamination.</li> <li>• To prevent skin irritation.</li> </ul>
4. Wash hands for at least 20 seconds using firm rotary and friction action. Scrub each hand with the other, front and back surfaces, between the fingers and under fingernails. Brushes are not recommended for routine handwashing.	<ul style="list-style-type: none"> <li>• Friction removes microorganisms from the hands mechanically.</li> </ul>
5. Rinse hands thoroughly by holding under running water.	<ul style="list-style-type: none"> <li>• Soap left on the hands may cause chapping.</li> </ul>
6. Dry hands well using a paper towel to dry hands first, then forearms.	<ul style="list-style-type: none"> <li>• To prevent skin irritation.</li> </ul>
7. If hand faucets are used, use a paper towel over the faucet as a barrier and turn off the water.	<ul style="list-style-type: none"> <li>• This prevents recontamination of the hands.</li> </ul>

Health care workers will routinely use appropriate barriers, including gloves and other **personal protective equipment (PPE)**, to prevent skin and mucous membrane exposure when contact with blood, body fluids, excretions, secretions, non-intact skin and mucous membranes is anticipated.

Gloves, protective fluid resistant gowns, masks and protective eyewear are provided for healthcare workers. PPE (gowns, gloves, masks, etc.) **must be removed prior to leaving the immediate work area to prevent contamination beyond the work area.**

Gowns, masks and protective eyewear are to be worn during procedures or activities that are likely to generate splashing of blood and other body fluids to prevent exposure of the mouth, nose and eyes.

**Respiratory hygiene/cough etiquette** includes covering the mouth and nose during coughing/sneezing with a tissue, coughing into the elbow instead of the hands or offering a surgical mask to the coughing patient, discarding the mask or tissue appropriately and performing hand hygiene.

Expanded mask or other PPE requirements may be instituted during times of highly infectious emerging pathogens such as COVID-19.

## APPROACH TO PATIENT CARE REGARDING INFECTION CONTROL

There are basically two approaches to infection prevention used for patient care within Kaleida Health. Standard Precautions and Transmission-Based Precautions (Refer to [Policy IC.12](#)) work together to provide mechanisms for protecting health care workers and patients from exposure to infectious agents.

1. **Standard Precautions** is designed to reduce the risk of transmission of micro-organisms from both recognized and unrecognized sources of infection. This is used for every patient and applies to all contact with blood, all body fluids, secretions and excretions regardless of whether or not they contain visible blood, This involves the use of basic infection control measures.
2. **Transmission Based Precautions of Contact, Droplet, Contact/Droplet and Airborne** are always used in addition to Standard Precautions and implementation is dependent upon the mode of transmission of the specific pathogen. Transmission Based Precautions are used when specific communicable diseases or pathogens are suspected or identified. They are designed to contain highly transmissible agents. Transmission Based Precautions will be initiated by the Infection Preventionist, Provider, or Nursing staff. All personnel are responsible for complying with these precautions.
  - **Contact Precautions** – Use Contact Precautions for patients with known or suspected infections or evidence of syndromes that represent an increased risk for direct or indirect contact transmission. Contact Precautions will be used for diseases transmitted by contact with the patient or the patient’s environment. A patient will be placed in a single/private room or cohorted under the direction of the Infection Preventionist. The appropriate hospital approved sign will be posted prominently outside the room on or near the door. Gowns and non-sterile gloves are required upon entry into the room. If the organism is C-diff, norovirus, diarrheal illness or candida auris, a hospital approved bleach-based disinfectant must be used for equipment and environmental cleaning. Remove gown and gloves immediately prior to leaving the patient room and always perform hand hygiene,
  - **Droplet Precautions** - Use Droplet Precautions to prevent transmission of diseases caused by respiratory droplets that are generated by coughing, sneezing crying, laughing, singing or talking. Droplet transmission involves contact of the mucous membranes of the nose, mouth or conjunctivae of a susceptible person with large-particle droplets. These droplets, (because of their larger size) travel short distances (up to 6 feet) before dropping to the ground. Wear surgical/procedure mask upon entry into the patient room. Eye protection must be worn when working closely with the patient or performing cough inducing procedures (suctioning, respiratory treatments). Use additional PPE as necessary, consistent with Standard Precautions.
  - **Contact/Droplet Precautions** – Use Contact/Droplet Precautions for patients known or suspected to be infection with infectious agents that may be transmitted person to person by both contact and droplet routes. Follow all recommendations as written above for both Contact and Droplet Precautions. Contact/Droplet signage should be posted prominently outside the room on or near the patient door.
  - **Airborne Precautions** - Use Airborne Precautions for patients known or suspected to be infected with infectious agents that are transmitted person to person by the airborne route. These organisms remain suspended in the air and travel great

distances due to their small size (less than 5 um). The patient will be placed in a Negative Air Pressure room which will be monitored daily by Plant Operations. The door to the patient room must remain closed to maintain negative pressure compliance. Anyone entering the room will need to be fit tested for a N-95 mask to be used whenever entering the room, or use a Powered Air Purifying Respiratory (PAPR). Airborne Precautions signage should be posted prominently outside the room on or near the patient door. Use additional PPE as necessary, consistent with Standard Precautions. Personnel restrictions will apply to susceptible healthcare personnel on entering the room of patients known or suspected to have measles (rubeola), varicella (chicken pox), disseminated herpes zoster or small pox if other immune personnel are available.

#### **TUBERCULOSIS (TB) CONTROL** (refer to [policy IC.09](#))

- Is dependent upon early identification and treatment of patients with suspected or confirmed TB disease. Effective isolation of patients with suspected or confirmed infectious TB is the primary protection against the spread of TB to other patients and staff.
- Strict adherence to Transmission Based Precautions policy
- Adequate environmental control
- Compliance with employee PPD skin testing and risk assessment
- Cooperation with state and county health departments, including prompt case reporting, reporting healthcare acquired transmission, and coordination of treatment and follow-up
- Exposure Testing: Conducted by Employee Health

Additional testing will be conducted for employees who are exposed to infectious TB patients for whom adequate control measures had not been taken.

Testing: Quantiferon or an initial skin test and if that is negative, a repeat skin test in 12 weeks. (A negative skin test, within the previous 3 months, will satisfy the initial skin test requirement and will only require the repeat 12 weeks post exposure.). Employees with previously known positive TST reaction, who have been exposed to an infectious patient will be evaluated for signs of active TB infection; a chest X-ray is not indicated unless there is a question of active disease. Persons with a positive Quantiferon or skin test reaction equal to or greater than 5mm induration **or** with symptoms suggestive of active TB will receive a chest X-ray.

#### **BLOODBORNE PATHOGENS** (refer to [Policy IC.22](#) Exposure Control Plan for Occupational Exposure to Bloodborne Pathogens)

It is the policy of Kaleida Health, ECMC and affiliates to comply in all respects with the standard promulgated by the Occupational Safety and Health Administration (OSHA), pursuant to Section 6 (b) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 655, for the purpose of eliminating or minimizing occupational exposure to the Hepatitis B virus (HBV), the Human Immunodeficiency Virus (HIV), the Hepatitis C virus (HCV) and other blood borne pathogens. All employees in job classifications with occupational exposure are required to comply.

Employees are categorized by risk of exposure to blood borne pathogens which requires the use of barriers when contact with body fluids is anticipated. Employees are referred to the Exposure Control Plan for task specific barrier requirements. Standard Precautions should be followed at all times.

**1. Category I**

Includes employees who perform tasks and procedures that involve an inherent potential for mucous membrane or skin contact with blood or other potentially infectious material

These employees perform tasks that involve direct patient contact.

Examples: Nurses, Patient Care Aides, Aides, Phlebotomists

**Category II**

Includes employees whose normal work routine does not involve direct patient contact, however, there is potential for contact with surfaces or items which may be contaminated with

Examples: Environmental Services, Bio-Medical Engineering, Laboratory, Central Processing

**Category III**

Employees whose tasks do not involve direct patient contact or the potential for exposure to

Examples: Admissions, Medical Records. Since medical history and examination cannot reliably identify all patients infected with Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), Hepatitis C (HCV) or other blood borne diseases, methods to prevent or minimize exposures to these diseases must be used consistently by all employees when in contact with ALL patients. Standard Precautions protects both employee and patient from all known pathogens except those transmitted via airborne route. Because it is the exposure to the blood or potentially infectious materials that carries the risk of infection, individuals whose occupational duties place those at risk of exposure to blood and OPIM are also at a risk of becoming infected with these blood borne pathogens and developing disease. Infected individuals are also capable of transmitting the pathogen to others.

Kaleida Health, ECMC and affiliates mandate that all employees determined to have occupational exposure to blood borne pathogens routinely use appropriate PPE when it is reasonably anticipated that skin, eye, mucous membrane or parenteral contact with blood or OPIM may result from the performance of an employee's duties.

Kaleida Health, as per OSHA 1910.1030 and 1910.141, is aware that hospital staff work in an environment which when in clinical areas, have the potential for exposure to contaminated surfaces where infectious pathogens are present. These contaminants pose infection risk if an employee ingests food or drink which has been in contact with these surfaces.

**\*\*Key point:** Food and beverages may not be consumed while delivering patient care.



**The following areas are designated as appropriate for food and beverage consumption if patient care equipment is not stored in this area:**

Cafeteria, Conference Rooms, Staff Lounge, Offices not located within clinical areas,  
Resident work rooms

**Food and beverages are prohibited in the following areas:**

Radiology Control Room Area, WOW's (Workstations on Wheels), Medication  
Carts/Room, Soiled/Clean Utility Rooms, Patient Rooms, Treatment Rooms, Holding areas

Each unit/clinical department will conduct a risk assessment with Infection Prevention to determine areas where covered beverages would be permitted if no risk of cross-contamination is possible.

The general public is at risk of exposure through sexual contact, sharing of needles among IV drug users, transfusion or transplant tissues, and from mother to infant in-utero or when breast feeding.

The risk of acquiring an infectious agent as the result of a blood-contaminated needle stick varies with each agent, type of injury, and amount of virus circulating in the source patient's bloodstream.

To protect employees from infection caused by blood borne pathogens, Kaleida Health offers the Hepatitis B Vaccine to all employees covered under the Exposure Control Plan and has established a post-exposure prophylaxis and follow-up program. This program is initiated if during the performance of job duties, an employee sustains a specific eye, mouth, other mucous membrane, non-intact skin or parenteral exposure to blood or other potentially infectious material. Both the HBV vaccination and post-exposure program are:

- a. Made available at no cost to the employee at a reasonable time and place.
- b. Performed by or under the supervision of a licensed physician or licensed healthcare professional in conjunction with an accredited laboratory.
- c. In accordance with current recommendations of the US Public Health Service (USPHS).

**Hepatitis B Vaccination** – (refer to Employee Health Policy for specific details) will be offered to the employee after the employee receives specific education that includes information of the HBV vaccine, its safety, efficacy and methods of administration as well as the benefits of being vaccinated. The vaccine will be given within ten (10) working days of initial assignment unless:

- a. The employee has previously received the complete HBV vaccination series.
- b. The employee demonstrates antibody level indicating immunity to HBV (pre-screening prior to administration of HBV vaccine is not required).
- c. Medical evaluation of the employee indicates that the vaccine is contraindicated for medical reason.

Participation in the program is voluntary and informed consent is required. However, those employees desiring **not** to receive the vaccine, must sign a declination statement. If at a future

time, the employee changes his/her mind and decides to receive the vaccine it will be provided in accordance with this plan (refer to Employee Health – Hepatitis B Vaccination Policy).

**Post Exposure Prophylaxis and Follow-Up** (Refer to Employee Health or Emergency Department for specific details).

1. Whenever an incident occurs resulting in employee exposure to blood or potentially infectious materials as previously described, the employee must report **immediately** to his/her supervisor for initiation of a confidential medical evaluation, incident report and follow-up. If the employee's immediate supervisor is unavailable or not on duty at that time, the employee must report to the Nursing Supervisor on duty at that time. After documentation of the route(s) of exposure and the circumstances under which the exposure occurred, the exposed employee will be directed to report to the Emergency Department for initial evaluation and follow-up which will include the following:
  - a. Identification and documentation of the source individual, if feasible, and collection and testing of this individual's blood for HBV, HCV and HIV, as soon as possible, if not already known, in order to provide the exposed employee with information that will assist him/her in making decisions regarding the testing of their own blood, complying with other elements of post-exposure management, and using precautions to prevent possible transmission of disease to others. The exposed employee will be informed of the NYS Confidentiality Law which prohibits disclosure to other persons of the identity and infectious state of the source individual.
  - b. Collection and testing of blood from the exposed employee, for HBV serologic status and after informed consent, HIV serologic testing. This baseline information can then be compared to future test results in order to determine if the exposed employee consents to baseline blood collection after an exposure incident but does not give consent for HIV serologic testing at that time, the sample will be preserved for 90 days in case the employee elects to have this testing done at a later time.
  - c. Counseling to assist the exposed employee in understanding the potential risk of infection and making decisions regarding prophylaxis and precautions necessary to protect personal contacts.
  - d. Post-exposure prophylaxis, when medically indicated, in accordance with current recommendations i.e. HBV vaccine, HBIG and antiretroviral prophylaxis.
2. A written copy of the evaluating healthcare professional's written opinion will be provided to the employee within 15 days of the completion of the evaluation, and shall be limited to stating that the employee has been informed of the results of the evaluation and any medical conditions resulting from exposure to blood or OPIM which require further evaluation and treatment. A copy of this written opinion will be maintained in the employee's medical record and may be utilized by OSHA or administration to assess compliance with this plan. However, all other findings or diagnoses will remain confidential, will not be included in the written opinion, or be available for review.

## EMPLOYEE TRAINING

Kaleida Health mandates that all employees with occupational exposure participate in an updated training program about the hazards associated with blood and other potential infectious material and the protective measures to be taken to minimize the risk of occupational exposure. This program will be provided free of charge during working hours and contain material appropriate in content and vocabulary to the educational level, literacy, and language of employees. This program will be conducted at the time of initial assignment when job categories are changed or anytime at the request of the employee and will include:

1. A copy of the OSHA blood borne pathogen standard pgs. 64175-64182 and an explanation of its contents.
2. A general explanation of the epidemiology and symptoms of blood borne diseases.
3. An explanation of the modes of transmission of blood borne pathogens.
4. An explanation of the Kaleida Health Exposure Control Plan and reference to its location within the Infection Control Manual on-line.
5. An explanation of how the employee can recognize tasks/procedures that may involve exposure to blood or other potential infectious material so that appropriate precautions can be taken.
6. An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices and PPE.
7. Information on the types, proper use, location, removal, handling, decontamination and disposal of PPE.
8. An explanation of the basis for selection of PPE.
9. Information on the Hepatitis B Vaccine, including its efficacy, safety, method of administration, benefits of being vaccinated, and the fact that the vaccine and vaccination will be offered free of charge.
10. Information on the appropriate action to take and persons to contact in an emergency involving blood or other potential infectious material
11. An explanation of the procedure to follow if an exposure incident occurs including the method of reporting the incident and medical follow-up that will be made available.
12. Information on the post-exposure evaluation and follow-up that Kaleida Health is required to provide following an exposure incident.
13. An explanation of Hazard Communication tools used at Kaleida Health (signs, labels, color-coding).
14. An opportunity for interactive questions and answers with the person(s) conducting the training session.
15. **Annual updates** will include any new or changed information and a brief review of the OSHA Blood borne Pathogen Rule.

# COVID-19 Mask and PPE Guidelines

## COVID-19 Policy and Guideline Changes Effective January 3, 2023

As we adapt to the evolving regulations of the ongoing pandemic, there are several key changes to Kaleida Health's COVID-19 policies and guidelines. These changes have been reviewed and approved by our infection prevention team and infectious disease leadership team.

## Masking

- All personnel, regardless of vaccination status, in a healthcare setting (i.e., facilities or entities regulated under Articles 28, 36 and 40 of the Public Health Law) must wear an appropriate face mask when they are in areas of the healthcare facility where they could encounter patients (e.g., patient rooms, hallways, lobbies, elevators, etc.)
  - Article 28 facilities include all hospitals, long-term care facilities, DeGraff Medical Park, all ambulatory surgery centers, Spindrift Infusion Center, Kensington OB/GYN, Niagara Street OB/GYN, Broadway Pediatrics, Niagara Street Pediatrics, Hertel-Elmwood Internal Medicine Center, Family Planning Center, school-based health centers, Buffalo Therapy Services, Diabetes-Endocrinology Center of WNY and any other Kaleida Health-operated clinics (including Kaleida Health clinics within Oishei Children's Outpatient Center)
  - Personnel could choose not to wear face masks when they are in well-defined areas that are restricted from patient access (e.g., staff meeting rooms, break rooms) if community transmission levels are not defined as "high" according to CDC guidelines
  - When community levels are "high," masking is required at all times in all areas
- Personnel in facilities that are not regulated under Article 28, 36 and 40 of the Public Health Law, such as Larkin, Kaleida Health Laboratories (Flint Road and Blood Draw Centers) and the adult day care, are no longer required to wear masks. Masking is still highly recommended when community levels are high
- A mask can be obtained at the screening stations upon entry to the facility daily. Additional masks will be available
- when masks are required to be replaced following extended use criteria
- Cloth masks are not to be worn since they do not provide filtration and tend to become damp quickly

## N95 Respirator Guidelines

- Any healthcare worker can obtain an N95 upon request.
- Staff using N95 respirators in designated areas must be fit tested on the specific respirator being used
- Staff should ONLY wear the N95 respirator style that they have been fit tested for and should not wear any other type of N95

# Eye Protection (Goggle and Face Shield) Guidelines

Kaleida Health strongly recommends universal use of eye protection by healthcare personnel for all patient interactions as

Per Standard and Transmission based Precautions.

Wearing both face masks and eye protection provides better protection for healthcare personnel who might unknowingly encounter asymptomatic, pre-symptomatic, or symptomatic but undiagnosed patients/residents with COVID-19.


Eye protection is required for any potential splash or spray and for all patients on Droplet or Contact/Droplet precautions.

Eye protection should be cleaned and disinfected per Kaleida Health recommendations.

## Other Important Points

All employees should be self-monitoring for symptoms. Stay home if you are ill. If you develop symptoms (fever over 100.0, cough or shortness of breath, loss of taste or smell, vomiting, diarrhea), the employee should stop working, isolate, and get tested for COVID-19.

[For further information about COVID 19, please go to Kaleidascope](#)

 <b>Kaleida Health</b> <b>POLICY</b>	<b>Title: Use and Disclosure of Protected Health Information for Research Purposes</b>	<b># ORSP.6</b>
	<b>Owner:</b> Research and Sponsored Projects	<b>Issued:</b> 8/9/10
<b>Keywords:</b> research, PHI		

**I. Statement of Purpose**

It is the policy of Kaleida Health to support research activities that have scientific merit and are compliant with all statutes and regulations pertaining to the release of Protected Health Information (PHI) and access to patient medical records.

Protected Health Information (PHI) obtained by Kaleida Health may not be used internally or disclosed to any persons or organizations outside Kaleida Health for research purposes without the prior approval of the Kaleida Health Department of Research and Sponsored Projects ("Research Office"). All requests for access to PHI for research purposes must be made and reviewed in accordance with the procedures explained below.

**II. Audience**

Medical Staff, hospital and nursing home staff including employees, students, interns, fellows, residents and volunteers. Consultants, contractors and vendors of Kaleida Health, as applicable

**III. Instructions – (Outline necessary steps for consistent completion of process/ procedure)**

**A. Definitions**

1. **Research.** Research includes any systematic investigation (including research development, testing, and evaluation) that has as its primary purpose the development of or contribution to *generalizable knowledge*. This includes the development of research repositories and databases for research.
2. **Generalizable Knowledge.** Knowledge may be generalizable even if a research study only uses PHI held within Kaleida Health and the results are generalizable only to the population served by Kaleida Health. Research is not limited to clinical trials funded by government sponsors (such as the National Institutes of Health) or commercial sponsors. Quality assurance and utilization management activities do not typically result in generalizable knowledge and thus ordinarily would not be governed by this policy.
3. **Principal Investigator.** The individual responsible for the scientific, technical, and administrative aspects of the project (e.g. for NIH-funded research, the person named at Item 3a, Form PHS 398).
4. **De-Identified Information.** Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.
5. **Limited Data Set.** A limited data set is protected health information that excludes 18 direct identifiers of an individual or of relatives, employers or household members of such individual, as specified in the HIPAA Privacy Rule at 45 CFR §164.514(e)(1).
6. **Kaleida Health Workforce.** The Kaleida Health Workforce refers to Medical Staff members, who have been credentialed by the Kaleida Health Medical Staff

Office and granted active privileges, Research Associates who have been credentialed by the Legal Department and granted privileges, Kaleida Health Employees, nursing home employees, and students, interns, residents, and volunteers.

7. **External Researcher.** Any individual who is not a member of the Kaleida Health Workforce and performs activities defined in this policy as Research.
8. **HIPAA.** The Health Insurance Portability and Accountability Act, 45 CFR Part 160 and Subparts A and E of Part 164.
9. **HIPAA Authorization.** HIPAA Authorization is required by the HIPAA Privacy Rule for uses and disclosures of protected health information not otherwise allowed by the Rule. Where the Privacy Rule requires patient authorization, voluntary consent is not sufficient to permit a use or disclosure of protected health information unless it also satisfies the requirements of a valid authorization. An authorization is a detailed document that gives covered entities permission to use protected health information for specific purposes, which are generally other than treatment, payment, or health care operations, or to disclose protected health information to a third party specified by the individual.

