Kaleida Health
Research Associate
Orientation
Manual
Research Associate Orientation Manual

Attestation*

Infection Control Policy

Corporate Compliance and HIPAA

Language Assistance Services

Request for Laboratory Support

* Must be returned to:

Kaleida Health
Office of Research and Sponsored Projects
726 Exchange Street
Suite 270
Buffalo, New York 14210
Attn: Kelly Gleason
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.

_______________________________
Name (Please Print)

________________________________________
Signature

_______________________________
Date

RETURN COMPLETED ATTESTATION TO:

Kaleida Health
Office of Research and Sponsored Projects
726 Exchange Street
Suite 270
Buffalo, New York 14210
Attn: Kelly Gleason
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 Policy Manual - The Infection Prevention Policy Manual can be found on-line 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.

Employee Health - Each employee must have an initial health assessment, which includes review of immunizations against rubella, measles and mumps, and a tuberculosis PPD skin test. If the required immunization documentation is not present, you will be offered to have your immunizations updated through Employee Health. New York State requires that all employees and volunteers at the hospital/health care facility 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. The Annual Health update includes a PPD skin test for tuberculosis.

Approach to Patient Care Regarding Infection Control

There are basically two approaches used for patient care within Kaleida Health. Standard Precautions and Transmission-Based Precautions work together to provide mechanisms for protecting health care workers and patients from exposure to infectious agents.

1. Standard Precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection. This applies to all contact with blood, all body fluids, secretions and excretions regardless of whether or not they contain visible blood, non-intact skin and mucous membranes. This involves the use of basic infection control measures.

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 for 15-20 seconds scrubbing all surfaces of the hands with friction. If hands and other skin surfaces are visibly soiled, hand hygiene with soap and water is required. Hand hygiene must be performed 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)

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<tr>
<th>Procedure</th>
<th>Rationale</th>
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<td>1. If the 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.</td>
<td>• To prevent splashing.</td>
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<td>• To prevent skin irritation.</td>
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<tr>
<td>2. Wet hands thoroughly, holding them downward over the sink.</td>
<td>• To enable water to run towards the fingertips.</td>
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<tr>
<td>3. Apply adequate soap. Hospital approved soap will be available on all clinical units.</td>
<td>• To decrease contamination.</td>
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<td>• To prevent skin irritation.</td>
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<td>4. Wash hands for at least 15-20 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.</td>
<td>• Friction mechanically removes microorganisms from the hands.</td>
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<td>5. Rinse hands thoroughly by holding under running water.</td>
<td>• Soap left on the hands may cause chapping.</td>
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<td>6. Dry hands well using a paper towel to dry hands first, then forearms.</td>
<td>• To prevent skin irritation.</td>
</tr>
<tr>
<td>7. If hand faucets are used, place a paper towel over the faucet and turn off the water.</td>
<td>• This prevents recontamination of the hands.</td>
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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.

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

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 or offering a surgical mask to the coughing patient, discarding the mask or tissue appropriately and performing hand hygiene.

2. **Transmission Based Precautions of Airborne, Droplet, and Contact are always used in addition to standard precautions dependent upon the mode of transmission.** Transmission Based Precautions are used when specific communicable diseases or pathogens are suspected or identified. They are designed to contain highly transmissible agents and are based on the mode of transmission of the specific pathogen. These
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 door to the patient’s room may remain open. Signage will be posted prominently outside the room. Gowns and gloves are required upon entry into the room. If the organism is C-diff, norovirus, diarrheal illness or candida auris, a hospital approved bleach disinfectant must be used for equipment cleaning and environmental cleaning.

- **Droplet Precautions** - Use Droplet Precautions to prevent transmission of diseases caused by respiratory droplets that are generated by coughing, sneezing or talking. Droplet transmission involves contact of the conjunctivae or mucous membranes of the nose or mouth of a susceptible person with large-particle droplets. These droplets, because of their larger size, travel short distances before dropping to the ground. Wear surgical/procedure mask upon entry