An authorization must specify a number of elements, including a description of the protected health information to be used and disclosed, the person authorized to make the use or disclosure, the person to whom the covered entity may make the disclosure, an expiration date, and, in some cases, the purpose for which the information may be used or disclosed. With limited exceptions, covered entities may not condition treatment or coverage on the individual providing an authorization.

## B. Use and Disclosure of PHI for Research

### 1. General Rule

- a. Certain requirements apply to the use and disclosure of PHI in connection with all research involving human subjects. As a general rule, the Research Office may *not* authorize the use or disclosure of PHI for research purposes except:
  - 1) For reviews preparatory to research;
  - 2) For research on the PHI of a decedent;
  - 3) If the Principal Investigator for a study has obtained the informed consent of the individual to participate in the research, or a waiver of such informed consent, prior to April 14, 2003 (this exception ceases to apply if informed consent is sought from the individual after April 14, 2003);
  - 4) If the information is “completely de-identified”;
  - 5) If the information is partially de-identified into a “limited data set” and the recipient of the information signs a “data use agreement” to protect the privacy of such information;
  - 6) If the Principal Investigator has obtained a valid authorization from the individual subject of the information; or

- 7) If an Institutional Review Board (an “IRB”) or a Privacy Board approves a waiver of the individual authorization requirement.
- b. The specific requirements for each of these exceptions are discussed below. The Research Office must determine that one of the exceptions described above applies before permitting the use or disclosure of PHI for research purposes. *The Research Office should require either an individual authorization or a waiver of authorization if he or she has any doubt about whether any other exception is applicable.* All Kaleida Health research activities must also comply with other applicable hospital policies relating to research (such as policies addressing Common Rule and FDA requirements for research) and with any additional requirements that apply to the specific types of information identified below as having special rules. Finally, to the extent hospital employees and medical staff provide treatment to human subjects as part of a research study, they must follow other hospital policies to the extent those policies apply to the provision of health care to individuals. Any questions should be directed to the Kaleida Health Research Office.

## 2. **Special Rules for Sensitive Information**

Special rules apply to the use and/or disclosure for research purposes of the following types of information:

- a. Genetic tests and results from genetic tests;
- b. HIV-related information;
- c. Alcohol and substance abuse treatment information;
- d. Psychotherapy notes; and
- e. Mental health information.
- f. Additional information on research involving these types of information can be found in **Appendices D, E, F, G, and H**, respectively, of this policy.

## C. **Requirements for Each Exception**

The Research Office will **not** authorize the use or disclosure of PHI for research purposes unless at least one of the following exceptions applies:

### 1. **Reviews Preparatory to Research.**

- a. The Research Office may permit the use and disclosure of PHI to develop a research protocol or for similar purposes preparatory to research (e.g. to determine whether Kaleida Health has information about prospective research participants that would meet the eligibility criteria for enrollment in a research study). It is not necessary for a researcher to obtain patient authorization or an IRB waiver of authorization to conduct a review preparatory to research. In order to permit a use or disclosure of PHI under this exception, the Research Office must obtain representations from the Principal Investigator that:
  - 1) The use or disclosure is sought solely to prepare a research protocol or for similar purposes preparatory to research;
  - 2) No researcher will remove any PHI from Kaleida Health’s premises in the course of the review; and
  - 3) The PHI for which use or access is sought is necessary for the research purposes.
- b. **Appendix A** is a request for access form that contains the above representations and must be signed by researchers seeking access to PHI for preparatory reviews. This document must be signed by



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researchers for each review preparatory to research request and kept on file by the Research Office.

- c. Researchers should be aware that they are *not* permitted to continue to use or disclose the PHI once they have decided to go forward with the study. For example, using PHI obtained during a Review Preparatory to Research to contact eligible subjects for recruitment purposes would *not* be permitted by a Researcher under this exception ***unless they obtain a partial IRB waiver of authorization***. If the researcher is a member of the Workforce, a partial IRB waiver of authorization is not required for recruitment purposes but the researcher must contact the prospective subject's treating practitioner before contacting the patient about participation in a research study.

2. **Research on the PHI of a Decedent.**

The Research Office may permit the use and disclosure of the PHI of a decedent for research purposes. In order to permit such a use or disclosure, the Research Office must obtain representations from the Principal Investigator that the use or disclosure is sought *solely* for research on the PHI of a decedent (e.g. researchers may not request a decedent's medical history to obtain health information about a decedent's living relative) *and* that the information for which use or disclosure is sought is necessary for the research purposes. Moreover, the Principal Investigator must provide, at the Research Offices request, documentation of the death of any individuals about whom information is sought. **Appendix B** includes a request for access form that must be signed by researchers seeking to engage in research on the PHI of a decedent.

3. **Informed Consents or Waivers of Informed Consent Obtained Prior to April 14, 2003.**

The Research Office may approve the use or disclosure of PHI for a specific research project provided that one of the three following requirements is met:

- a. Express Legal Permission For Use And Disclosure Of PHI. If the researcher has obtained, prior to April 14, 2003, express legal permission from the individual that *specifically authorizes* a use or disclosure of PHI for purposes of the research project, the Research Office may permit such use or disclosure for purposes of that project. However, any restrictions on the use and disclosure of health information provided in such express legal permission must be honored.
- b. General Informed Consent. If the researcher has obtained, prior to April 14, 2003, the individual's *informed consent* to participate in a specific research project, the Research Office may permit a use or disclosure for purposes of that project even though the informed consent *does not* specifically authorize the use or disclosure of PHI for purposes of the research project. However, any restrictions on the use and disclosure of health information provided in such informed consent must be honored.
- c. Waiver Of Informed Consent. If the researcher has obtained, prior to April 14, 2003, an IRB waiver of the informed consent requirement (in accordance with the Common Rule) for a specific research project, the Research Office may permit a use or disclosure of the individual's PHI for purposes of that project.

4. **Completely De-identified Information.**

Kaleida Health does not have the ability to de-identify PHI for research purposes.

5. **Limited Data Set.**

- a. A limited data set ("LDS") is protected health information that **excludes** the following direct identifiers of the individual or of relatives, employers, or household members of the individual:
- 1) Names;
  - 2) Postal address information, **other than** town or city, State, and zip codes;
  - 3) Telephone numbers;
  - 4) Fax numbers;
  - 5) Electronic mail addresses;
  - 6) Social security numbers;
  - 7) Medical record numbers;
  - 8) Health plan beneficiary numbers;
  - 9) Account numbers;
  - 10) Certificate/license numbers;
  - 11) Vehicle identifiers and serial numbers, including license plate numbers;
  - 12) Device identifiers and serial numbers;
  - 13) Web Universal Resource Locators (URLs);
  - 14) Internet Protocol (IP) address numbers;
  - 15) Biometric identifiers, including finger and voice prints; and
  - 16) Full face photographic images and any comparable images.
- b. The Research Office may approve the disclosure of a LDS for research purposes, as permitted under 45 CFR §164.514(e)(1), provided that a data use agreement ("DUA") (see **Appendix I**) is executed between Kaleida Health and the LDS recipient.
- c. Protected Health Information may be disclosed to a third party for the purpose of creating a LDS on behalf of Kaleida Health provided that a Business Associate Agreement is executed between the third party and Kaleida Health

6. **Research Subject Signs HIPAA Authorization Research Form.**

- a. The Research Office will allow the use and disclosure of PHI pursuant to a properly completed and signed research study consent containing a HIPAA Authorization that has been approved by the Institutional Review Board ("IRB") of record for the study. Permissible uses and disclosures are limited to those described in the authorization, even though those permissible uses and disclosures may be more limited than what Kaleida Health's Notice of Privacy Practices describes.
- b. The IRB approved research study consent containing a HIPAA Authorization must be completed by the Principal Investigator for the research subject's review and signature. It is the responsibility of the Principal Investigator to ensure that the IRB approved research study consent containing a HIPAA Authorization covers the uses and disclosures necessary for the research study.
- c. If hospital staff or medical staff will provide any treatment to subjects on hospital premises in connection with the study, Kaleida Health or the treating provider must ensure that the signed research study consent

containing the HIPAA Authorization and a signed Consent for Treatment and Payment form (for the use and disclosure of PHI for treatment, payment and health care operations) is obtained from every research subject who does not already have one on file at Kaleida Health.

- d. When obtaining a research study consent, an individual's ability to receive research-related treatment as part of a research study may be conditioned upon the individual's agreement to sign the research study consent. However, in presenting the research study consent to prospective subjects, researchers should never suggest that failure to sign the consent will limit access to any treatment that may be available *outside* the study. Any questions about the availability of such treatment outside the study should be referred to the prospective research subject's physician(s).
- e. Any original documentation (except Kaleida Health's own forms) relied upon by the Research Office in connection with the disclosure of PHI for research purposes will be maintained by the Principal Investigator and will be made available to Kaleida Health upon request. Kaleida Health will maintain copies of all such documentation in its files.

**7. IRB or Privacy Board Approval of Waiver.**

The Research Office may allow the use and disclosure of PHI for research purposes if either an IRB or a committee sitting as a "Privacy Board" grants a partial or total waiver of the patient authorization requirement. The Research Office may rely on a request for disclosure made by a researcher pursuant to total or partial IRB waiver of authorization for purposes of the minimum necessary requirement.

- a. **Partial Waiver.** If the IRB or Privacy Board grants only a *partial waiver* – the Research Office must condition the use and/or disclosure of any PHI for research purposes on compliance with any authorization requirements not waived and as modified. For example, if an IRB grants a partial waiver of authorization to allow a researcher to obtain PHI to recruit potential research participants, the researcher would still have to obtain authorizations from the subjects to use or disclose PHI for the study itself.
- b. **Total Waiver.** The Research Office may only grant final approval of any requested uses or disclosures of PHI for research purposes pursuant to an IRB (or Privacy Board) waiver if the Research Office has received appropriate documentation of the waiver. Such documentation must include at least:
  - 1) The name of the IRB (not the names of individual members of the board);
  - 2) The date on which the waiver was approved;
  - 3) The signature of the IRB chair, or other member designated by the chair;
  - 4) A statement that the IRB has determined that the waiver satisfies the required criteria;

- 5) A brief description of the PHI that the IRB has determined is necessary for research purposes<sup>1</sup>; and
  - 6) A statement that the waiver has been reviewed and approved under either normal or expedited review procedures and that all applicable procedures were followed.
- c. If any such documentation is missing or inadequate, the Research Office will notify the Principal Investigator and will not approve the requested uses or disclosures until the documentation is complete.

**\*\*Keypoint:** A waiver of individual authorization under this policy is *not* a waiver of the requirements of informed consent for the project or of any other consent required by Kaleida Health's policies. The IRB may waive or alter informed consent requirements, but the IRB must review a request to waive or alter informed consent requirements *separately* under criteria set forth in the Common Rule.

**D. Release of Medical Records**

- 1. If the research subject's HIPAA Authorization or IRB waiver of authorization permits disclosure of the subject's *entire* medical record, the disclosure of such complete record will occur once the Research Office has reviewed the IRB approval letter and approved the disclosure.

If the research subject's authorization or IRB waiver authorizes disclosure of a *portion* of the subject's medical records, (i.e. only data relating to treatment of asthma), the research data set to be disclosed by Kaleida Health will be created by one of two mechanisms:

- a. If the researcher is a member of the Kaleida Health Workforce, he or she may extract the data on behalf of Kaleida Health and then disclose it to the researcher (i.e. to themselves). The Workforce member is responsible for ensuring that only the data approved by the IRB or IRB waiver of authorization is disclosed.
- b. If the researcher is not a member of the Workforce, the researcher must be credentialed as a Kaleida Health Research Associate.

**E. Individual Right to Access and Amend PHI/Temporary Suspension**

Individuals, including research subjects, generally have a right under HIPAA to access and amend their PHI maintained by Kaleida Health or its business associates. See Kaleida Health's Policy MR.14 - Release of Patient Protected Health Information. However, a research subject's right to access and to amend PHI created or obtained by Kaleida Health or any covered health care provider in the course of research that includes treatment may be temporarily suspended during the term of the research study if the research subject agreed to the denial of access/amendment when he or she signed an informed consent to participate in the research study, and if the research subject was advised in the informed consent documents that the right of access/amendment will be reinstated upon completion of the research study.

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<sup>1</sup> If the IRB approves only the use or disclosure of *certain information* from individuals' medical records, and not individuals' *entire* medical records, this must be stated on the document certifying IRB Board approval.

**F. Accounting of Disclosures made for Research Purposes**

The Research Office will maintain a list of research activities. The Health Information Management Department should consult with the Research Office to determine whether a patient's information has been used or disclosed for one or more of these research activities. If so, the Health Information Management Department should obtain from the Research Office, and include in the patient's accounting, a properly completed *Accounting for Disclosures for Research Activities Form* for each research activity (see **Appendix C** attached). If a patient requests further information about how to contact the researchers or research sponsors to whom the patient's information may have been disclosed, Health Information Department staff should refer the patient's request to the Research Office.

**G. Violations**

Kaleida Health's Research Office has general responsibility for implementation of this policy. Kaleida Health Workforce members who violate this policy will be subject to disciplinary action up to and including termination of employment or contract with Kaleida Health. Anyone who knows or has reason to believe that another person has violated this policy should report the matter promptly to his or her supervisor or Kaleida Health's Research Office. All reported matters will be investigated, and where appropriate, steps will be taken to remedy the situation. Where possible, Kaleida Health will make every effort to handle the reported matter confidentially. Any attempt to retaliate against a person for reporting a violation of this policy will itself be considered a violation of this policy that may result in disciplinary action up to and including termination of employment or contract with Kaleida Health.

**H. Questions**

Questions about this policy should be directed to the Research Office. It is important that all questions be resolved as soon as possible to ensure PHI is used and disclosed appropriately.

**I. Documentation**

The Research Office must retain any writings or documentation required by this policy for six years from the date of its creation or the date when it last was in effect, whichever is later.

**IV. Approved by - (Include date)**

Office of General Counsel	6/10, 5/18
Medical Executive Committee	6/16/10, 7/18/18
Board of Directors	8/2/10, 8/18

**V. References (Include evidence based research, Kaleida Health policy, and regulation as applicable)**

Federal: 45 CFR Part 164.512(i)

**Version History:**

Effective Date:	Reviewed/ Revised
8/13/18	Revised
7/18/16	Reviewed no changes
2/14	Reviewed no changes

<b>Title: Use and Disclosure of Protected Health Information for Research Purposes</b>	<b># ORSP.6</b>
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Kaleida Health developed these Policies, Standards of Practice, and Process Maps in conjunction with administrative and clinical departments. These documents were designed to aid the qualified health care team, hospital administration and staff in making clinical and non-clinical decisions about our patients' care and the environment and services we provide for our patients. These documents should not be construed as dictating exclusive courses of treatment and/or procedures. No one should view these documents and their bibliographic references as a final authority on patient care. Variations of these documents in practice may be warranted based on individual patient characteristics and unique clinical and non-clinical circumstances. Upon printing, this document will be valid for 2/12/2021 only. Please contact Taylor Healthcare regarding any associated forms.

## APPENDIX A

**REQUEST FOR ACCESS TO PROTECTED HEALTH INFORMATION (PHI)  
FOR A REVIEW PREPARATORY TO RESEARCH**

To the facility records department (or other site contact as designated by your HIPAA privacy officer): This is a request for PHI to conduct a review preparatory to research. HIPAA requires that each facility keep track of all records accessed as part of its requirement to account for disclosures of PHI. ***NB: No contact of potential research subjects is permitted as part of any review preparatory to research unless you are a member of the Kaleida Health Workforce. Workforce members must contact the potential subject's treating practitioner prior to any contact with potential subject.***

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Principal Investigator's Name

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Address  

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Phone

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FAX

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Email**Statement of the Principal Investigator**

*I affirm:*

- *That this request for access to PHI is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;*
- *That no PHI will be removed from the site that houses it in the course of the review;*
- *That no potential research subjects will be contacted as part of the review preparatory to research if I am not a member of the Kaleida Health Workforce; and*
- *That the PHI for which use or access is sought is necessary for research purposes.*

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Principal Investigator signature

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Date

1/27/05

## APPENDIX B

### REQUEST TO ACCESS PROTECTED HEALTH INFORMATION (PHI) TO PERFORM RESEARCH ON DECEDENTS

To the Kaleida Health site Health Information Management Department: This is a request for PHI to conduct research on decedents. HIPAA requires that each facility keep track of all records accessed as part of its requirement to account for disclosures of PHI under HIPAA. Your site may also impose additional restrictions on access to the PHI of decedents.

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Principal Investigator's Name

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Address

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Phone

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FAX

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Email

#### **Statement of the Principal Investigator**

*I affirm:*

- *That PHI is sought solely for research on decedents;*
- *That, at the request of the covered entity, documentation of the death of such individuals will be provided; and*
- *That the PHI for which use or disclosure is sought is necessary for research purposes.*

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Principal Investigator/signature

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Date

8/9/10



## **APPENDIX C**

### **Accounting for Disclosures for Research Activities**

#### **I. Information Required to be Recorded For Each Disclosure**

- A. Standard Accounting. The following information must be included in the Accounting Database found on Kaleidascope:
1. The date the disclosure was made
  2. The name and address of the person or entity receiving the PHI
  3. A brief description of the PHI disclosed
  4. A brief statement of the reason for the disclosure
- B. When a disclosure is made for research purposes for 50 or more individuals for the same research project, the following information must be included in the Accounting Database found on Kaleidascope:
1. The name of the protocol or other research activity;
  2. A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
  3. A brief description of the type of Protected Health Information that was disclosed
  4. The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;
  5. The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and
  6. A statement that the Protected Health Information of the individual may or may not have been disclosed for a particular protocol or other research activity.
- C. If the Covered Entity provides an accounting for research disclosure and if the Protected Health Information of the individual was disclosed for such research protocol or activity, Kaleida Health will, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

#### **II. Patient Requests for an Accounting.**

A patient may request an accounting at any time. Hospital staff and medical staff must therefore record all disclosures of information that could possibly be needed to respond to a patient's future request. Certain detailed information must be recorded for each disclosure. While the Health Information Department staff is responsible for making disclosures and recording their own disclosures, other medical and hospital staff members also make disclosures. This process therefore will require the participation of many hospital staff members and medical staff members in a wide range of departments within the hospital. Any hospital staff member or medical staff member who discloses a patient's Protected Health Information for research purposes must enter the required information in the Accounting Database found on KaleidaScope. Health Information Department staff should respond to a patient request for an accounting of disclosures in accordance with the procedures stated in Kaleida Health Policy MR.22 - Accounting of Disclosures.

## APPENDIX D

### USE AND DISCLOSURE OF GENETIC INFORMATION FOR RESEARCH PURPOSES

Special restrictions apply to (1) the genetic testing of human biological samples for research purposes by any hospital staff or on the hospital's premises, and (2) the disclosure of information derived from genetic tests to any person or organization. *In addition to* complying with the hospital's policy on *Use and Disclosure of PHI for Research Purposes*, the following requirements must be met:

**Testing of Human Biological Samples.** If a Research Authorization is obtained, the subject must also sign the hospital's "specific consent" form for genetic testing under NY Civil Rights Law § 79-l(2)(b). Otherwise, testing of human tissue for research is only permissible if *either*:

- (1) the tissue sample is anonymous, the research protocol has been approved by an IRB, and the research protocol assures the anonymity of the sources of the samples; *or*
- (2) the individual from whom the sample was taken has signed the hospital's "general consent" form for use of samples for research purposes under NY Civil Rights Law § 79-l(9)(a), the sample is either permanently stripped of identifying information or is coded in accordance with an IRB-approved coding methodology, and the research protocol has been approved by an IRB.

**Disclosure of Genetic Testing Information.** The Research Office may allow a disclosure of information (1) about an individual derived from genetic tests performed on stored human tissue, or (2) linking an individual with specific results of genetic tests, to an organization or person – including researchers or research sponsors – if the individual from whom the sample was taken has signed an IRB approved research subject consent form that includes a HIPAA Authorization.

## APPENDIX E

### USE AND DISCLOSURE OF HIV-RELATED INFORMATION FOR RESEARCH PURPOSES

This Appendix applies to all confidential HIV-related information. *Confidential HIV-related information* means:

1. Information that:
  - is in the possession of a person who provides health or social services or who obtains the information pursuant to a release of confidential HIV-related information, *and*
  - concerns whether an individual has been the subject of an HIV-related test, or has HIV infection, HIV-related illness or AIDS; *or*
2. Information that identifies or reasonably could identify an individual as having one or more of such conditions, including information pertaining to such individual's contacts.

No member of the hospital staff or medical staff may disclose such information for research purposes without the prior approval of the Research Office. The Research Office may allow such disclosure pursuant to a completed and signed IRB approved research subject consent form that includes a HIPAA Authorization. The Research Office may allow such disclosure *without* a signed Research Authorization *only* if:

1. The disclosure would be permitted without such an authorization under the hospital's policy *Use and Disclosure of PHI for Research Purposes*; *and*
2. The disclosure is either:
  - To a health facility or health care provider, in relation to the procurement or use of a human body or a human body part, including organs, tissues, blood, semen, or other body fluids, for use in research; *or*
  - To an agent or employee of the hospital, if:
    - the agent or employee is permitted to access medical records,
    - the hospital itself is authorized by law to obtain the HIV-related information, *and*
    - the agent or employee either provides health care to the protected individual or maintains or processes medical records for billing or reimbursement.

**Researchers and/or hospital staff should obtain a Kaleida Health Individual Authorization for the Use and Disclosure of Protected Health Information from patients who may be the subject of confidential HIV-related information on the researcher's or hospital's first contact with such patients.**

Note that HIV-related tests performed for research purposes must also comply with Kaleida Health Policy MR.15 - Confidentiality of HIV related Information. Additional information on HIV-related testing and HIV-related information can be found in such policy. Note, however, that this policy controls with respect to the use and disclosure of HIV-related information *for research purposes*.

## APPENDIX F

### USE AND DISCLOSURE OF ALCOHOL AND SUBSTANCE ABUSE TREATMENT INFORMATION FOR RESEARCH PURPOSES

Special restrictions apply to the disclosure for research purposes of certain information maintained in connection with the operation of an alcohol or substance abuse treatment program.

- These special restrictions *do* apply to names, addresses, social security numbers, fingerprints, photographs, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed, either directly or by reference to other publicly-available information. The restrictions therefore, by implication, extend to all alcohol and substance abuse treatment information maintained by the hospital and its clinics.
- These restrictions *do not* apply to any number or numbers assigned to a patient by an alcohol or substance abuse treatment program, so long as no such number consists of or contains numbers which could be used to identify a patient with reasonable accuracy and speed from sources external to the substance abuse program.

The Research Office may allow a disclosure of information of the type described above pursuant to a signed Kaleida Health Individual Authorization Form (Form #KH00043) and a signed IRB approved research subject consent form that includes a HIPAA Authorization. A signed IRB approved research subject consent form that includes a HIPAA Authorization alone will **not** constitute a valid consent under 42 CFR Part 2. Thus, researchers should obtain both an IRB approved research subject consent form that includes a HIPAA Authorization and a Kaleida Health Individual Authorization Form from subjects when seeking alcohol or substance abuse treatment records or information.

If the Research Office grants a researcher access to information subject to this Appendix, that researcher may re-disclose such information only back to the alcohol or substance abuse treatment program from which the information was obtained. The researcher may *not* identify any individual patient in any report of that research or otherwise disclose patient identities.

## APPENDIX G

### USE AND DISCLOSURE OF PSYCHOTHERAPY NOTES FOR RESEARCH PURPOSES

Special restrictions apply to the use and disclosure of psychotherapy notes for research purposes.

*Psychotherapy notes* are notes recorded (in any medium) by a mental health professional that (1) document or analyze the contents of conversation during a private counseling session or a group, joint, or family counseling session and (2) that are kept separately from the rest of the individual's medical record. *Psychotherapy notes* do not include medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date. Note that psychotherapy notes and mental health information (**Appendix H**) are different in that mental health information is found in a clinical record, and psychotherapy notes are not.

## APPENDIX H

### USE AND DISCLOSURE OF MENTAL HEALTH INFORMATION AND/OR RECORDS FOR RESEARCH PURPOSES

Special restrictions apply to the use and disclosure of mental health information and/or records ("mental health PHI") by hospitals (or individual units or clinics within hospitals) licensed by the New York Office of Mental Health or the New York Office of Mental Retardation and Developmental Disabilities for research purposes. *Mental health PHI* refers to clinical records or clinical information tending to identify patients who are receiving or have received mental health treatment or care. *Mental health PHI* will not include psychotherapy notes (Appendix H) separately maintained by a practitioner.

The Research Office may allow a release of mental health PHI pursuant to a Research Authorization in accordance with the hospital's policy *Use and Disclosure of PHI for Research Purposes*. The Research Office may allow a release of mental health PHI *without* an IRB approved research subject consent form that includes a HIPAA Authorization only if (1) the release would not violate the hospital's policy *Use and Disclosure of PHI for Research Purposes*, (2) the Chief of Behavior Health consents to the release, and (3) the release is to qualified researchers requiring mental health information for a particular research project who have obtained appropriate approval from an IRB. *All* disclosures of mental health PHI for research purposes must be limited to the minimum necessary for the research purposes.

Researchers may not, under any circumstances, re-disclose mental health PHI to research sponsors, contract research organizations, or any other person or organization.

## APPENDIX I

### DATA USE AGREEMENT FOR DISCLOSURE OF A LIMITED DATA SET FOR RESEARCH PURPOSES

This Data Use Agreement ("Agreement"), effective as of the date of the last signature below ("Effective Date"), is entered into by and between \_\_\_\_\_ ("Recipient") and Kaleida Health ("Kaleida") (each a "Party" and collectively the "Parties"). The purpose of this Agreement is to provide Recipient with access to a Limited Data Set ("LDS") of Patient Information for use in its Research activities in accord with the HIPAA Regulations.

1. Definitions. Unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the "HIPAA Regulations" codified at Title 45 parts 160 through 164 of the United States Code of Federal Regulations, as amended from time to time.
2. Preparation of the LDS. Kaleida will prepare, or cause to be prepared by a third party, and furnish to Recipient a LDS in accord with the HIPAA Regulations.
3. Minimum Necessary Data Fields in the LDS. In preparing the LDS the following identifiers will only be included to the extent they are absolutely needed to accomplish the research task, identifiers on the following list not needed, will not be disclosed:
  - a) Postal information including zip codes, city, town and state (Note: **street address cannot be included**)
  - b) Dates including: Birth date (birth dates of data subjects over 89 years old will only be permitted by aggregating into a single category for those *90 or older*), Admission date, Discharge date, Date of death
  - c) Ages (ages of data subjects over 89 years old will only be permitted by aggregating into a single category of *90 or older*)

4. Responsibilities of Recipient.

Recipient agrees to:

- a) Use or disclose the LDS only as permitted by this Agreement or as required by law;
  - b) Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law;
  - c) Report to Kaleida any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law;
  - d) Require any of its subcontractors or agents that receives or has access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to Recipient under this Agreement; and
  - e) Not use the information in the LDS to identify or contact the individuals who are data subjects.
5. Permitted Uses and Disclosures of the LDS. Recipient may use and/or disclose the LDS for research activities under the research protocol entitled \_\_\_\_\_
- 

6. Term and Termination.

- a) Term. The term of this Agreement will commence as of the Effective Date and will continue for so long as Recipient retains the LDS, unless terminated sooner as set forth in this Agreement.

- b) Termination by Recipient. Recipient may terminate this Agreement at any time by notifying Kaleida and returning or destroying the LDS.
- c) Termination by Kaleida. Kaleida may terminate this agreement at any time by providing 30 days prior written notice to Recipient.
- d) For Breach. Kaleida will provide written notice to Recipient within 10 days of any determination that Recipient has breached a material term of this Agreement. Kaleida will afford Recipient an opportunity to cure said alleged material breach on mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within 30 days will be grounds for the immediate termination of this Agreement by Kaleida.
- e) Effect of Termination. Sections 1, 4, 5, and 7 of this Agreement will survive any termination of this Agreement under subsections 6(c) or 6(d).

7. Miscellaneous.

- a) Change in Law. The Parties agree to negotiate in good faith to amend this Agreement to comport with changes in applicable federal law that materially alter either or both Parties' obligations under this Agreement; provided, however, that if the Parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law, either Party may terminate this Agreement as provided in section 6.
- b) Construction of Terms. The terms of this Agreement will be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.
- c) No Third Party Beneficiaries. Nothing in this Agreement will confer upon any person other than the Parties and their respective successors or assigns any rights, remedies, obligations, or liabilities whatsoever.
- d) Governing Law. The Agreement will be governed by and interpreted in accordance with the laws of the State of New York.
- e) Institutional Review Board. Kaleida must obtain appropriate approval from its Institutional Review Board before submitting LDS to Recipient.
- f) Headings. The headings and other captions in this Agreement are for convenience and reference only and will not be used in interpreting, construing, or enforcing any of the provisions of this Agreement.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

**Kaleida Health**

By: \_\_\_\_\_

Date: \_\_\_\_\_

**COVERED ENTITY**


By: \_\_\_\_\_

Name:

Title:

Date: \_\_\_\_\_



 <b>Kaleida Health</b> <b>POLICY</b>	<b>Title: Research Record Retention</b>	<b>#ORSP.4</b>
	<b>Owner: Office of Research and Sponsored Projects (ORSP)</b>	<b>Issued:</b> 12/13/10
<b>Keywords:</b> Research records retention, Clinical Trial Records, Research Documentation		

**I. Statement of Purpose**

The Principal Investigator (PI) or designee thereof is responsible for the collection, management, storage and retention of research records. Principal Investigators will adopt an organized system of data collection and record retention and ensure compliance by all his/her direct reports regarding such data. Research records will be maintained in the department in which they were produced or in an electronic file with access limited to authorized personnel. Legal documents such as the clinical trial agreements will be maintained by) contracting entity.

Where necessary, Kaleida Health reserves the right to access all research records and to take custody of the records if it believes that the records are not being properly maintained in compliance with this policy.

This policy assures that research records are appropriately archived and retained, and available for review as needed. The PI is responsible for the maintenance and retention of Research Records in accordance with this policy and this policy exists so that Kaleida Health and a PI can:

- A. Verify compliance with Federal and State laws and supporting regulations;
- B. Fulfill contractual obligations and sponsored project agreement requirements;
- C. Support issues of scientific integrity;
- D. Support issues of human subject and animal use; and
- E. Protect the rights of all those participating in research, including research subjects, principal Investigators, and Kaleida Health.

**II. Audience**

Medical Staff, hospital and nursing home staff including employees, students, interns, fellows, residents and volunteers, consultants, contractors and vendors of Kaleida Health, as applicable

**III. Instructions – (Outline necessary steps for consistent completion of process/ procedure)**

**A. Research Records – General Requirements**

Unless otherwise specified below, PI's must retain or otherwise archive research records for a minimum period of 7 years on research. If the research is funded by a clinical trial agreement (contract) or grant, the terms of the contract or grant will supersede this policy if the retention period is longer. If records are to be stored off-site it is the responsibility of the Principal Investigator to ensure that adequate funding is built into the research budget to pay for off-site record storage.

If research involves pediatric (minor) subjects then the records must be retained for a minimum of 21 years of age, or ten years after completion or termination of the study, whichever date is later.

If the research involves Protected Health Information (PHI), the PI must retain the permission to use the PHI for 6 years beyond the expiration date of the HIPAA authorization (i.e. the consent form or authorization).

**B. Federal Food and Drug Administration ("FDA") Requirements**

1. **Investigational drugs**

Principal Investigators involved in the research of drugs being tested in humans for FDA approval must retain records for a minimum period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

The following records must be retained for investigational drug studies:

- a. **Disposition of the investigational drug.** If the investigation is terminated, suspended, discontinued, or completed the PI is responsible for returning the unused supplies of the drug to the sponsor or disposing of the drug according to the terms of the clinical trial agreement. Adequate records of the disposition of an investigational drug, including dates, quantities, and use by subjects must be maintained by the PI as specified above.
- b. **Case histories.** The PI is required to prepare and maintain adequate case histories that record all observations and other data pertinent to the investigation on each research subject administered the investigational drug or employed as a control in the investigation. Case histories must include the case report forms ("CRF") and supporting data, including signed and dated consent forms and medical records, including progress notes of the physician and research nurse, and the subject's entire hospital medical record. The case history for each subject must document that informed consent was obtained prior to participation in the study.
- c. Form FDA 1572

2. **Investigational devices**

Principal Investigators involved in research of devices being tested in humans for FDA approval must retain records for a minimum of two years after the date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application, or a notice of completion of a product development protocol, whichever is later.

The following records must be maintained for investigational devices studies:

- a. All correspondence with another investigator, an Institutional Review Board ("IRB"), the study sponsor, a monitor, or the FDA (including required reports).
- b. Records of receipt, use or disposition of a device that relates to:
  - 1) The type and quantity of the device, the dates of its receipt, and the batch number or code mark;
  - 2) The names of all persons who received, used, or disposed of each device; and
  - 3) Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.
- c. Records of each subject's case history and exposure to the device. Case histories must include the case report forms and supporting data,

including signed and dated consent forms and medical records, including progress notes of the physician and research nurse, and the subject's entire hospital medical record. The case history for each subject must document that informed consent was obtained prior to participation in the study.

- d. Documents evidencing informed consent obtained prior to participation in the study, and for any use of a device without informed consent (as permitted under 21 CFR 812.36), the written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent.
- e. All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests.
- f. A record of all exposures of each subject to the investigational device, including the date and time of each use, and any other therapy.
- g. The protocol with documents showing the dates and reasons for each deviation from the protocol.
- h. FDA Form 1571

**C. Research Misconduct**

All records or documents involved in proceedings related to an allegation of research misconduct must be maintained by Kaleida Health in a secure manner for 7 years after completion of the proceeding by any agency or regulatory body (i.e., Public Health Service or other government agency) involving the research misconduct allegation.

**D. Government Sponsored Projects**

Records related to research studies sponsored by the state or federal government, including but not limited to NIH grants, must be retained for a minimum of 10 years after research is completed, final expenditure reports are submitted, and all audit issues resolved; whichever period is longer. This requirement includes all financial records, supporting documents, time and effort reports, statistical records, the study contract, study grant, Medicare related documentation, and all other records pertinent to an award or receipt of government monies to conduct a research study.

**E. Destruction of Records**

When research records have met the applicable retention guidelines, the documents will be shredded and the following recorded: PI name; protocol identifiers such as funding source or sponsor (when applicable), protocol number (when applicable), date shredded; person shredding the documents; and a summary of documents shredded.

If the study is an industry-sponsored study, prior to shredding documents or disposal of materials, the sponsor will be contacted and written permission obtained to destroy the documents.

Written confirmation should be received from the study sponsor and/or FDA granting permission to destroy investigational drug or investigational device study related records.

All clinical trial agreements will be retained by the contracting entity for a minimum of six years from the date of execution and then destroyed as confidential documents by shredding.

**IV. Approved by - (Include date)**

Office of General Counsel	8/1/10, 12/20
Medical Executive Committee	10/20/10, 1/21
Board of Directors	12/6/10, 2/21


**V. References (Include evidence based research, Kaleida Health policy, and regulation as applicable)**

Federal: 21 CFR 312.62, 21 CFR 812.140, 45 CFR 164.530(j)(l)(ii), Office of Management and Budget (OMB) Circular A-110, Section 53b, 45 CFR 74.53, 2 CFR 215.53, 42 CFR 93.317


**Version History:**

Effective Date:	Reviewed/ Revised
3/23/21	Revised
11Nov2020	Reviewed with changes
8/13/18	Reviewed no changes
7/18/16	Reviewed no changes
2/14	Reviewed no changes

Kaleida Health developed these Policies, Standards of Practice, and Process Maps in conjunction with administrative and clinical departments. These documents were designed to aid the qualified health care team, hospital administration and staff in making clinical and non-clinical decisions about our patients' care and the environment and services we provide for our patients. These documents should not be construed as dictating exclusive courses of treatment and/or procedures. No one should view these documents and their bibliographic references as a final authority on patient care. Variations of these documents in practice may be warranted based on individual patient characteristics and unique clinical and non-clinical circumstances. Upon printing, this document will be valid for 5/10/2023 only. Please contact Taylor Healthcare regarding any associated forms.

 <b>Kaleida Health</b> <b>POLICY</b>	<b>Title: Standard &amp; Transmission-Based Precautions</b>	<b># IC.12</b>
	<b>Owner:</b> Infection Control and Prevention	<b>Issued:</b> 5/1/01
<b>Keywords:</b> transmission, infection, precautions, isolation, respiratory etiquette		

<https://kaleidahealth.ellucid.com/pman/documents/view/80>

 <b>Kaleida Health</b> <b>POLICY</b>	<b>Title: Code of Conduct and Business Ethics</b>	<b># IAC.19</b>
	<b>Owner: Chief Compliance Officer</b>	<b>Issued:</b> 3/30/98
<b>Keywords:</b> compliance, ethics, fraud, abuse, confidentiality, respect, conflict of interest, gifts, gratuities, inducements, disclosure statement		

## I. **Statement of Purpose**

Kaleida Health aspires to maintaining the highest level of corporate integrity and expects all of its workforce members (as defined under Audience) to commit themselves to the same end. Kaleida Health is committed to complying with all applicable federal and state standards. This Code of Conduct and Business Ethics (the Code) has been adopted by the Kaleida Health Board of Directors to provide standards by which workforce members will conduct themselves in order to protect and promote system-wide integrity and core values, and to enhance Kaleida Health's ability to achieve the organization's mission and vision. The Core Values of Kaleida Health mandate a patient-centered commitment, the pursuit of excellence and quality in all endeavors, personal accountability, and integrity in everything we do.

Kaleida Health expects each workforce member to whom this Code applies to abide by the Principles and Standards set forth herein, to conduct the business and affairs of and/or with Kaleida Health in a manner consistent with the general statement of principles set forth herein and to comply with all relevant health care laws, regulations and policies.

This Code contains **Principles** articulating the policy of the organization and **Standards** that are intended to provide additional guidance to workforce members. All persons associated with Kaleida Health are responsible to ensure that their behavior and activity is consistent with this Code.

In addition to this Code, Kaleida Health has adopted policies and procedures related to the operation of the Compliance Program, to specific services we provide and to address certain risk areas. If workforce members have specific responsibilities that are addressed by a **Compliance Policy and Procedure**, they must ensure that they are familiar with the applicable policy and procedure. These documents are available upon request from the Chief Compliance and Privacy Officer at any time and are available on *KaleidaScope*.

Failure to abide by the Compliance Program, this Code or the guidelines may lead to disciplinary action. In implementing corrective or disciplinary action, Kaleida Health will weigh relevant facts and circumstances, including, but not limited to, the extent to which the behavior was contrary to the express language or general intent of the Code, the egregiousness of the behavior, history with the organization and other factors which Kaleida Health deems relevant. Discipline for failure to abide by the Code may, in Kaleida Health's discretion, range from oral correction to termination of employment or contract. All Disciplinary actions will be fairly and firmly enforced. If in Kaleida Health's discretion circumstances warrant it, criminal or civil prosecution will be pursued. Some of the Standards set forth herein apply only to Kaleida Health employees, and are so noted.

## II. **Audience**

This policy applies to all Kaleida Health workforce members.

As used in this Code:

- A. The term "workforce member" includes all governing body members (i.e. Directors) and Corporate Officers as well as executives, employees, independent contractors, subcontractors, agents, vendors, students, interns, residents, fellows, volunteers, appointees or other persons or entities who perform services or functions for Kaleida Health or who otherwise contribute to Kaleida Health's entitlement to payment from Federal health care programs. This includes, but is not limited to, full and part time employees, affiliates, associates, managers and leaders (individuals with the designation of supervisor and above), physicians employed by or otherwise affiliated with Kaleida Health, medical residents, nursing students or others receiving training at any Kaleida Health facility, and others who provide goods or services to Kaleida Health. As used

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within this definition, “employee” refers to an individual who performs services as a W-2 employee of Kaleida Health.

- B. The term “Kaleida Health” means Kaleida Health and each of its divisions, affiliates and operating or business units. An affiliate of Kaleida Health means any entity controlled by or in control of Kaleida Health.
- C. The term “Director” refers to members of Kaleida Health Boards of Directors.
- D. The term “Board” means the Kaleida Health Boards of Directors.
- E. The term “Federal health care program” means any plan or program that provides health benefits whether directly, through insurance or otherwise, which is funded directly, in whole or in part, by the United States Government, and includes certain State health care programs. Examples include, but are not limited to: Medicare, Medicaid, Veterans’ programs and the State Children’s Health Insurance Programs. The Federal Employees Health Benefits Program is not included in this definition.
- F. This Code of Conduct applies to workforce members who are independent contractors only in their capacity as independent contractors of Kaleida Health and shall not apply to the activities of workforce members while acting as individuals or on behalf of entities other than Kaleida Health, so long as such individual or non-Kaleida Health activities are distinct from, and do not directly relate to, Kaleida Health, health care items and services, which are provided by an affiliated physician.

### III. Instructions –

- A. **Reporting Requirements/ Policy of Non-Intimidation and Non-Retaliation**  
Any workforce member who has witnessed inappropriate conduct by another workforce member(s) or who otherwise has a compliance-related concern is required to report on such conduct or concern. Inappropriate conduct includes any type of activity that this Code is designed to eliminate by encouraging system-wide integrity. This may include questionable accounting or auditing matters, kickbacks, sub-quality care, patient abuse, harassment, fraud and abuse and other illegal activities discussed in Principle 1, Legal Compliance.
- B. **Reporting options include:**
  - 1. Calling the Kaleida Health Chief Compliance and Privacy Officer at (716) 859-8633;
  - 2. E-mailing the Kaleida Health Chief Compliance and Privacy Officer at [vbelniak@kaleidahealth.org](mailto:vbelniak@kaleidahealth.org);
  - 3. Sending a written report to the Kaleida Health Chief Compliance and Privacy Officer through inter-office or regular mail;
  - 4. Calling the Compliance Hotline at (833) 990-0040.
- C. Employees are encouraged, but not required, to report concerns first to their supervisor or manager.<sup>1</sup>
- D. Any workforce member reporting inappropriate conduct may do so anonymously through the Compliance Hotline. The identity of workforce members reporting through the Hotline will be kept confidential, whether requested or not, unless the matter is turned over to law enforcement or is required during a legal proceeding.
- E. In addition to the **requirement** that you contact the Chief Compliance and Privacy Officer regarding possible violations, you are invited and encouraged to raise any questions or seek clarification regarding the Compliance Program, Compliance Program training or any compliance-related concerns you might have with the Chief Compliance and Privacy Officer.
- F. Workforce members making a report in good faith or otherwise participating in the Kaleida Health Compliance Program are assured that Kaleida Health does not tolerate intimidation or retaliation of any kind for such good faith participation.  
Good faith participation in the Kaleida Health Compliance Program includes, but is not limited to:

<sup>1</sup> Members of the Internal Audit and Corporate Compliance department, Audit and Corporate Compliance Committee, Office of General Counsel, supervisors or managers who receive information regarding a possible compliance issue or suspected violation, must immediately inform the Chief Compliance and Privacy Officer so that she may promptly address the issue.

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1. Reporting actual or potential issues or concerns,
  2. Cooperating with or participating in the investigation of such matters;
  3. Assisting with or participating in self-evaluations, audits, and/or implementation of remedial actions; or
  4. Reporting to appropriate regulatory officials.<sup>2</sup>
- G. This protection is mandated by Federal and state laws as well as Kaleida Health policy. **Acts of intimidation or other retaliation should be reported to Internal Audit and Corporate Compliance or Kaleida Health's Office of General Counsel.**

#### **Principle 1 - Legal Compliance**

**Kaleida Health requires that all activities by or on behalf of the organization be in compliance with applicable laws and regulations, as well as applicable Kaleida Health policies.**

The following Standards are intended to provide guidance to workforce members to assist them in their obligation to comply with applicable laws and regulations. These Standards are neither exclusive nor complete. Workforce members are required to comply with all applicable laws and regulations whether or not specifically addressed in this Code. If questions regarding the existence, interpretation or application of any law arise, they should be directed to Kaleida Health's Office of General Counsel, which includes Internal Audit and Corporate Compliance, Risk Management, Research and Sponsored Projects and Labor Counsel.

#### **Standard 1.1 - Fraud and Abuse**

Kaleida Health expects all workforce members to refrain from conduct that may violate the fraud and abuse laws, particularly those pertaining to Federal health care programs. Briefly, these laws prohibit:

1. The submission of false, fraudulent or misleading claims to any governmental entity or third party payor, including claims for services not rendered or supplies not used, claims that characterize the service differently than the service actually rendered, or claims that do not otherwise comply with applicable program or contractual requirements;
2. Making false representations to any person or entity in order to gain or retain participation in a program or to obtain payment for any service;
3. Retaining an overpayment made by a governmental program, insurance company or patient;
4. Improper financial reporting as further described in Standard 9.2; and
5. The knowing and willful offering, paying, asking or receiving any money or other benefit, directly, or indirectly, overtly or covertly, in cash or in kind, for the purpose of influencing patient referrals or procuring goods or services; and
6. A physician patient referral to an entity, such as Kaleida Health, for a designated health service if the physician or a member of his or her immediate family has a financial relationship with the entity, unless an exception applies.

Specific questions regarding the false claims laws and anti-referral laws should be directed to Kaleida Health's Office of General Counsel or the Chief Compliance and Privacy Officer.

#### **Standard 1.2 – Tax-Exempt Entity Rules**

As a tax-exempt, not-for-profit entity, Kaleida Health has a legal and ethical obligation to act in compliance with applicable laws, to engage in activities in furtherance of its charitable purpose, and to ensure that its resources are used in a manner that furthers the public good rather than the private or personal interests of any individual. Consequently, Kaleida Health and workforce members will avoid compensation arrangements in excess of fair market value, will accurately report payments to appropriate taxing authorities, and will file all tax and information returns in accordance with applicable laws. Standards for indigent and non-compensated care and community service will comply with relevant Internal Revenue Service regulations.

<sup>2</sup> For a brief summary of New York State Labor Law §§ 740-741, as of October 2018, please see IAC.18 (Fraud, Waste and Abuse Compliance including Federal and New York State False Claims Act Information and Whistleblower Protections).



Standard 1.3 - Antitrust

All workforce members must comply with applicable antitrust and similar laws that regulate competition. Examples of conduct prohibited by the laws include (1) agreements to fix prices, bid rigging, and collusion (including price sharing) with competitors; (2) boycotts, certain exclusive dealing and price discrimination agreements; and (3) unfair trade practices including bribery, misappropriation of trade secrets, deception, intimidation and similar unfair practices.

Standard 1.4 - Lobbying/Political Activity

All workforce members will refrain from engaging in any activity that may jeopardize the tax-exempt status of the organization, including lobbying and political activities.

1. No workforce member may make any agreement to contribute any money, property, or services of any employee at Kaleida Health's expense to any political candidate, party, organization, committee or individual in violation of any applicable law. Employees may **personally** participate in and contribute to political organizations or campaigns, but they must do so **as private individuals**, not as representatives of Kaleida Health, and they must use their own funds. Such individuals will not use "the power of the office" to encourage other workforce members to support a candidate for office financially or otherwise.
2. Where its experience may be helpful, Kaleida Health may publicly offer recommendations concerning legislation or regulations being considered for the purpose of educating/informing public officials. In addition, it may analyze and take public positions on issues that have a relationship to the operations of Kaleida Health when Kaleida Health's experience contributes to the understanding of such issues. Communications of this sort are to be coordinated with the Chief Marketing Officer.

Standard 1.5 - Environmental

It is the policy of Kaleida Health to manage and operate its business in a manner that respects our environment and conserves natural resources. Workforce members will strive to utilize resources appropriately and efficiently, to recycle where possible and otherwise dispose of all waste in accordance with applicable laws and regulations (including HIPAA regulations), and to work cooperatively with the appropriate authorities to remedy any environmental contamination for which Kaleida Health may be responsible.

Standard 1.6 - Government Inquiries

1. Kaleida Health occasionally receives inquiries from government agencies and departments in the form of letters, telephone calls, or personal visits.
2. Kaleida Health complies with all applicable laws and cooperates with any lawful request for information from Federal, State and Local authorities.
3. All non-routine requests for information from any government agency must be forwarded to the Chief Compliance Officer.
4. Workforce members must receive authorization from the Office of General counsel before responding to any request to disclose Kaleida Health's documents to any outside party.
5. Workforce members may speak voluntarily with government agents, and Kaleida Health will not attempt to obstruct such communication. It is recommended, however, that workforce members contact the Chief Compliance Officer before speaking with any government agents.
6. It is Kaleida Health's policy to comply with the law and cooperate with legitimate governmental investigations or inquiries. All responses to requests for information must be accurate and complete. Any action by workforce members to destroy, alter, or change any Kaleida Health records in response to a request for such records is strictly prohibited and shall subject the individual to immediate termination of employment or contract and possible criminal prosecution.
7. In the event of an attempted service of a subpoena, search warrant, summons or other legal process, Risk Management must be immediately notified.

Principle 2 - Business Ethics

**In furtherance of Kaleida Health's commitment to the highest standards of business ethics and integrity, workforce members will accurately and honestly represent Kaleida Health and will not engage in any activity or scheme intended to defraud anyone or any entity of money, property or services.**

The Standards set forth below are designed to provide guidance to ensure that Kaleida Health's business activities reflect the highest standards of business ethics and integrity. Conduct not specifically addressed by these standards must be consistent with Principle 1, Legal Compliance.

#### 2.1 - Honest Communication

Kaleida Health requires candor and honesty from workforce members in the performance of their responsibilities and in communication with its attorneys, auditors and regulatory bodies. No workforce member will make false or misleading statements to any patient, person or entity doing business with Kaleida Health about themselves or about other patients, persons or entities doing business or competing with Kaleida Health, or about the products or services of Kaleida Health or its competitors. All communication, but most particularly with Kaleida Health patients, will be conducted with civility and respect.

#### 2.2 – Accuracy and Fairness in Billing/ Documentation Practices

Kaleida Health takes great care to ensure that all claims submitted to Federal health care programs and other insurance payors reflect truth and accuracy, and conform to all federal and state laws and regulations. Consistent with these laws and regulations, workforce members will assure that all Kaleida Health patients receive an itemized bill and explanation of all charges. Billing practices are guided by a regulatory environment external to Kaleida Health. Kaleida Health, its medical staff and all of its affiliates who provide billable services to patients will invoice only for the services provided. Bills will be disbursed in a timely manner and assistance will be provided to patients in need of understanding the cost related to their care. Questions and objections that arise pertaining to the cost of services provided by Kaleida Health, as well as the ability to pay, will be addressed promptly.

All billing must be accurate and truthful and based on adequate documentation of the medical justification for the services provided. Workforce members involved in delivering care will properly assess and document each patient's medical condition and treatment timely and accurately. Documentation forms must truthfully and accurately reflect the patient's clinical condition, orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, vital signs and other information necessary to monitor the patient's condition. Patient medical records must contain appropriate documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia. Under no circumstances may anyone knowingly misrepresent any information on any patient-related forms, or in any other document, in an attempt to ensure reimbursement or obtain a higher reimbursement rate.

Workforce members involved in any way with false, fictitious or fraudulent claims are subject to the most severe disciplinary measures.

#### 2.3 - Marketing and Fund Raising Practices

Kaleida Health is committed to having all information provided to the media accurately portray the facts in compliance with HIPAA and other patient confidentiality regulations. Every effort will be made to avoid any statements that could lead to misinterpretation. All media contacts that implicate a Kaleida interest, including patient confidentiality of a Kaleida patient, a proprietary interest of Kaleida, or a legal interest or effect on Kaleida will be coordinated through the Chief Marketing Officer who will review public statements to ensure patient confidentiality and adherence to ethical marketing practices. Kaleida Health fund raising or friend raising activities that may involve protected health information must be cleared through Kaleida Health's Office of General Counsel or Internal Audit and Corporate Compliance.

Nothing in this section 2.3 shall prevent a workforce member from communicating with media contacts in the workforce member's capacity outside Kaleida Health. This section shall not apply to the activities of workforce members while acting as individuals or on behalf of entities other than Kaleida Health, so long as such individual or non-Kaleida Health activities are distinct from, and do not directly relate to, Kaleida Health, health care items and services, which are provided by an affiliated physician.

#### 2.4 - Purchasing Practices

Kaleida Health has supply chain management policies and procedures that address competitive bidding and vendor qualifications. Services, supply items or equipment costing over a specified amount are purchased on competitive bid in accordance with Kaleida Health policy through a group purchasing

organization or directly from approved vendors. Selection of vendors, subcontractors and suppliers are made by Supply Chain Management on the basis of objective criteria including quality, technical excellence, price, delivery, adherence to schedules, service and maintenance of adequate sources of supply. Purchasing decisions are made on the supplier's ability to meet Kaleida Health's needs and standards, and not on personal relationships, friendships, or inducements of any sort.

Kaleida Health employees who leave Kaleida Health and are subsequently hired by a vendor or prospective vendor may not call on or represent said vendor in any manner to Kaleida Health as a customer or prospective customer as required by a non-compete clause. Any exception to this restriction may only be made, in writing, by Kaleida Health's Office of General Counsel.

### 2.5 - Integrity and Quality of Clinical Decision Making

Kaleida Health and all workforce members are committed to protect the integrity and quality of clinical decision making, regardless of how Kaleida Health compensates or shares financial risk with its leaders, managers, clinical staff and licensed independent practitioners. To avoid compromising the quality of care, clinical decisions (including tests, treatments, and other interventions) are based on identified patient health care needs.

## **Principle 3 – Standards Related to Quality of Care and Services**

### 3.1 - Generally

Kaleida Health is committed to providing quality care that is medically necessary to our patients. As part of this commitment, Kaleida Health will ensure that necessary quality assurance systems are in place and functioning effectively. Kaleida Health will continuously strive toward a culture of patient safety and provide quality, medically necessary care to its patients. To this end, we have implemented and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.

### 3.2 - Respect for the Patient

All workforce members who have contact with Kaleida Health patients will treat all patients with dignity and respect and afford every patient the rights to which he or she is entitled under applicable law, regulation, and Kaleida Health policy.

All patients of Kaleida Health will be treated with:

1. Consideration, respect and with full recognition of their individuality and personal needs, including their cultural, psychosocial and spiritual beliefs;
2. The right to privacy of treatment under HIPAA and any other patient privacy regulations, consistent with providing adequate medical care to the patient; and
3. No discrimination as to race, color, religion, sex, sexual orientation, gender identity and expression, ethnic origin, age, disability, citizenship status, veteran status, language or financial limitation, or any other classification protected by law, and within the capacity of Kaleida Health to provide treatment or identify a source of payment.

All workforce members involved with patient care have an obligation to inform patients or their representatives of patient's rights and responsibilities. Open and honest communication will occur with all patients and/or their representatives with regard to the medical care provided. Patients or their representative should be involved in the decision-making process regarding the care that is provided. All patients should be informed of the significant risks and alternatives associated with the care they are receiving. Kaleida Health will continually seek to understand patients' objectives for care and respect their requests to the extent clinically appropriate. Research involving human subjects will be performed only with the informed consent of the patient and will follow high ethical standards, as well as relevant regulatory standards. Patients will be given a full explanation of the risks, expected benefits and alternatives.

### 3.3 - Emergency Treatment

When a patient presents with an emergency medical condition, Kaleida Health clinical staff will provide that patient with a screening examination and stabilization of any emergency condition in accordance with applicable laws, rules and regulations, regardless of the patient's ability to pay.

Patients will be transferred only after they have been medically stabilized and an appropriate transfer has been arranged.

#### 3.4 - Limited English Proficiency

When a person has limited ability to speak or understand English, his or her participation in health care can be hindered and lead to a lack of meaningful access to care. Kaleida Health will make every attempt to provide patients with limited English proficiency or hearing impairment (and their guardians) a medical interpreter without any charge to them.

#### 3.5 – Financial Assistance

The Financial Assistance Programs are designed to assist patients with their financial obligations when they seek and receive care at Kaleida Health. Information regarding these programs is appropriately posted on Kaleida Health's website and in admission and emergency room areas. These programs are also designed to ensure Kaleida Health provides non-discriminatory emergency medical care, regardless of whether the individual is eligible for financial assistance under its financial assistance policy.

### **Principal 4 – Standards Relating to Credentialing**

#### 4.1 - Exclusions

Kaleida Health is committed to using good faith efforts to not employ, contract or affiliate with individuals or entities that are currently excluded, debarred or otherwise ineligible to participate in Federal health care programs. The Hospital has a system for checking such individuals and entities against the government exclusion databases. You are required to notify the Chief Compliance Officer within two (2) business days of being found to have committed a crime (this does not include traffic or other low-level "violations") or receiving notification that you have been excluded from a Federal health care program.

#### 4.2 - Credentialing

Kaleida Health complies with all applicable Federal and state laws, rules and regulations governing the credentialing process. This is a key element to ensuring that Kaleida Health provides high quality care and services to its patients. Kaleida Health has processes in place for the on-going and continuous credentialing and competency reviews of clinical and non-clinical staff.

### **Principal 5 - Standards Relating to Mandatory Reporting**

**Kaleida Health will ensure that all incidents and events that are required to be reported are done so in timely manner to the appropriate agency.**

Kaleida Health will also ensure compliance with mandatory reporting obligations under New York's Social Services Law, 18 N.Y.C.R.R. Part 521, and other reporting obligations, as necessary and appropriate.

All identified overpayments are timely reported, explained and returned in accordance with applicable law and contractual requirements. It is Kaleida Health's policy to not retain any funds which are received as a result of overpayments and to report, return and explain any overpayments from Federal health care programs within 60 days from the date the overpayment was identified (or within such time as is otherwise required by law or contract). Any monies improperly collected from Federal health care programs are promptly refunded to the Department of Health, the Office of the Medicaid Inspector General, the Medicare Administrative Contractor or other payor, as applicable.

In certain circumstances (e.g. after an internal investigation confirms possible fraud, waste, abuse or inappropriate claims), and with the advice and assistance of legal counsel, as necessary and appropriate, Kaleida Health will avail itself of the appropriate self-disclosure process and report, as necessary and appropriate, to the New York State Department of Health, Office of the Medicaid Inspector General, the U.S. Department of Health and Human Services, Office of Inspector General, or other appropriate governmental agency.

### **Principle 6 - Confidentiality**

**Workforce members will maintain the confidentiality of patient and other confidential information in accordance with applicable legal and ethical standards.**

Kaleida Health and other workforce members are in possession of and have access to a broad variety of confidential, sensitive and proprietary information, of which the inappropriate release could be injurious to

individuals, Kaleida Health's business partners and Kaleida Health itself. Workforce members have an obligation to actively protect and safeguard confidential, sensitive and proprietary information in a manner designed to prevent the unauthorized disclosure of information. Anyone who knows or has reason to believe that another person has violated the confidentiality of patient or other confidential information should report the matter promptly.

#### 6.1 - Patient Information

Workforce members have an obligation to maintain the confidentiality of patient protected health information (PHI). Workforce members will refrain from revealing any patient's PHI unless supported by legitimate treatment or payment purposes pursuant to relevant policies, regulations and laws or if permitted by the patient. Workforce members who learn confidential information about Kaleida Health or its patients, shall not disclose that information to third parties, including family or friends. This includes, without limitation, disclosure of pictures or any patient information on any form of social media. Kaleida Health has also implemented and maintains a HIPAA Compliance Program that addresses privacy and security. Workforce members must adhere to the standards of the HIPAA Compliance Program.

If questions arise regarding an obligation to maintain the confidentiality of information or the appropriateness of releasing PHI, workforce members should seek guidance from Risk Management, Kaleida Health's Office of General Counsel or Internal Audit and Corporate Compliance.

#### 6.2 - Proprietary Information

Information, ideas and intellectual property assets of Kaleida Health are important to organizational success. Information pertaining to Kaleida Health's competitive position or business strategies, payment and reimbursement information, and information relating to contract negotiations must be protected and shared only with workforce members having a need to know such information in order to perform their job responsibilities. Workforce members must exercise care to ensure that intellectual property rights, including patents, trademarks, copyrights and software licenses are carefully maintained and managed to preserve and protect their value.

Workforce members will not misappropriate confidential or proprietary information belonging to another person or entity or utilize any publication, document, computer program, information or product in violation of a third party's interest in such product. All workforce members are responsible to ensure they do not improperly copy for their own use documents or computer programs in violation of applicable copyright laws or licensing agreements. Employees will not utilize confidential business information obtained from Kaleida Health or its competitors, including but not limited to customer lists, price lists, contracts or other information in violation of a covenant not to compete, or prior employment agreements, or in any other manner likely to provide an unfair competitive advantage to Kaleida Health. In addition, workforce members may not disclose such confidential information to any third party after leaving employment except with the prior written consent of Kaleida Health, or as required by applicable law.

#### 6.3 - Personnel Actions/Decisions

Salaries, benefits, contracts and other personal information relating to workforce members will be treated as confidential. Personnel files, payroll information, disciplinary matters and similar information will be maintained in a manner designed to ensure confidentiality. Workforce members will exercise due care to prevent the release or sharing of information beyond those persons who may need such information to fulfill their job function.

#### **Principle 7 - Conflict of Interest**

**All workforce members are expected to act with integrity, honesty and fairness to avoid any conflict, or appearance of a conflict between personal or external interests and the interests of Kaleida Health. A conflict of interest arises during any circumstance in which one's personal interest or relationships might affect his or her objectivity or ability to fulfill responsibilities, with regard to the organization.**

Any person in a position of authority over the affairs of Kaleida Health may not use his or her position to benefit personally or to assist others in benefiting from a decision he or she could make.

Any workforce member engaging in an activity deemed a conflict of interest by the Chief Compliance Officer or Kaleida Health's Office of General Counsel will be required to immediately cease participation in such activity or remediate the conflict as further instructed by the Office of General Counsel, including termination of employment. Questions regarding the application of this Principle to a particular circumstance shall be referred to Kaleida Health's Office of General Counsel or Chief Compliance Officer for determination.

#### 7.1 – Disclosure and Procedure

As set forth more fully in the Hospital's Conflicts of Interest and Related Party Transactions policy, all members of the Boards of Directors, Officers, and other key persons, including physicians, who are in a position to influence any substantive business decision by Kaleida Health must complete an annual Conflict of Interest Disclosure Statement disclosing all potential and actual interests (including those of relatives) that compete or do business with Kaleida Health.

Other workforce members faced with a potential conflict of interest have an obligation to disclose it immediately to their supervisor, or, to protect confidentiality, the Site Administrator of Human Resources, Kaleida Health's Office of General Counsel or the Chief Compliance Officer.

#### 7.2 - Participation on Boards

An employee must obtain written approval from the Vice President within his or her reporting structure prior to serving as a member on the Board of Directors/Trustees of any organization whose interest may conflict with those of Kaleida Health. Furthermore, employees must annually disclose all Board of Directors/Trustees activities in the Kaleida Health Conflict of Interest Disclosure Statement. All fees/compensation (other than reimbursement for expenses arising from board participation) that are received by an employee for board services provided during normal work time at Kaleida Health will be paid directly to Kaleida Health or a Kaleida Health affiliated foundation.

An employee who is asked, or seeks to serve on the Board of Directors/Trustees of any organization whose interest would not impact Kaleida Health (for example, civic [non-governmental], charitable or fraternal) will not be required to obtain such vice president approval.

However, Kaleida Health retains the right to prohibit membership by an employee on any Board of Directors/Trustees where such membership might conflict with the best interest of Kaleida Health.

Questions regarding whether or not board participation might present a conflict of interest should be discussed by the employee with his or her supervisor and referred to the Vice President within his or her reporting structure for resolution.

#### **Principle 8 - Business Relationships**

**Business transactions with vendors, contractors and other third parties will be an arms-length transaction, free from offers, direct or indirect, of anything of value, including gifts, trips, accommodations, travel expenses, events, meals, or favors of any sort that could serve as an inducement for Kaleida Health or any workforce member to influence or provide assistance in a purchase or referral of health care items or services. Educational grants to Kaleida Health by vendors for educational events are permissible only as outlined below. Violations of this Principle could result in termination of the workforce member involved and/or the termination of the existing or proposed relationship between Kaleida Health and the vendor, contractor or other third party.** For the purpose of this Principle, including Section 8.1 to the end of Section 8.3, "vendors, contractors and other third parties" excludes educational institutions in their regular educational interactions, between or amongst attending physicians and residents, medical students, fellows, undergraduates or other clinical students. This exclusion does not permit offers, direct or indirect, of anything of value, including gifts, trips, accommodations, travel expenses, events, meals, or favors of any sort, that could serve as an inducement for Kaleida Health or any workforce member (as defined in II. Audience) in the purchase or referral of health care items or services.

It is the intent of Kaleida Health that this policy be construed broadly to avoid even the appearance of improper activity. At all times, Kaleida Health remains committed to regulatory and statutory compliance

as well as any compliance guidance published by federal or state authorities. Questions or clarification regarding the appropriateness of specific conduct or activities should be addressed to the Chief Compliance Officer or Kaleida Health's Office of General Counsel.

#### 8.1 - Gifts and Funding Sources

At all times it is Kaleida Health's desire to preserve and protect its reputation and avoid any impropriety or appearance of impropriety. Kaleida Health's Office of General Counsel or Internal Audit and Corporate Compliance must approve exceptions to any of the following.

1. Gifts from Patients. Workforce members are prohibited from soliciting tips, personal gratuities or personal gifts from patients or families of patients. Workforce members may accept unsolicited gifts or gratuities of a nominal value (worth less than \$50) from patients or families of patients, such as candy or flowers. Gifts of cash or cash equivalents (i.e. gift cards) are prohibited. If a patient or other individual wishes to present a gift valued at more than \$50, he or she should be directed to the Kaleida Health Foundation.
2. Funding for Educational Events for Workforce Members. A vendor may provide or support an educational program or event that is to be held on Kaleida Health property, other than property that Kaleida Health has leased to a third party, only in accordance with the following requirements:
  - a. Educational events on a Kaleida Health site are to be approved by the Site President or other Vice President responsible for the area involved.
  - b. Educational events that are off site or require out of town travel will be recommended by the Site President or other Vice President for the area involved to the Chief Compliance Officer for approval. No vendor funding for the educational event or for accompanying travel, meals, or entertainment is permitted other than as set forth in this section.
  - c. In all cases, the validity of the educational event will be approved in advance by the Site President or other Vice President responsible for the area involved. The input of Kaleida Health's Chief Compliance Officer as well as areas of clinical expertise may be sought to determine whether the event violates the Federal Anti-Kickback Statute or federal or state compliance guidance.
  - d. Educational events may be funded by vendors/vendor foundation grants. To support the educational mission of Kaleida Health, grants may be made by vendors/vendor foundations to the Kaleida Health Foundation. In making educational grants to Kaleida Health, vendors must follow the guidelines established by the HHS OIG and the Pharmaceutical Manufacturers of America. Such grants will be without restriction, other than for educational purposes, and will be controlled by the Foundation. A written agreement must be in place between the vendor and Kaleida Health before the funds can be accepted.
3. Gifts or Entertainment from Existing or Prospective Vendors. Kaleida Health workforce members may not accept any gifts, recreation activities, entertainment or meals from existing or prospective Kaleida Health vendors without the approval of the Chief Compliance Officer. An educational session to workforce members along with a modest meal in the hospital setting is permitted as long as the meal is part of the educational program. Non-educational gifts, such as promotional materials are not permitted.
4. Certain Vendor Reporting Requirements under the Affordable Care Act for physicians and teaching hospitals. Annually, applicable manufacturers of covered drugs, devices, biologicals, and medical supplies must report payments or other transfers of value they make to physicians and teaching hospitals to the Centers for Medicare and Medicaid Services (CMS). Applicable manufacturers must report all remuneration to physicians and teaching hospitals above the de minimis amount of \$10 per payment or \$100 in the aggregate for a calendar year. Applicable manufacturers must report payments by the nature of the activity in one of the following categories: (1) consulting fees; (2) compensation for services other than consulting; (3) honoraria; (4) gift; (5) entertainment; (6) food; (7) travel (including the specified destination); (8) education; (9) research; (10) charitable contribution; (11) royalty or license; (12) current or perspective ownership or investment interest; (13) compensation for serving as faculty or as a speaker for a

noncertified or accredited continuing education program; (14) compensation as a faculty at certified or accredited continuing educational program; (15) grant; or (16) space rental or facility fees for events held at a teaching hospital site. CMS will make the information publicly available on its website. Specific questions regarding the applicability of the Affordable Care Act to hospital-related activities should be directed to Kaleida Health's Office of General Counsel.

## 8.2 – Honoraria/Consulting Arrangements and Outside Employment.

1. Honoraria. With the permission of their manager, employees are encouraged to participate as faculty and speakers at educational programs and functions and to contribute to professional publications. However, any honoraria or compensation in excess of one hundred dollars (\$100) will be turned over to Kaleida Health or a Kaleida Health affiliated foundation unless the employee used paid time off or off-duty time to attend the program, or that portion of the program for which the honoraria is paid, or to produce the material for publication for which compensation is received.

## 2 Consulting Arrangements and Outside Employment

### a. All Employees:

Employees may act as consultants and employees of other entities/organizations provided that the consulting arrangement and/or outside employment in no way interferes with the performance of the employee's duties on behalf of Kaleida and is performed outside the employee's approved work schedule.

Employees may not directly contract with another entity to act as a consultant or employee when the consulting arrangement or outside employment is conducted during regular work hours, on premises, or if it presents a real or perceived conflict of interest.

### b. Management:

Management employees may not directly contract with another entity to act as a consultant or employee when the consulting arrangement or outside employment is conducted during regular work hours, on premises, **or if it requires the same job skills and/or qualifications used in his/her employment**, or if it presents a real or perceived conflict of interest.

If an employee is approached to consult or work on behalf of another entity because of their Kaleida Health credentials, the employee should contact the Chief Human Resources Officer and/or the Chief Compliance Officer to determine if the arrangement will be approved. Should another entity seek to leverage Kaleida Health employees, Kaleida Health may choose to contract with the other entity and any payment from that company will be turned over directly to Kaleida Health.

KEY NOTE: Employees covered by a Collective Bargaining Agreement (CBA) should contact their Site Human Resource leader to determine if outside employment and/or consulting (such as per diem preceptorship) is covered by a relevant CBA.

KEY NOTE: All Key Persons covered by Kaleida Health's Conflict of Interest Disclosure Process must disclose any outside employment and/or consulting arrangements as required by the Kaleida Health Conflict of Interest policy. Kaleida Health construes this obligation broadly.

## 8.3 - Contracting

Workforce members may not utilize "insider" information for any business activity conducted by or on behalf of Kaleida Health. All business relations with contractors must be conducted at arms-length both in fact and in appearance and in compliance with Kaleida Health policies and procedures. Workforce members must disclose personal relationships and business activities with contractor personnel who may be construed by an impartial observer as influencing the performance or duties of a Kaleida Health



employee. Workforce members have a responsibility to obtain clarification from management on questionable issues to assure compliance with Kaleida Health's Conflict of Interest Policy.

#### 8.4 - Business Inducements

Kaleida Health will never use gifts or any form of inducement to improperly influence business relationships or outcomes. Offering, giving, soliciting or receiving any form of inducement or other improper payment is prohibited. Kaleida Health accepts patient referrals based solely on the patient's medical needs and Kaleida Health's ability to render the needed services. Kaleida Health does not pay or offer to pay employees, physicians, or physician groups or other persons for referral of patients. Likewise, Kaleida Health does not accept any remuneration for referrals made by Kaleida Health.

Appropriate business commissions, rebates, discounts and allowances that are customary and conform to all regulatory and legal standards are acceptable if they are approved by a Kaleida Health Vice President. Any such payments must be reasonable in value, competitively justified, properly documented, and made to the business entity to which the original agreement or invoice was made or issued. Such payments should not be made to individual employees or agents of business entities.

With the approval of a Vice President, Kaleida Health managers or authorized Kaleida Health employees may provide entertainment and modest meals of nominal value to Kaleida Health customers, current and prospective business partners and other persons when such activities have a legitimate business purpose and are reasonable and consistent with all applicable laws.

This section shall not apply to the activities of workforce members while acting as individuals or on behalf of entities other than Kaleida Health, so long as such individual or non-Kaleida Health activities are distinct from, and do not directly relate to, Kaleida Health, health care items and services, which are provided by an affiliated physician.

#### **Principle 9 - Protection of Assets**

**All workforce members will strive to preserve and protect the corporation's assets by making prudent and effective use of Kaleida Health resources and properly and accurately reporting its financial condition.**

The Standards set forth below are intended to guide key employees by articulating Kaleida Health's expectations as they relate to activities or behaviors which may impact Kaleida Health's financial health or which reflect a reasonable and appropriate use of the assets.

#### 9.1 - Internal Control

Kaleida Health has established control standards and procedures to ensure that assets are protected and properly used, and that financial records, reports and cost reports are accurate and reliable. All workforce members of Kaleida Health share the responsibility for maintaining and complying with required internal controls. Activities perceived to be non-compliant should be reported to the appropriate manager, Internal Audit and Corporate Compliance or Kaleida Health's Office of General Counsel.

#### 9.2 - Financial Reporting

Kaleida Health has established and maintains a high standard of accuracy and completeness in the documentation and reporting of all financial records. Financial reports, accounting records, cost reports, research reports, expense accounts, time and attendance records must accurately and clearly represent the relevant facts and true nature of a transaction. Improper or fraudulent accounting, documentation or financial reporting is contrary to Kaleida Health policy and national standards and may be in violation of federal and state laws. Illegal or inappropriate activities of this sort must be reported immediately to Kaleida Health's Office of General Counsel, Internal Audit and Corporate Compliance and the external auditors for Kaleida Health.

#### 9.3 - Expense Reimbursement

Reimbursable expenses should be consistent with the workforce member's job responsibility and Kaleida Health's needs and resources. It is Kaleida Health's policy that a workforce member should neither suffer a financial loss nor realize a financial gain as a result of business travel, entertainment, or other appropriate expenses incurred. Workforce members are expected to exercise reasonable judgment in the

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use of Kaleida Health’s assets and to spend the organization’s assets as carefully as they would spend their own. Workforce members must also comply with Kaleida Health policy relating to expense reimbursement and special purpose funds.

#### 9.4 - Personal Use of Corporate Assets

All workforce members are expected to refrain from employing Kaleida Health assets for personal use. It is the responsibility of each workforce member to preserve the organization’s assets including time, materials, supplies, equipment, services and information. All property and business of Kaleida Health will be used or conducted in a manner designed to further Kaleida Health’s interests rather than the personal interests of a workforce member. Workforce members are strictly prohibited from the unauthorized use of or taking of Kaleida Health’s assets.

Engaging in any activity on company time that will result in remuneration to a workforce member, or the use of Kaleida Health’s equipment, supplies, materials or services for personal or non-work related purposes is prohibited. Any exception to this standard requires written approval of the Vice President responsible for the individual and/or area involved.

#### **Principal 10 - Policy of Non-Intimidation and Non-Retaliation**

All workforce members are expected to participate in and comply with Kaleida Health’s Compliance Program, including the reporting of any violation or compliance issue. Retaliation or intimidation in any form against an individual who in good faith reports possible unethical or illegal conduct or otherwise participates in the Compliance Program is strictly prohibited and is itself a serious violation of the Code of Conduct. Acts of retaliation or intimidation should be immediately reported to the Chief Compliance and Privacy Officer and, if substantiated, will be disciplined appropriately.

**\*\*Keypoint: Nothing in this Code of Conduct and Business Ethics is intended to, or will be construed as providing any additional employment rights to employees or other persons.**

**In cases where employees are represented under a collective bargaining agreement, Kaleida Health will administer policies and procedures including this Code as outlined in the respective collective bargaining agreement.**

#### **IV. Approved by -**

General Counsel	9/10, 6/13, 12/14, 5/18, 3/19, 10/20
Audit and Corporate Compliance Committee	10/10, 8/13, 12/14, 5/18, 8/19, 8/21, 9/22
Board of Directors	4/08, 12/10, 12/14, 6/18, 4/15/19

#### **V. References**

N.Y. State Finance Law, § 39, Article XIII (“**New York State False Claims Act**”)  
N.Y. Soc. Serv. Law § 366-d; Consolidated Laws Service Unconsolidated Laws of NY ch. 35 (“**Not-for-Profit Corporation Law**”); 18 N.Y.C.R.R. § 515.2

Social Security Act § 1877, 42 U.S.C. 1395nn (“**Physician Self-Referral Law**”) (codified as amended at 42 C.F.R. §§ 411.350-411.357); 42 U.S.C. § 1320a-7a (“**Civil Monetary Penalties Law**”)  
Social Security Act § 1128B, 42 U.S.C. 1320a-7b (“**Criminal Penalties for Acts Involving Federal Health Care Programs**”)  
31 U.S.C. §§ 3729 - 3733 (“**False Claims Act**”)  
Title VI of the Civil Rights Act of 1964; Health Insurance Portability & Accountability Act of 1996 (**HIPAA**), Public Law 104-191 (codified as amended in 45 C.F.R. Parts 160 and 164); Emergency Medical Treatment and Active Labor Act (**EMTALA**),  
42 USC 1395 dd; Federal Sentencing Guidelines  
Federal Deficit Reduction Act of 2005  
Pub.L. 109–171, § 1932, 120 Stat. 4; Patient Protection and Affordable Care Act  
Pub. L. 111–148, 124 Stat. 119 (codified as amended at scattered sections of the Internal Revenue Code and in 42 U.S.C.); 26 C.F.R. § 53.4958-3(c).


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IAC.20 - Corporate Compliance Program Structure and Guidelines  
 IAC.18 - Fraud, Waste and Abuse Compliance Including Federal and New York State False Claims Act Information  
 IAC.31 - Language Assistance Plan  
 FI.01 - Expense Reimbursement  
 FI.05 - Kaleida Health Special Purpose Funds  
 HR.24 - Harassment  
 HR.15 - Standards of Personal Conduct  
 HR.100 - Equal Employment Opportunity/ Affirmative Action  
 MED.9 – Medical Staff Professional Conduct  
 ORSP.5 - Responding to Allegations of Research Misconduct  
 ORSP.11 - Human Subject Protection  
 PFS.3 – Financial Assistance  
 PT.08 - Notification of Patient Rights

#### Version History:

<b>Effective Date:</b>	<b>Reviewed/ Revised</b>
1/24/24	Revised
9/22	Reviewed no changes
8/21	Reviewed no changes
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9/16/19	Revised
7/30/18	Revised
9/18/17	Reviewed no changes
9/5/17	Reviewed no changes
8/29/16	Reviewed no changes

Kaleida Health developed these Policies, Standards of Practice, and Process Maps in conjunction with administrative and clinical departments. These documents were designed to aid the qualified health care team, hospital administration and staff in making clinical and non-clinical decisions about our patients' care and the environment and services we provide for our patients. These documents should not be construed as dictating exclusive courses of treatment and/or procedures. No one should view these documents and their bibliographic references as a final authority on patient care. Variations of these documents in practice may be warranted based on individual patient characteristics and unique clinical and non-clinical circumstances. Upon printing, this document will be valid for 1/24/2024 only. Please contact Taylor Healthcare regarding any associated forms.

 <b>Kaleida Health</b> <b>POLICY</b>	<b>Title: Human Subject Protection</b>  <b>Owner:</b> Office of Research and Sponsored Projects	<b>#</b> <b>ORSP.11</b>
		<b>Issued:</b> 10/4/10
<b>Keywords:</b> Human Subject, Research		

### I. Introduction

This policy is intended to protect the rights and welfare of human subjects and to ensure that human research activities conform to the ethical codes of conduct for human experimentation, federal and state statutes, Department of Health and Human Services (DHHS), and the Food and Drug Administration (FDA) regulations, policies and guidelines; and applicable Kaleida Health policies and procedures that are referenced in this policy.  
See Addendum A for definitions.

### II. Audience

- A. Medical Staff, hospital and nursing home staff including employees, students, interns, fellows, residents and volunteers. Consultants, contractors and vendors of Kaleida Health, as applicable.
- B. Human subject research is covered under this policy if it satisfies any of the following criteria.
  - 1. It is conducted by or under the direction of Kaleida Health personnel;
  - 2. It uses Kaleida Health property, facilities, or resources to support or carry out the research;
  - 3. The name of Kaleida Health is used in applying for research funds;
  - 4. The name of Kaleida Health is used in explanations and/or representations to research subjects;
  - 5. The principal investigator plans to use his/her Kaleida Health affiliation in any dissemination, publication or public presentation resulting from the research;
  - 6. Kaleida Health's non-public information will be used to identify or contact human research subjects or prospective subjects.

### III. Instructions

Kaleida Health is committed to the ethical principles for the protection of human subjects in research set forth in the *Belmont Report* of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Kaleida Health recognizes and accepts responsibility, which it shares with principal investigators and other research personnel, for determining that research involving human subjects fulfills these ethical principles.

- A. The basic ethical principles outlined in the *Belmont Report* include respect for persons, beneficence, and justice. A summary of these principles follows:
  - 1. *Respect for persons.* Researchers must obtain informed consent from all human subjects asked to participate in research. In order to respect human subject autonomy, the consent process includes giving human subjects full and comprehensible information about the research and providing a clear assurance of the subjects' voluntary participation.
  - 2. *Beneficence.* Concern for the well-being of subjects, and requires that the risk of harm to human subjects is the least possible, and that the sum of benefits to the human subject and the importance of the knowledge to be gained so outweighs the remaining harm as to waive a decision to allow this risk.

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3. *Justice.* The selection of human subjects must be fair and equitable and the risks and benefits of research should be distributed among human subjects in a fair and equitable manner, with particular concern for human subjects whose personal status or condition, e.g. children, patients, impoverished persons, places them in a vulnerable or dependent position.
- B. It is Kaleida Health's policy that the regulations of the Department of Health and Human Services (HHS), set forth in 45 CFR Part 46, are applicable to all research involving human subjects for which Kaleida Health is responsible, regardless of the source of funding or whether the research is funded. In the case of conflict between regulations of the funding or regulatory agency and HHS, the more restrictive regulations will prevail. Kaleida Health is also obligated by law to adhere to the regulations of the Food and Drug Administration (21 CFR Parts 50 and 56) governing projects involving investigational new drugs (within the meaning of 21 U.S.C. sections 355(i) or 357(d)), or investigational new devices (within the meaning of 21 U.S.C. section 360(g)).
- C. **Human Subject Protection Program**  
Kaleida Health achieves its stated purpose for the protection of human subjects in research through the following mechanisms:
1. **Federalwide Assurance (FWA)**  
Kaleida Health is considered to be "engaged in research" as defined by the OHRP, and has an OHRP approved FWA certifying that it is in compliance with regulations for the protection of human subjects found at 45 CFR Part 46, Subparts A,B,C,D, for all research conducted by or at Kaleida Health, regardless of its funding source  
  
The Kaleida Health FWA is administered by the Office of Research and Sponsored Projects, and must be renewed every three years.
  2. **IRB Review and approval**  
All research conducted by or at Kaleida Health must be reviewed by the University of Buffalo IRB (UB IRB), the Social and Behavioral Sciences IRB (SBSIRB), or the Children and Youth IRB (CYIRB), and receive both initial and annual approval. The Kaleida Health Office of Research and Sponsored Projects will not approve research studies unless an IRB approval letter has been submitted along with the protocol, consent, and clinical trial agreement. Kaleida Health, as the institution or research site, will also review, and approve or disapprove all clinical research, but will not approve a research study that has not been approved by the appropriate IRB.
  3. **Informed Consent**  
No Principal Investigator may involve a human being as a subject in research unless the Principal Investigator has obtained informed consent of the subject or the subject's legally authorized representative. A Principal Investigator will seek consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence. The information that is given to the human subject or the legally authorized representative will be in language understandable to the human subject or the legally authorized representative.

Before informed consent may be obtained the Principal Investigator will provide the potential research subject ample time and opportunity to inquire about the details of the trial and to decide whether or not to participate in the trial. All questions about the trial should be answered to the satisfaction of the potential research subject.

If a potential research subject is unable to read an impartial witness should be present during the entire informed consent discussion. After the written informed consent form and any other written information to be provided to subjects is read and explained to the subject, and after the subject has orally consented to participation in the trial, and if capable of doing so has signed and personally dated the informed consent form, the witness must also sign and personally date the consent form.

Informed consent forms may not include exculpatory language through which the human subject or the legally authorized representative is asked to waive or appear to waive any of the human subject's legal rights, or releases or appears to release the Principal Investigator, the sponsor, Kaleida Health, or its agents from liability for negligence.

Informed consent will be documented through the use of an IRB approved written consent form that includes a statement that the patient received information to help determine whether or not to participate in the study.

The written consent form and any other written information to be provided to subjects should be revised whenever important new information becomes available that may be relevant to the subject's consent. Any revised written informed consent form, and written information must be reviewed and approved by the UB IRB.

- a. **Basic elements of informed consent.** The following basic elements must be included in the informed consent process:
- 1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, including all invasive procedures, and identification of any procedures which are experimental;
  - 2) A description of any reasonably foreseeable risks or discomforts to the subject;
  - 3) A description of any benefits to the subject or to others which may reasonably be expected from the research. When there is no intended clinical benefit to the subject, the subject should be informed of this;
  - 4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
  - 5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
  - 6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

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- 7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
  - 8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- b. **Additional elements of informed consent.** When appropriate, one or more of the following elements of information will also be provided to each subject:
- 1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
  - 2) Anticipated circumstances under which the subject's participation may be terminated by the Principal Investigator without regard to the subject's consent;
  - 3) Any additional costs to the subject that may result from participation in the research;
  - 4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
  - 5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
  - 6) The approximate number of subjects involved in the study, and if applicable, the probability for random assignment to each treatment.
- c. All consents used in research at Kaleida Health must be approved by the UB IRB and signed by the research subject, or the research subject's legally authorized representative. A copy of the consent must be given to the research subject, or the research subject's legally authorized representative.
- d. A consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waives the requirement to obtain informed consent may be approved by the IRB , provided that:
- 1) The research involves no more than minimal risk to the subjects;
  - 2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - 3) The research could not practicably be carried out without the waiver or alteration; and
  - 4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

- e. **Exemption from the general informed consent requirements for device or drug studies.** Informed consent must be obtained before a study drug or device (Test Article) is used, except under the following circumstances:
- 1) The Principal Investigator and a physician who is not otherwise participating in the clinical trial certify in writing all of the following:
    - a) The human subject is confronted by a life-threatening situation necessitating the use of the test article.
    - b) Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from the subject.
    - c) Time is not sufficient to obtain consent from the subject's legal representative.
    - d) There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.
  - 2) If immediate use of a test article is, in the Principal Investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the second opinion of a physician who is not otherwise participating in the clinical trial, the determination of the Principal Investigator will be documented and within 5 working days after the use of the test article the Principal Investigator's determination will be reviewed and evaluated by a physician who is not otherwise participating in the in the clinical trial.
  - 3) The documentation required under paragraph (1) and (2) above will be submitted to the IRB within 5 working days of the use of the test article.
- f. **Non-Therapeutic Trials.** Non-therapeutic trials should be conducted using subjects who are able to personally give consent and sign and date the written consent form.
- 1) Non-therapeutic trials may be conducted in subjects with the consent of a legally authorized representative provided the following conditions are met:
    - a) The objectives of the trial can not be met by means of a trial in subjects who can give informed consent personally.
    - b) The foreseeable risks to the subject are low.
    - c) The negative impact on the subject's well-being is minimized and low.
    - d) The trial is not prohibited by law.
    - e) The approval of the IRB is expressly sought on the inclusion of such subjects, and this is specifically addressed in the IRB approval letter.
  - 2) Non-therapeutic trials in which the subject cannot personally consent should be conducted in subjects having a disease or condition for which the test article is intended. Subjects in these trials should be closely monitored and withdrawn if they appear to be unduly distressed.



**D. Additional Safeguards for Children and Viable Neonates as Human Subjects in Research.**

The Children & Youth IRB (CYIRB) must review and approved any research project involving children as research subjects, regardless of the funding source or the departmental affiliation of the Principal Investigator. Any research study conducted at Oishei Children's Hospital (OCH) that involves the use of an investigational drug in a non-approved patient population must also obtain approval from the OCH Investigational Drug Subcommittee.

1. **Research not involving greater than minimal risk.** Kaleida Health will permit research in which the CYIRB finds that no greater than minimal risk to children is presented, only if the CYIRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.
2. **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.** Kaleida Health will permit research in which the CYIRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the CYIRB finds that:
  - a. The risk is justified by the anticipated benefit to the subject;
  - b. The relation of the anticipated benefit to the risk is at least as favorable to the subject as that presented by available alternative approaches; and
  - c. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
3. **Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.** Kaleida Health will permit research in which the CYIRB finds that more than minimal risk to subjects is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the CYIRB finds that:
  - a. The risk represents a minor increase over minimal risk;
  - b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
  - c. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
  - d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.
4. **Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.** Kaleida Health will permit research that the CYIRB does not believe meets the requirements of 1 through 3 above only if:
  - a. The CYIRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

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- b. The research will be conducted in accordance with sound ethical principles;
- c. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

5. **Requirements for permission by parents or guardians and for assent by children.**

- a. The CYIRB will determine that adequate provisions are made for soliciting the assent of children, when in the judgment of the CYIRB the children are capable of providing assent. In determining whether children are capable of assenting, the CYIRB will take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the CYIRB deems appropriate. If the CYIRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the CYIRB determines that the subjects are capable of assenting, the CYIRB may still waive the assent requirement under circumstances in which consent may be waived in accordance with Section 3.d of this policy.
- b. In addition, the CYIRB will determine whether adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the CYIRB may determine when the permission of one parent is sufficient for the research to be conducted, or permission must be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- c. If the CYIRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided that the waiver is not inconsistent with federal or state law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

E. **Additional Protections for Pregnant Women, Human Fetuses or Nonviable Neonates Involved in Research**

- 1. **Research involving pregnant women or fetuses.** Pregnant women or fetuses may be involved in research if all of the following conditions are met:
  - a. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

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- b. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
- c. Any risk is the least possible for achieving the objectives of the research;
- d. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman or the fetus, when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, the pregnant women's consent must be obtained in accordance with the informed consent requirements of Section B.3. of this policy;
- e. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father must be obtained in accordance with the informed consent provisions of Section B.3. of this policy. The father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- f. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- g. For children, as defined in this policy, who are pregnant, assent and permission are obtained in accord with the provisions of Section C. 5. of this policy;
- h. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- i. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- j. Individuals engaged in the research will have no part in determining the viability of a neonate.

- 2. **Research involving neonates of uncertain viability and nonviable neonates as subjects.** Kaleida Health does not permit research to be conducted on neonates of uncertain viability or nonviable neonates.

- F. **Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects.** Kaleida Health does not permit research to be conducted on prisoners.

- G. **Cooperative Research.** For those collaborative research projects with the potential for pediatric subject enrollment from Roswell Park Cancer Institute ("RPCI"), Oishei Children's Hospital (OCH) or both sites, each site is responsible for safeguarding the rights and welfare of human subjects.

- 1. A reciprocal agreement is in place between the RPCI IRB and the CYIRB for the joint review of collaborative pediatric research protocols which addresses the following issues:
  - a. Use of a single consent form, precluding the necessity for duplicate enrollment at both sites.
  - b. Duplicative IRB submissions.

- c. The single IRB of record requirement of various collaborative sponsoring such protocols.
2. Two CYIRB members (at least one being a CYIRB Co-Chair) will attend RPCI IRB meetings as non-voting members to provide expertise regarding human subject protection pertaining to children and youth, and identify concerns that would normally be discussed at CYIRB meetings and ensure resolution of such concerns. CYIRB member satisfaction with resolution of identified concerns will constitute CYIRB approval. In the event that concerns identified by the CYIRB are not resolved, the CYIRB Co-Chair(s) will provide a final decision, which may include referral to the full CYIRB for separate review.
3. **Informed consent**
  - a. Wording of consent forms will include language agreeable to both the RPCI IRB and the CYIRB and may be revised periodically by joint IRB decision to address emerging issues pertaining, but not limited to, human subject protection and HIPAA.
  - b. In the event that a physician determines that obtaining a minor's assent is appropriate, the CYIRB will accept the RPCI IRB assent policy for minors, which permits a minor to assent via documentation on the consent form instead of the minor signing a separate assent form.
  - c. Documentation of joint CYIRB and RPCI IRB approval will be made on the first page and signature page(s) of the consent form by a stamp reflecting the joint approval process and dates of the approval.
4. **Unanticipated Problems** - Occurrence of an unanticipated problem at OCH during a collaborative research study will be reported on the RPCI Unanticipated Problems Form and sent to the RPCI IRB for disposition within ten business days of the Principal Investigator becoming aware of the problem or within 24 to 48 hours of the Principal Investigator becoming aware of a subject death.

<b>IV. Approved by - (Include date)</b>	
Medical Executive Committee	8/18/10
Office of General Counsel	3/23/10
Ethics Committee	6/25/10
Medical Executive Committee	8/18/10
Board of Directors	10/4/10

**V. References**

Addendum A - Definitions

NYS: 45 PHL §2440; 10 NYCRR 405.2(f)(6)  
 Federal: 45 CFR Part 46, 21 CFR Parts 50 and 56

University at Buffalo Human Research Protection Program

Belmont Report

Guidelines for Good Clinical Practice

<b>Title: Human Subject Protection</b>	<b># ORSP.11</b>
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**Version History:**

<b>Effective Date:</b>	<b>Reviewed/ Revised</b>
12/11/17	Revised
8/29/16	Reviewed no changes
7/14	Reviewed no changes

Kaleida Health developed these Policies, Standards of Practice, and Process Maps in conjunction with administrative and clinical departments. These documents were designed to aid the qualified health care team, hospital administration and staff in making clinical and non-clinical decisions about our patients' care and the environment and services we provide for our patients. These documents should not be construed as dictating exclusive courses of treatment and/or procedures. No one should view these documents and their bibliographic references as a final authority on patient care. Variations of these documents in practice may be warranted based on individual patient characteristics and unique clinical and non-clinical circumstances. Upon printing, this document will be valid for 3/24/2023 only. Please contact Taylor Healthcare regarding any associated forms.


## Addendum A - Definitions

1. **Assent** means a child's affirmation agreement to participate in research. Mere failure to object may not, absent affirmative agreement, be construed as consent.
2. **Children** means persons who have not attained the legal age for consent to treatment or procedures involved in research. In New York, age 18.
3. **Clinical Investigation** means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under 21 CFR §505(i) or §520(g)
4. **Cooperative Research** means research projects that involve more than one institution (e.g. Kaleida Health and Roswell Park).
5. **De-Identified Information.** Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.
6. **"Engaged in research"**, as defined by OHRP, means an institution that, by its employees or agents:
  - a. obtains data about living individuals for research purposes through intervention or interaction with them;
  - b. obtains individually identifiable private information for research purposes (45 CFR 46.102(d),(f)); or
  - c. seeks or obtains informed consent from a human research subject.
- d. An institution is considered to be engaged in human subjects research whenever it receives a direct HHS award (e.g. NIH grant) to support such research, even if all of the human subjects activities will be performed by agents or employees of another institution.
7. **External Researcher.** Any individual who is not a member of the Kaleida Health Workforce and performs activities defined in this policy as Research.
8. **FDA** means the DHHS Food and Drug Administration. The FDA oversees the safety of foods, drugs, devices, biologics and cosmetics for human use, and enforces DHHS regulations (21 CFR Parts 50 and 56) for the protection of human subjects and the general standards for the composition, operation, and responsibility of an Institutional Review Board ("IRB") that reviews clinical investigations.
9. **Guardian** means an individual who is authorized under New York State law to consent, on behalf of a child or adult deemed by a court to lack capacity, to general medical care or to participate in research.
10. **Generalizable Knowledge.** Knowledge may be generalizable even if a research study only uses Protected Health Information ("PHI") held within Kaleida Health and the results are generalizable only to the population served by Kaleida Health. Research is not limited to clinical trials funded by government sponsors (such as the National Institutes of Health) or commercial sponsors. Quality assurance and utilization management activities do not typically result in generalizable knowledge and thus ordinarily would not be governed by this policy.
11. **Human Subject**, under 45 CFR section 46, means a living individual about whom a principal investigator (whether professional or student) conducting research obtains:
  - a. Data through intervention or interaction with the individual, or
  - b. Identifiable private information.

12. **Human Subject**, under 21 CFR section 50.3, means an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy human or a patient.
13. **Human Subjects Research** means any project that represents “research” and involves “human subjects” (45 CFR 46); and, when applicable, the activity represents a “clinical investigation” of a “test article” (21 CFR 50).
14. **Interaction** means communication or interpersonal contact between principal investigator and human subject.
15. **Intervention** means physical procedures by which data are gathered (e.g. venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
16. **IRB** means an Institutional Review Board established in accord with DHHS and FDA regulations.
17. **IRB Approval** means the determination of the IRB that a human subject research protocol has been reviewed and may be conducted at Kaleida Health within the constraints set forth by the IRB and by other institutional and federal requirements.
18. **Kaleida Health Resources** are funds, facilities, employee time, equipment, supplies, services, and nonpublic information.
19. **Kaleida Health Workforce.** The Kaleida Health Workforce refers to Medical Staff members, hospital staff, and nursing home staff, including employees, students, interns, residents, and volunteers.
20. **Legally Authorized Representative** means a person authorized either by New York statute or by court appointment to make legal decisions on behalf of another person. In human subject research, an individual, or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.
21. **Limited Data Set.** A limited data set (LDS) is protected health information that excludes 18 direct identifiers of an individual or of relatives, employers or household members of such individual, as specified in the HIPAA Privacy Rule at 45 CFR §164.514(e)(1).
22. **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
23. **Non-Therapeutic Clinical Trial** means a trial in which there is no anticipated direct clinical benefit to the human research subject
24. **OHRP** means the DHHS Office of Human Research Protections. The OHRP implements a program of compliance oversight for DHHS regulations (45 CFR Part 46) for the protection of human subjects.
25. **Parent** means a child’s biological or adoptive parent.
26. **Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in research.

27. **Principal Investigator.** The individual responsible for the scientific, technical, and administrative aspects of the project.
28. **Private information** means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for a specific purpose by an individual and which the individual can reasonably expect will not be made public (e.g. a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may be readily ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
29. **Protected Health Information (“PHI”)** means any information, whether oral or recorded in any form or medium: (1) that relates to the past, present or future physical or mental condition of an individual, the provision of health care to an individual, or the past, present or future payment for the provision of health care for an individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.
30. **Research.** Research includes any systematic investigation (including research development, testing, and evaluation) that has as its primary purpose the development of or contribution to *generalizable knowledge*. This includes the development of research repositories and databases for research.
31. **Test Article** means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under U.S.C. 262 and 263b-263n.
32. **Ward** means a child who is placed in the legal custody of the State or other agency, institution or entity, consistent with applicable federal, state, or local law.



 <b>Kaleida Health</b> <b>POLICY</b>	<b>Title: Language Assistance Plan</b>	<b># IAC.31</b>
	<b>Owner:</b> Office of General Counsel	<b>Issued:</b> 9/28/01
<b>Keywords:</b> language assistance, limited English proficiency, interpreter, translation, Voyce		

## I. Statement of Purpose

Kaleida Health does not discriminate against patients who are Limited in English Proficiency (LEP). Kaleida Health endeavors to ensure that our patients receive the Language Assistance Services (LAS) necessary to afford them meaningful access to the health care services provided by Kaleida Health. This policy outlines the process and procedure for identifying and assessing the language needs of LEP patients. Kaleida Health provides language assistance through a range of options, and provides notice to patients of their right to receive such free language assistance. Interpreting services for Limited English Proficiency (LEP) and Deaf/Hard of Hearing patients must be provided by law.

## II. Audience

*Workforce Members* including employees, independent contractors, agents, volunteers, trainees or other persons who perform work for Kaleida Health. This includes, but is not limited to, full and part time employees, per diem and contract employees, affiliates, associates, directors, officers, managers, supervisors, volunteers, physicians employed by or otherwise affiliated with Kaleida Health, medical residents, nursing students or others receiving training at any Kaleida Health facility, and others who provide goods or services to Kaleida Health.

## III. Instructions

### A. Definitions

- Language Assistance Services (LAS)** are services that organizations use to bridge the communication barrier with LEP individuals.
- Limited English Proficiency (LEP)** is defined as individuals who do not speak English as their primary language AND who have a limited ability to read, speak, write, or understand English. LEP persons may be competent in certain types of communication (e.g., introductions or basic questions), but still have limited English proficiency for other purposes (e.g., reading or understanding medical terms). Any individual has the right to communicate in a language other than English for their healthcare.
- English Proficiency** the ability to read, write, speak, and understand English with enough fluency to translate or interpret healthcare information.

4. **English as a Second Language (ESL)** refers to the study or use of English in individuals whose native language is something other than English.
5. **Bilingual** refers to the ability to understand and communicate fluently in two languages (generally, as used here, English and another language). If a patient is fluent in English (i.e., they can read, write, speak, and understand English) they are considered Bilingual rather than LEP. Bilingual individuals would not require interpretive services but they may still request services at any time.
6. **Deaf** refers to those who have profound hearing loss with very little to no hearing.
7. **Hard of Hearing** refers to people with hearing loss ranging from mild to severe.
8. **Interpreting** is the process of converting conversation between two or more people from one language into another.
9. **Translating** is converting written words from one language to another.
10. **Over-the-Phone Interpretation (OPI)**, also known as telephonic interpreting, refers to the act of translating one language to another over the phone. This can be done via a 2 or 3-way call and happens between you, the interpreter, and the party you are trying to reach.
11. **Video Remote Interpretation** is a service that connects people who don't speak the same language using video conferencing technology and an interpreter. The interpreter is typically located at a call center and uses a headset to hear what the other person is saying. They then sign or voice the interpretation to the other person.
12. **Face-to-Face Interpretation** is a form of interpretation in which the interpreter translates spoken language, orally, between parties who are present and interacting with each other in person.
13. **Urgent or Emergent Situations** are defined as imminent threat to the safety or welfare of an individual or the public.

#### B. Section 1557 Coordinator

1. Section 1557 prohibits discrimination based on race, color, national origin, sex, age, disability or any other status protected by law in health programs.
2. The Section 1557 Coordinator retains ultimate oversight for ensuring compliance and coordination of responsibilities under 42 USC section 18116 and attendant regulations for all Kaleida Health facilities. As appropriate, a covered entity may assign one or more designees on site that carry out some of the responsibilities found in this Section- such as investigation of any grievance or review of allegations prohibited by this regulation.

### C. Department Responsibility

1. The department where the patient presents is responsible for initiating interpreter services as outlined in this policy. Any department referring an LEP patient to another Kaleida Health department must notify the receiving department of the patient's identity, the language they speak, and approximate arrival time. Front desk and guest relations staff assisting family members and guests should refer to their department manager for internal workflow processes.
2. All workforce members are responsible for staying in compliance with annual training for Language Assistance Services. Workforce members should refer to this policy if there are questions when referring patients and family members.

### D. Time Limits

1. **New York State law requires** that the following **time limits** be followed when securing language assistance services:
  - a. Inpatient and Outpatient Areas- Services are made available to the LEP person(s) within 20 minutes of a request by the patient, the patient's family or representative, or the provider of medical care.
  - b. Emergency Departments- Services are made available to the LEP person(s) within 10 minutes of a request made by the patient, the patient's family or representative, or the provider of medical care.
2. Face-to-face interpretation may be delayed while an interpreter is being secured for the LEP person(s). During this time, the staff may use other communication tools, such as the pain scale or over-the-phone interpreting, to determine whether the patient has any immediate needs. For the purposes of the above, a request for language assistance is constituted by:
  - a. An individual who has a limited ability to read, speak, write, or understand English
  - b. A verbal request from the LEP person(s)
  - c. The determination of a language barrier by the workforce member

### E. Emergencies

1. In urgent or emergent situations, where a patient's medical condition might be compromised by waiting for a face-to-face interpreter to arrive or when an over-the-phone interpreter is not appropriate or available, workforce members should render the necessary and appropriate medical treatment, and use their best efforts to effectively communicate until an interpreter is available. Individuals younger than 18 years of age should only be used in emergent situation, and their use and details of the situation documented in the medical record.

2. Employees should not be using personal phones to translate. Phone use (ie., Google Translate) should only be used if staff needs to inform patients that they are working to obtain Kaleida Health's Language Assistance Services or in emergency situations.

**\*\*Key point:** If an event occurs that resulted in or could have resulted in an unintended adverse development in patient's condition as a result of a language/communication barrier (for example, unavailability of an interpreter), an incident report must be completed. In the incident report, best efforts should be made to include the date and approximate time and specific event details.

3. After all reasonable attempts have been made to secure an interpreter; patient/family will be advised they may need to wait for an interpreter to be available. If the patient/family does not want to wait, they may sign a waiver to allow interpretation by a non-vendor.

#### F. Interpreter Services – Free to Patient

1. Kaleida Health staff must inform the LEP patient of their right to free language interpretation services. These services are provided to the patient, family member, and/or companion at no cost. Notification of this free service should be provided by one of the following interpreting methods:
  - a. VOYCE Video Remote Interpretation (including American Sign Language)
  - b. VOYCE Over-the-Phone (OPI)
  - c. Face-to-Face Interpreting from a Kaleida Health approved vendor
  - d. In the case of an emergency, a Kaleida Health work force member who is fluent in the LEP patient's language
2. Information on how to access interpretative services can also be found on Kaleidascope or KaleidaHealth.org and informational posters/brochures located across the organization. The patient's family members (friends or non-hospital personnel) should not act as interpreters unless free interpreter services have been offered and refused, and the patient agrees to their use. Issues of interpreter age, interpreter competency, confidentiality, or conflicts of interest should still be taken into account.

#### G. Circumstances Requiring Interpreter Services

1. Interpreter services must be provided in all circumstances when a person is unable to speak, read, write or understand the English language at a level that permits him/her to interact effectively with health providers. In order to determine the language needed to be interpreted, have the patient point to the correct language on the language assistance poster located in the department. If a language assistance poster is not available or the patient is unable to read in their native language, put the patient on the phone with the VOYCE translation service directly or, where possible, consult with the patient's primary care office.

2. Examples of circumstances in which interpreters should be used include but are not limited to the following:
  - a. Determination of a patient's medical history or presenting problem
  - b. Provision of patient's rights, informed consent or permission for treatment
  - c. Explanation of advanced directives
  - d. Explanation of diagnosis or prognosis
  - e. Explanation of procedures, tests, treatment, treatment options, or surgery
  - f. Explanation of medication regime and possible side effects
  - g. Explanation of follow-up treatment, dietary restrictions, therapy, test results, or recovery
  - h. Interviews to ascertain the validity of accusations/suspicions of any abuse, or domestic violence/treatment in such cases
  - i. Discharge instructions
  - j. Educational classes related to illness, birth, or rehabilitation
  - k. Billing or insurance issues

#### H. Accessing Interpreters

1. Kaleida Health offers VOYCE video remote interpreting, VOYCE over-the-phone interpreting (OPI), and face-to-face interpreting services to its patients.

**\*\*Key point:** Employees should not be using personal phones to translate. Phone use (ie: Google Translate) should only be used if staff needs to inform patients that they are working to obtain Kaleida Health's approved vendors for Language Assistance Services.

#### 2. VOYCE Video Remote Interpreting

Video remote interpretation is available through VOYCE, which offers video translation services for over 200 languages. The service is available 24 hours per day/seven days per week. VOYCE has supplied iPads which have been dispersed throughout the organization to ensure effective access to VOYCE. Instructions for use are available on the Language Assistance Services page of *KaleidaScope*. Requests to repair broken VOYCE iPads and technical support should be directed to the Kaleida Health IT Technology Assistance Center.

#### 3. VOYCE Over-the-phone Interpreting

Telephonic interpretation is available through VOYCE, which offers telephonic interpretation for over 200 languages. The service is available 24 hours per day, 7 days per week. Black dual handset and cordless phone set units have been dispersed throughout the organization to ensure effective access to VOYCE. This service can additionally be accessed through any Kaleida Health touch-tone phone or Ascom device by calling (716) 303-3216. Instructions for use of the VOYCE phones are kept with the VOYCE phones.

Requests to repair broken VOYCE phones and technical support should be directed to the Kaleida Health IT Technology Assistance Center. Requests for additional VOYCE corded and cordless phones should be directed to Kaleida Health's IT department through the IT Service Portal or via phone.

VOYCE is SOC2 type2 compliant and their interpreters receive 120 hours of standardized training. In training, interpreters learn medical terminology, anatomy and physiology, and other topics essential for healthcare interpreting. VOYCE's interpreters are tested to demonstrate their competence.

#### 4. Face-to-face Interpreting

Departments may request an interpreter through the following Kaleida Health approved community vendor organizations. Services provided by these organizations are available during business hours or after hours/weekends if scheduled prior to when the service is needed. When possible, face-to-face interpreters should be requested in advance. See timelines for specific services below.

- a. **International Institute of Buffalo** –Provides certified interpreters. Interpreting services may be requested by calling (716)249-1234 or using International Institute of Buffalo's Global Interpreter Platform available at <https://iibuffalo.interpretmanager.com/>. Booking online is strongly encouraged and requires a unique log-in. Workforce members should contact [interpretation@iibuf.org](mailto:interpretation@iibuf.org) to set up an account. **Booking is strongly encouraged 48 hours in advance.**
- b. **Journey's End** – Interpreting service can be requested by calling (716)882-4963, ext. 201 or 207. Alternatively, requests can be made by emailing [interpreting@jersbuffalo.org](mailto:interpreting@jersbuffalo.org) or by using JER's online scheduling system Aqua Schedules. Use of Aqua Schedules is encouraged. Appointments through Aqua Schedules require a unique log-in and requesters can sign up to use the system at <http://jersbuffalo.scheduling.online>. **Booking is strongly encouraged 48 hours in advance.**
- c. **Jericho Road** – Interpreting service can be requested by calling (716)201-0623 for a doula interpreter (labor and delivery, postpartum, and MFM) or (716)381-2725 for non-labor and delivery patients. **Booking is strongly encouraged 24 hours in advance.**

**\*\*Key point:** Homecare staff should contact their supervisor/manager for authorization for face-to-face interpreter services. Please refer to your facility policy for more detailed instructions.

#### 5. Written Materials

Any written material such as consents or patient teaching material provided to the patient in a non-translated version requires that staff members arrange to have an on-site or telephonic interpreter.

Staff should contact the Section 1557 Coordinator with requests to have frequently used documents translated to other languages. The Patient Bill of Rights and many other documents have been translated into several languages and can be accessed via *Forms on Demand*.

Continental Translation Services, Inc. does the majority of Kaleida Health's document translations and performs the following linguistic verification testing:

- a. Verification of translation accuracy
- b. Checking for typographical errors
- c. Checking for truncated or misallocated text
- d. Assessment of cultural appropriateness
- e. Checking for politically sensitive content

#### 6. Family Member or Patient-Provided Interpreter Services

If a patient with limited English proficiency declines the offer of an interpreter and requests that a family member, friend, or other party, facilitate communication on their behalf, such a person may be used only if the workforce member is reasonably comfortable that the person will provide effective communication on the patient's behalf (if the workforce member is unsure, consult with a clinical manager/designee). If the staff questions the effectiveness of the patient-provided interpreter, they may suggest that a trained interpreter sit in on the encounter to ensure accurate information is being communicated. Workforce members must provide effective communication on the patient's behalf.

Workforce members must request that the patient or their legal representative sign a "Waiver of Interpreter/Translator Services" in the patient's primary language (KH01004) found on Forms on Demand. A waiver form (KH01004) must also be completed for patients accompanied to an appointment by a sponsor/agency that is not from one of the Kaleida approved face-to-face interpreter services vendors named in this policy.

**\*\*Key point:** Individuals younger than 18 years of age should only be used in emergent situations that involve imminent threat to the safety or the welfare of the individual or public. Once an appropriate interpreter is obtained, the minor should be removed from the situation and any information obtained from the minor should be verified by the interpreter.

After all reasonable attempts have been made to secure an interpreter; patient/family will be advised they may need to wait for an interpreter to be available. If the patient/family does not want to wait, they may sign a waiver to allow interpretation by a non-vendor.

## 7. Kaleida Health's Bilingual Staff

A bilingual workforce member who is fluent in the patient's language may be used to interpret non-clinical information, such as appointments or demographic information. Workforce members may be used to interpret clinical information in emergency situations only. However, a provider who is a part of that patient's care team AND is fluent in the patient's language may, at any time, interpret clinical and non-clinical information.

### I. Documentation

Admission/registration staff will determine the patient's LEP status and language of preference, and enter the information into the appropriate registration system. This information will subsequently appear on the patient's face sheet and in the electronic demographic tab. Patients who have been identified as requiring language assistance services will also have a notification/alert in the Pop-up pane on the Cerner window.

**\*\*Key point:** A bilingual patient that can read, write, and understand English should be considered an English speaker for the encounter and documented as such. Additionally, there is an English Proficiency documentation field that exists in the EMR where staff can document if the patient speaks, reads, writes, and understands English.

Workforce staff are required to document that interpreter services were offered and that the services were either accepted or declined.

1. If services are **Accepted**, document as follows:

- a. Name of agency providing the service
- b. Name of person interpreting and, if VOYCE, the interpreter's ID number
- c. Language being interpreted
- d. Method of interpretation (telephone, face-to-face, video)
- e. Date and time services were provided
- f. Topic of discussion during interpretation

2. If services are **Declined**, document as follows:

- a. Complete and have patient sign the "Waiver of Interpreter/Translator Services" (KH01004) in the patient's primary language. Waivers have been translated into 22 languages. If the waiver is not available in the patient's primary language, use VOYCE or face-to-face interpreter to interpret the waiver.
- b. Document the name of the interpreter who explained the waiver form (KH01004), if necessary, and the patient's reason for refusing.



3. Waivers are placed in the medical record as follows:

Waivers for interpreting services should be filed in the regulatory section of the medical record/EMR.

a. Ambulatory Services

- 1) A new "Waiver of Interpreter/Translator Services" (KH01004) must be completed or the existing one updated for every encounter with an LEP patient who has refused language services provided by Kaleida Health.
- 2) The updated section on the waiver form can be used if all information about the patient, a parent or guardian, reason for refusal and the person interpreting remains the same.
- 3) A new waiver must be completed if the information has changed or if the care level or the facility in which care is being provided has changed.

b. Inpatient Care, Ambulatory Surgery, or Emergency Department

- 1) The original waiver will remain in effect throughout the entire stay unless the patient requests a change.
- 2) A new waiver must be completed when the patient requests a change in interpreter services.

c. Home Care

- 1) The original waiver will remain in effect throughout the entire stay unless the patient requests a change.
- 2) A new waiver must be completed when the patient requests a change in interpreter services.

## J. Complaints

Workforce members may receive complaints from an LEP patient or family member. These complaints should be taken very seriously. Upon receipt of a complaint, follow RM.9 – Customer Relations – Grievance (Complaint) Process, or in Long Term Care, LTCA.3 – Customer Relations Form – Complaint/Compliment Process.

If an event occurs that resulted in or could have resulted in an unintended adverse development in patient's condition as a result of a language/communication barrier (for example, unavailability of an interpreter), an incident report must be completed. In the incident report, best efforts should be made to include the date and approximate time and specific event details.

**I. Approved by**

Chief Compliance and Privacy Officer  
 Corporate Policy Approval Committee  
 General Counsel  
 Nurse Executive Committee  
 Medical Executive Committee  
 Clinical Interdisciplinary Committee  
 Associate General Counsel  
 Section 1557 Coordinator

9/9/11, 5/8/15, 6/9/17, 7/14/17, 12/15/22, N/A  
 9/05, 9/13, 4/15, 7/16, 2/17, 5/17, 6/17, 11/21  
 9/9/05, 5/5/15, 8/17/16, N/A  
 9/19/01, 10/19/05, 5/20/15, 12/15/21, 1/18/23  
 11/18/21, 12/15/22, N/A

**V. References**

Customer Relations- Grievance (Complaint) Process (RM.9)

Code of Conduct and Business Ethics (IAC.19)

Informed Consent (Capacity) (LE.19)

Informed Consent (Documentation) (LE.20)

Customer Relations Form- Complaint/ Compliment Process (LTCA.3)

Bill of Rights – LTC (LTCSW.13)

Communicating with Deaf/Hard of Hearing (IAC.29)

Anti-Discrimination and Anti-Harassment Policy (HR.3)

Notification of Patient Rights (PT.8)

State: NYS Title 10 NYCRR 405.7

Federal: Civil Rights Act of 1964, Title VI; Executive Order 13166

42 USC section 18116 (Section 1557 of the Affordable Care Act)

45 CFR Part 92, subparts A-D

KH01207 – Interpreter Documentation for Limited English Proficiency and Deaf Patients (via Forms on Demand)

KH00130, AN IMPORTANT MESSAGE FROM MEDICARE – English, Arabic, Bengali, Burmese, French, Karen, Nepali, Russian, Somali, Spanish, Swahili

KH01192, Detailed Notice of Discharge - All Sites  
 Arabic, Bengali, Burmese, French, Karen, Nepali, Russian, Somali, Spanish, Swahili

KH24839, Medicare Outpatient Observation Notice - CMS-10611 MOON  
 Arabic, Bengali, Burmese, French, Karen, Nepali, Russian, Somali, Spanish, Swahili

KH01004, Waiver of Interpreter/Translator Services – English, Albanian, Arabic, Bengali, Burmese, German, Greek, Farsi, French, Hindi, Croatian, Italian, Japanese, Karen, Karenni, Korean, Kunama, Nepali, Polish, Portuguese, Russian, Somali, Spanish, Vietnamese, Chinese

DOH-1470, Parents Bill of Rights – English, Arabic, Bengali, Burmese, Chinese, Haitian Creole, Karen, Korean, Nepali, Russian, Somali, Spanish

DOH-1500, Patients Bill of Rights – English, Arabic, Bengali, Burmese, Chinese, Haitian Creole, Karen, Korean, Nepali, Russian, Somali, Spanish

[International Institute of Buffalo](#)

[Login | Visitor | Journey's End Refugee Services](#)

**Version History:**

Effective Date:	Reviewed/Revised
2/18/25	Revised
8/2/24	Reviewed no changes
2/1/23	Revised
12/30/21	Revised
10/26/20	Revised
8/7/17	Revised
6/26/17	Revised
3/20/17	Revised
9/12/16	Revised
6/22/15	Revised

Kaleida Health developed these Policies, Standards of Practice, and Process Maps in conjunction with administrative and clinical departments. These documents were designed to aid the qualified health care team, hospital administration and staff in making clinical and non-clinical decisions about our patients' care and the environment and services we provide for our patients. These documents should not be construed as dictating exclusive courses of treatment and/or procedures. No one should view these documents and their bibliographic references as a final authority on patient care. Variations of these documents in practice may be warranted based on individual patient characteristics and unique clinical and non-clinical circumstances. Upon printing, this document will be valid for 2/21/2025 only. Please contact Taylor Healthcare regarding any associated forms.

## Corporate Compliance

Kaleida Health's mission is to advance the health of our community and we must do so in a compliant manner. Below are important compliance concepts that all research associates must understand. Every research associate must comply with all regulations and must bring forward potential or clear violations.

### Fraud, Waste and Abuse

#### **Fraud**

- Fraud refers to an intentional deception or misrepresentation made by a person with the knowledge that deception could result in some unauthorized benefit to himself or herself or some other person.
- Includes any act that constitutes fraud under applicable Federal or State law.
- For example, purposely billing for services that were never provided or intentionally executing or attempting a scheme to obtain money from a healthcare benefit program.

#### **Waste**

- Over-utilization of services.
  - Deficient management, practices or controls.
- Waste also refers to useless consumption or expenditure without adequate return.

#### **Abuse**

- Provider practices that are inconsistent with sound fiscal, business or medical practices and result in an unnecessary cost to federal health care programs (e.g. Medicare and Medicaid), or reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for healthcare programs.

### False Claims Act

New York State and the Federal False Claims Act encourage citizens with knowledge of fraud against either state or federal governmental programs, such as Medicare or Medicaid, to come forward and file a lawsuit in the name of the government. This is known as a "whistleblower" suit. If a provider is found guilty under the False Claims Act, the potential monetary penalties are very large and the provider may also be excluded from Medicare and Medicaid.

Examples of false claims include:

- Billing for services not rendered
- Billing for equipment or supplies that are not provided
- Billing for unnecessary services
- Keeping an identified overpayment

### The Federal Anti-Kickback Statute

It is a crime to knowingly and willfully solicit, receive, offer or pay any remuneration to induce or reward referrals for which payment may be made in whole or in part under a Federal health care program (e.g. Medicare, Medicaid and others).

- The Federal Anti-Kickback Statute is known by the initials "AKS."
- Criminal, civil and administrative penalties may result.

- For example, under the AKS: up to 10 years imprisonment, \$100,000 in fines or both.
- “Safe harbor” regulations protect certain types of arrangements where the potential for abusive referral practices is deemed to be minimal.
  - Must meet all of the relevant safe harbor requirements to be protected.

### **What is Remuneration?**

- Includes virtually anything of value, whether given directly or indirectly, overtly or covertly, in cash or in kind.
  - For example, cash equivalents, kickbacks, bribes, rebates, etc.
- Both sides of an illegal arrangement are liable.

### New York State Anti-Kickback Laws

Prohibit a Medicaid provider or any person acting in concert with a Medicaid provider from:

- Soliciting, receiving, accepting, agreeing to receive or accept, or offering, agreeing to give, or giving, any payment or other consideration in any form for the referral of services for which payment is made under the Medicaid program, or to purchase, lease or order any good, facility, service or item for which payment is made under the Medicaid program.

### The Federal Stark Law

Strict liability law

Basic Self-Referral Prohibition:

- A physician may not make a referral:
  - a. To an entity for the furnishing of designated health services (DHS) for which Medicare payment may be made (and the entity may not present or cause to be presented a claim or bill for DHS provided as a result of such referral).
  - b. If the physician or immediate family member of the physician has a financial relationship with the entity.
  - c. Unless an exception to the law applies.

Designated Health Services (DHS) are defined as:

- Clinical laboratory services
- Physical therapy, occupational therapy, speech language pathology services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Home health services
- Prosthetics and orthotics and prosthetic devices and supplies
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

Exceptions to the Stark Law:

- In-office ancillary services
- Physician services
- Bona fide employment relationships

- Personal service arrangements
- Rental of office space
- Rental of equipment
- Physician recruitment
- And others...

#### New York State Stark Law

New York State's Stark Law covers all payers (e.g. it is not limited to Medicare).

Applies to "practitioner" referrals to a "health care provider" for the following services:

- Clinical laboratory
- Pharmacy
- Radiation therapy
- X-ray or imaging services
- Physical therapy

#### Compliance Program Contacts

Vice President, Internal Audit and Corporate Compliance, Chief Compliance and Privacy Officer –  
Victoria Belniak

- Phone: (716) 859-8633
- Email: [vbelniak@kaleidahealth.org](mailto:vbelniak@kaleidahealth.org)
- Mail to: Chief Compliance and Privacy Officer  
726 Exchange Street  
Suite 200  
Buffalo, NY 14210
- Interoffice mail

The dedicated compliance hotline voicemail number is:

- English speaking USA and Canada: (833) 990-0040
- Spanish speaking USA and Canada: (800) 216-1288

You can also mail a written "Compliance Report" to the Chief Compliance and Privacy Officer, or via [www.lighthouse-services.com/kaleidhealth](http://www.lighthouse-services.com/kaleidhealth).

Reports may be made anonymously. The identity of individuals reporting through the Compliance Hotline will be kept confidential unless the matter is turned over to law enforcement or disclosure is required during a legal proceeding.

#### HIPAA

Health Insurance Portability and Accountability Act (HIPAA) is a Federal Law that applies to covered entities. Covered entities are health plans, healthcare clearing houses or healthcare providers (pharmacy, doctors, hospitals, nurses). All of Kaleida Health is the covered entity (e.g. BGMC, GVI, MFS, DMH, VNA, OCH, etc.).

#### HITECH Act

Health Information and Technology for Economic and Clinical Health Act (the HITECH Act) was enacted on February 17, 2009 as part of the American Recovery and Reinvestment Act of 2009.

- The HITECH Act made significant modifications to HIPAA including:
  - Making HIPAA applicable to Business Associates
  - Increasing penalties
  - Establishing the breach notification requirements

### General Privacy Rule

**You may not USE, ACCESS or DISCLOSE patient-related information (e.g. PHI) except as necessary to do your job. This includes yourself or family/friends.**

### What is Protected Health Information (PHI)?

PHI is any information relating to an individual's health status, treatment or payment for health services that is created or received by the covered entity (Kaleida Health) and that may identify the individual.

- Includes: Oral, written and electronic records and communications
- Examples of PHI:
  - A patient's name
  - A patient's email address
  - A patient's health plan ID
  - A patient's date of birth
  - A date of service
  - A medical record number, even if not linked to a patient name

PHI regarding deceased individuals is handled in the same manner as for living patients. In other words, the same privacy protections apply for deceased individuals.

### Minimum Necessary Rule

- You must limit the patient information that they use or disclose to the minimum necessary to accomplish their job responsibilities.
- Limit your access: You may not access patient information unless you have a specific job related purpose for doing so. This includes accessing your own records.

### Breach Definition and Examples

- A breach is an unauthorized access, use or disclosure of unsecured PHI that compromises the unsecured PHI.
- An unauthorized access, use or disclosure of unsecured PHI is considered to be a breach unless the covered entity (Kaleida Health) can demonstrate, through a written risk assessment, that there was a low probability that the information was compromised.

### Breach Notification

- A breach is considered to be discovered when the incident becomes known (or should have become known with reasonable diligence), not when the covered entity (Kaleida Health) concludes the investigation.
- It is very important that all potential breaches are immediately reported to one of the following:
  - Chief Compliance and Privacy Officer – Victoria Belniak at (716) 859-8633
  - Privacy Manager – Melissa Chieffo at (716) 859-5817

- [Privacy@kaleidahealth.org](mailto:Privacy@kaleidahealth.org)
- Privacy Hotline (English speaking USA and Canada: (833) 990-0040; Spanish speaking USA and Canada: (800) 216-1288)
- [www.lighthouse-services.com/kaleidahealth](http://www.lighthouse-services.com/kaleidahealth)
- STARS Event Reporting on KaleidaScope

### Who is a Business Associate under the Privacy Regulations?

A Business Associate is a person who performs, or assists in the performance of, a function or activity involving the use, access or disclosure of PHI on behalf of a covered entity (Kaleida Health). The covered entity must have a written Business Associate Agreement with each of its Business Associates. HIPAA has specific requirements for the content of the Business Associate Agreement.

### Patient Rights

Under HIPAA, patients have the following rights:

- To access their PHI
- To request amendments to their PHI
- To receive communications by alternate means (e.g. email or fax) or to alternative locations (the program must accommodate all “reasonable” requests)
- To receive an accounting of certain disclosures of their PHI
- To request that the covered entity (Kaleida Health) limit its use and disclosure of their PHI

### De-Identification and Disposal

#### De-Identification

- Information that has been de-identified is not subject to HIPAA
- In order to de-identify PHI, 18 unique identifiers must be removed (name, dates, address, social security numbers, images) or an expert must determine that the information is de-identified.

#### Disposal

In order to avoid potential breaches, PHI must be disposed of appropriately, such as:

- Paper records containing PHI should be shredded.
- Hard drives must be wiped clean before a computer is thrown away.
- Zip drives and CDs must be appropriately destroyed so that PHI cannot be obtained from them.

### Sanctions

- The covered entity (Kaleida Health) will take disciplinary action if it is determined that an employee failed to comply with the covered entity’s HIPAA policies.
- An employee who violates the covered entity’s HIPAA policies may be subject to various sanctions including written censure, suspension or termination.
- The covered entity is required to maintain a log of all employee sanctions for six (6) years.

### Security and Encryption

- **Sharing of computer passwords or logon IDs is prohibited!**
- **Do not leave portable devices (e.g. laptops, phones, pagers) containing PHI unattended in cars or public areas.**



- Use encryption when sending PHI over the Internet or storing PHI on portable devices. Please refer to Kaleida Health Policy #MR.17 – Faxing, Emailing and Texting of Patient Protected Health Information.
- **DO NOT OPEN ATTACHMENTS SENT FROM PEOPLE YOU DON'T KNOW!**
- We will notify you if we become aware that anyone in the company has been infected or if a particular virus is known to be generally troublesome.
- Do not respond or click on an email hyperlink that you are not expecting to receive.
- You need to let the Privacy or Security Officer know if you have any concerns that you may have exposed your computer to a virus.
- Examples:
  - Use **khencrypt** in the subject line when sending PHI in the body of the email or attachments.
  - Cortext app must be downloaded and used when sending PHI on a mobile device.

### Audits

- We can and do perform audit trails of access to documents containing PHI.
- Unauthorized access can lead to disciplinary action.
- You should not be looking at documents containing PHI unless you are authorized to do so.

Failure to comply with HIPAA requirements can result in civil and criminal penalties, as well as progressive discipline by Kaleida Health up to and including termination. Civil and criminal penalties can apply to both Kaleida Health and individuals.

### Nondiscrimination

Kaleida Health complies with applicable civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Kaleida Health does not exclude people or treat them differently because of race, color, religion, sex, national origin, disability, sexual orientation, gender identity or expression, physical appearance, source of payment or age. The nondiscrimination statement is given to patients at the time of registration.

Language Assistance as well as other accommodations for people with disabilities are required by Section 1557 of the Affordable Care Act. This law is administered by the U.S. Office of Civil Rights. Section 1557 also includes a grievance procedure. A grievance can be filed with the Legal Department of Kaleida Health or with the U.S. Office of Civil Rights. Directions are included on the Kaleida Health nondiscrimination statement.

Are you aware of potential ethical, legal and/or business conduct violations or concerns at Kaleida Health?

## **SPEAK UP. IT MATTERS.**

Call the Compliance Hotline  
**1-833-990-0040**

- Administered through an independent company
- Available 24 hours a day, 7 days a week, 365 days a year
- Anonymous and confidential reporting

### **Examples of Potential Violations or Concerns**

- Theft
- Fraud, waste or abuse
- Conflicts of interest
- Research misconduct
- Billing misconduct
- Harassment
- Discrimination
- Violations of Kaleida Health's Code of Conduct
- Patient safety or quality of care
- Workplace safety
- Other potential ethical, legal, and/or internal business policy compliance violations or concerns

### **Other Ways to Make a Confidential Report**

- ✓ Submit a STARS report on *KaleidaScope*
- ✓ Submit a report online at [www.lighthouse-services.com/kaleidahealth](http://www.lighthouse-services.com/kaleidahealth)
- ✓ Email [reports@lighthouse-services.com](mailto:reports@lighthouse-services.com) (must include company name with report)
- ✓ Fax (215) 689-3885 (must include company name with report)
- ✓ Schedule a meeting with the Corporate Compliance Officer, Victoria Belniak, at 859-8633
- ✓ Submit a report using the Compliance Report Form on *KaleidaScope*



*Retribution or retaliation by Kaleida Health or its staff against any employee who makes a report will not be tolerated.*



## Kaleida Health

# COMPLIANCE REPORT FORM

Any employee using this form to report non-compliant behavior is assured that by making this report there will be no retribution or retaliation by Kaleida Health or any staff member against the employee making the report. Federal and New York State laws, as well as Kaleida Health policies, protect employees in this regard. The report will be maintained in a confidential file, and the reporting employee's name will be treated confidentially unless disclosure is required as a matter of law. An employee may make a report verbally by calling the Compliance Hotline at 1-833-990-0040.

Date: \_\_\_\_\_

Name of Employee Making Report (optional): \_\_\_\_\_

Site: ☐ BGMC ☐ GVI ☐ OCH ☐ MFS ☐ DMH ☐ Larkin ☐ VNA

☐ Other (specify): \_\_\_\_\_

Department: \_\_\_\_\_

Subject of Report (Please be as detailed as possible, providing dates, individual and department names and details of incident(s) or activities believed to be non-compliant.):

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Convenient times, locations and telephone numbers where you can be reached if additional information is needed:

Time: \_\_\_\_\_ Location: \_\_\_\_\_ Phone: \_\_\_\_\_

Time: \_\_\_\_\_ Location: \_\_\_\_\_ Phone: \_\_\_\_\_

Please place this report in a sealed envelope and send it to: Victoria Belniak, Corporate Compliance Officer  
Kaleida Health  
Larkin Building  
726 Exchange Street  
Buffalo, NY 14210



## **Language Assistance Services**

### **What is Language Assistance Services?**

- Designed to provide assistance with interpreting and translation services for Limited English Proficient (LEP) patients.
- Kaleida Health is required by law to provide these services free-of-charge to ensure compliance with federal and state laws.

### **Why Offer Language Assistance Services?**

- Kaleida Health is committed to providing the best possible healthcare to our patients.
- Without effective communication, meaningful access to and the participation in quality healthcare can be compromised.
- Every patient or patient representative who enters our facilities with a communication barrier should be advised of his or her right to Language Assistance Services, free-of-charge. Kaleida Health uses medical interpreting as a primary method to remove those barriers.

### **Who Uses Language Assistance Services?**

- Visually impaired.
- Hearing impaired.
- Limited English Proficiency (LEP) -- the patient does not speak English as their primary language and has a limited ability to read, write, speak or understand English.

### **Six Points to Remember**

1. Always offer interpreter services free-of-charge.
2. Always offer an interpreter to a patient with Limited English Proficiency (LEP) by CyraCom-Over-the-Phone or Video services, or Face-to-Face interpreting by International Institute of Buffalo or Journey's End.
3. A bilingual staff member who is fluent in the patient's language may interpret non-clinical information.
4. Always arrange for interpreter services to be available in a timely manner.

#### Timely is:

For **emergency services**, within **10 minutes** of the request for an interpreter. For **inpatient/outpatient services** within **20 minutes** of the request for an interpreter.

5. Never allow a friend, family member, or other party to interpret unless the LEP patient signs a waiver and you believe the person will provide effective communication.
6. Never allow children under the age of 16 to interpret except in an emergent situation.
7. Always document that interpreter services were offered and that the service was either accepted or declined.

### **If Services Are Accepted Document**

- Name of agency providing the service.
- Name of person interpreting and, if CyraCom, the interpreter's ID number.
- Language being interpreted.
- Method of interpretation (telephonic, face-to-face, video).
- Date and time services were requested.
- Date and time services were provided.
- Topic of discussion during interpretation.

### **If Services Are Declined**

- Complete and have patient sign the Waiver of Interpreter/Translator Services in the patient's primary language.
- If the waiver is not available in the patient's primary language, use CyraCom or Face-to-Face interpreting to interpret the waiver.
- Document the name of the interpreter who explained the waiver form (unless it was by the patient in his/her primary language) and the patient's reason for refusing.

If you have any questions regarding Language Assistance Services, please contact Kaleida Health's Civil Rights Coordinator at 859-8020 or via email at [LanguageAssistanceServ@kaleidahhealth.org](mailto:LanguageAssistanceServ@kaleidahhealth.org)



Effective 09/2003  
Approved 06/2024  
Last Revised 08/2015  
Expiration 06/2025

Owner Holly Ranger: Sr  
Director of Core  
Laboratory  
Services  
Policy Area Administration  
Procedure  
Applicability All Kaleida Labs

## Requests For Support Of Research Activities

### GENERAL STATEMENT:

To provide a consistent procedure for investigator's to follow when requesting a research account. This procedure will also provide guidelines for laboratory staff to follow, allowing for expediency and consistency when initiating the account.

### SCOPE:

All research activities, testing, and sample handling.

### POLICY:

Research request procedure must be followed to ensure timely and appropriate handling of research accounts. Appropriate paperwork must be completed, relevant signatures must be obtained, information must be entered into the computer and pertinent staff members notified of the new account. A lead time of thirty (30) days is requested.

### ADMINISTRATION:

Laboratory Administration and Management.

### PROCEDURE:

- I. "Request for Laboratory Support" Form
  - A. Primary investigator requests research support from Outreach Manager, Kaleida Laboratories or designee. An information request form along with covering memo outlining procedure is forwarded to investigator.

- B. Form is to be completed and **signed** by the investigator. Investigator will return information to the Outreach Manager.

## II. Setting up the Research Account

- A. Outreach Manager will review the form for completeness and follow through on setting up the account and complete the following:

1. Request a client number using account start up form and procedure.
2. Generate file folder with account name/number.
3. In conjunction with Laboratory Administration, provide pricing for testing, phlebotomy, and sample handling as applicable.
4. Investigate the feasibility of any special requests (i.e. aliquoting of specimens, special stains, smears, etc.) and follow the guidelines below:
  - a. The laboratory will accept research samples for testing on-site or at a reference laboratory.
  - b. Storage of research samples will be for a maximum of seven days at the appropriate temperature for the test(s).
  - c. A fee per sample will be assessed to cover the cost of preparation and shipping to a non-affiliated laboratory. A test code will be created to allow tracking of the samples to the testing facility.
  - d. Phlebotomy will be provided at designated sites. A fee will be charged for drawing the sample.
  - e. If Kaleida Health Laboratories cannot provide services to the researcher, it will assist by providing, if at all possible, a list of laboratories or phlebotomy services that supply the needed services.
5. Make special arrangements for specimen pick up with dispatch.
6. Provide laboratory request forms as needed.
7. Obtain appropriate approvals as per the new account start form.
8. Contact investigator to pick up requisitions and to arrange start date of service.
9. Distribute account start up form and particulars of study to all affected parties including:
  1. Technical Director's/Medical Director's whose laboratory will be directly impacted by the study
  2. Laboratory Administration
  3. Laboratory Manager
  4. Others as appropriate

The original paperwork will be kept on file at the Center for Laboratory Medicine.

### III. Follow up on Research Accounts

- A. The investigator may request changes to an existing account. The Outreach Manager will evaluate the request and make changes as needed or possible.
- B. The Outreach Manager will follow through as necessary and facilitate review and resolution of specific problems i.e. investigator not receiving results. The Outreach Manager will bring to the attention of the Technical Director's/Medical Director's etc. any issue that needs their input. If necessary, meetings will be arranged with key people when an especially involved research study is to be done.
- C. "Research" will be a standing agenda item at the Administrative Council meeting.

## RESPONSIBILITY:

The Outreach Manager will be responsible for handling the day-to-day routine duties involved in setting up/changing accounts. The Outreach Manager will be responsible for notifying appropriate Management staff of problem areas or extenuating circumstances.

## DISTRIBUTION:

This policy shall be distributed to all pathologists, technical and support staff of the Department of Pathology and Laboratory Medicine.

## REVISION:

It shall be the responsibility of those designated in Prepared by or Approved by above, or their designees, to initiate revisions to this Policy as appropriate and necessary.

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## Attachments

 [A - Research Intro Letter](#)

 [B - Request For Research Support](#)

 [C - Human Subjects Research Request For AP Support Approval Form](#)

 [D - Research Request For AP Support Not Involving Human Subjects Approval Form](#)

## Approval Signatures

Step Description	Approver	Date
Final Approval	John Tomaszewski, MD: Clinical Service Director	06/2024



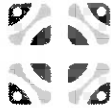
Final Approval	Hassan Nakhla, MD: Medical Lab Director, DMH	04/2024
Final Approval	Keith Krabill, MD: Laboratory Medical Director, Flint and Oishei	03/2024
Final Approval	Lalarukh Aftab: Laboratory Director of BGMC/Pathologist	03/2024
Final Approval	Elizabeth Marchetti Korangy: Medical Laboratory Director, Suburban	03/2024
Manager/Supervisor Team	Holly Ranger: Director of Core Laboratory Services	03/2024

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## Applicability

Buffalo General Medical Center Laboratory , Center for Laboratory Medicine, DeGraff Memorial Hospital Laboratory, John Oishei Children's Hospital Laboratory, Kaleida Health Laboratories, Millard Fillmore Suburban Hospital Laboratory

COPY



Kaleida Health

**DEPARTMENT OF PATHOLOGY  
AND LABORATORY MEDICINE**

Center for Laboratory Medicine - 115 Flint Road, Williamsville, NY 14221  
Buffalo General Hospital - 100 High Street, Buffalo, NY 14203  
John R. Oishei Children's Hospital - 818 Ellicott Street, Buffalo, NY 14222  
DeGraff Memorial Hospital - 445 Tremont Street, N. Tonawanda, NY 14120  
Millard Fillmore Suburban Hospital - 1540 Maple Road, Williamsville, NY 14221

Dear Investigator,

Kaleida Health Department of Pathology and Laboratory Medicine are pleased to offer support for your research project.

In order to facilitate your request and meet your needs, please complete all areas on the attached "Request for Research Support" form and forward to me, 115 Flint Road, Williamsville, NY 14221 or fax to 633-2361. We also will require a copy of the IRB approval for this study.

To ensure that we can effectively meet all of your needs, we greatly appreciate the attached "Request for Research Support" form submitted 30 days prior to the beginning date of the study.

We are happy to support your efforts and appreciate that you have selected Kaleida Laboratories. If you have any additional comments and/or questions, please do not hesitate to contact me at 626-7912 or Bill Dormann at 626-7925.

Sincerely,

**Victoria R. Frano**  
Project Manager for Research  
Kaleida Health  
Department of Pathology  
& Laboratory Medicine  
Phone 716-626-7912  
Fax 716-626-7274  
[vfrano@kaleidahealth.org](mailto:vfrano@kaleidahealth.org)

Enclosure



**DEPARTMENT OF PATHOLOGY  
AND LABORATORY MEDICINE**

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Millard Fillmore Suburban Hospital - 1540 Maple Road, Williamsville, NY 14221

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## **Request for Research Support**

Name of Research Project: \_\_\_\_\_

Date of Request: \_\_\_\_\_

Research Start Date: \_\_\_\_\_

Researcher's Name: \_\_\_\_\_

Duration of Study: \_\_\_\_\_ Anticipated # of Participants: \_\_\_\_\_

Results Sent To: \_\_\_\_\_

Address: \_\_\_\_\_ City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone #: \_\_\_\_\_ Contact Person: \_\_\_\_\_

Phone # To Call Results: \_\_\_\_\_ (If different # from above)

Phone # For Critical Results: \_\_\_\_\_ (Availability 24hr/7days)

Fax #: \_\_\_\_\_

Email Address: \_\_\_\_\_

Charting: Reports Will Be Issued Upon Completion of the Testing.

**Please list the lab tests that you would like performed and estimated volume. Call 626-7912 or 626-7925 or 626-7916 if you have any questions.**

_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

**Billing Sent To:** \_\_\_\_\_

**Address:** \_\_\_\_\_ **City:** \_\_\_\_\_ **State:** \_\_\_\_\_ **Zip:** \_\_\_\_\_

**Phone #:** \_\_\_\_\_ **Contact Person:** \_\_\_\_\_

**Email Address:** \_\_\_\_\_

**Source of Funding:** Federal Grant \_\_\_\_\_ Departmental \_\_\_\_\_ Pharmaceutical \_\_\_\_\_

Other (Specify) \_\_\_\_\_

**IS THIS A FEDERAL FUNDED STUDY** YES/NO \_\_\_\_\_

**Copy of Research Protocol Attached:** Yes/No \_\_\_\_\_

**IRB Approval Attached:** Yes/No \_\_\_\_\_

**\*\*A copy of the IRB is required for the Research Pricing to be applied.**

**\*\*\*\*\*All testing will be billed on a monthly basis to the Requesting Researcher.\*\*\*\*\***  
Payments should be made in a timely manner

**Signature of Primary Investigator** \_\_\_\_\_ **Date** \_\_\_\_\_

\*\*\*\*\*  
**For Laboratory Use Only:**

**Account Number:** \_\_\_\_\_

**Account Set Up Date:** \_\_\_\_\_

**Kaleida Health Department of Pathology  
Human Subjects Research Request for AP Support  
Approval Form**

**STUDY INFORMATION**

Protocol Title: \_\_\_\_\_  
\_\_\_\_\_

*See attached Protocol*

Principal Investigator: \_\_\_\_\_

**TISSUE TYPE**

\_\_\_ **Previously Prepared Kaleida Blocks - Case Specific**  
see attached spreadsheet listing cases being requested

\_\_\_ **Previously Prepared External Blocks**

\_\_\_ **Previously Prepared Blocks by Diagnosis**

Search Diagnosis: \_\_\_\_\_  
\_\_\_\_\_

\_\_\_ **Fixed/Fresh/Frozen Tissue - Paraffin Block to be Prepared**

\_\_\_ **Fresh/Frozen Tissue – Frozen Block to be Prepared**

**CASE INFORMATION**

Number of Cases Requested: \_\_\_\_\_

Date Needed By: \_\_\_\_\_

**SLIDE TYPE**

Slide Type: \_\_\_\_\_

Number of Recuts per Case: \_\_\_\_\_

Slide Type: \_\_\_\_\_

Number of Recuts per Case: \_\_\_\_\_

Slide Type: \_\_\_\_\_

Number of Recuts per Case: \_\_\_\_\_

Slide Type: \_\_\_\_\_

Number of Recuts per Case: \_\_\_\_\_

***Kaleida Health Department of Pathology  
Human Subjects Research Request for AP Support  
Approval Form***

<b>REQUEST EVALUATION SUMMARY</b>
<b>Request Approved By:</b> _____
<b>Request Modified or Not Approved By:</b> _____
<b>Comments:</b> _____ _____ _____

***Please forward completed form to Vicky Frano***

**Kaleida Health Department of Pathology  
Research Request for Anatomic Pathology Support  
Involving Non Human Subjects**

Note: All AP Research Requests will be evaluated to determine feasibility

**STUDY INFORMATION**

Protocol Title: \_\_\_\_\_  
\_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Associate Investigator: \_\_\_\_\_

**BILLING INFORMATION**

Contact Person for Bill: \_\_\_\_\_

Facility: \_\_\_\_\_ Building/Room: \_\_\_\_\_

Street Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

**FUNDING INFORMATION**

Source of Funding:    ☐ Grant    ☐ Departmental    ☐ Pharmaceutical  
                                 ☐ Other(specify) \_\_\_\_\_

**IS THIS A FEDERAL FUNDED STUDY** YES/NO \_\_\_\_\_

Copy of Research Protocol Attached: Yes/No \_\_\_\_\_

**AGREEMENT SIGNATURE**

\*\*\*\*\*All testing will be billed on a monthly basis to the Requesting Researcher.\*\*\*\*\*  
Payments should be made in a timely manner

Signature of Primary Investigator \_\_\_\_\_ Date \_\_\_\_\_

**Kaleida Health Department of Pathology  
Research Request for AP Support  
Not Involving Human Subjects  
Approval Form**

**STUDY INFORMATION**

Protocol Title: \_\_\_\_\_

\_\_\_\_\_

*See attached Protocol*

Principal Investigator: \_\_\_\_\_

Date Needed By: \_\_\_\_\_

**TISSUE TYPE REQUESTED**

\_\_\_\_\_

**SLIDE TYPE**

Slide Type: \_\_\_\_\_

Number of Slides: \_\_\_\_\_

Slide Type: \_\_\_\_\_

Number of Slides: \_\_\_\_\_

Slide Type: \_\_\_\_\_

Number of Slides: \_\_\_\_\_

Slide Type: \_\_\_\_\_

Number of Slides: \_\_\_\_\_

**SPECIAL REQUEST**



**Kaleida Health Department of Pathology  
Research Request for AP Support  
Not Involving Human Subjects  
Approval Form**

REQUEST EVALUATION SUMMARY
Request Approved By: _____
Request Modified or Not Approved By: _____
Comments: _____
_____
_____

***Please forward completed form to Vicky Frano***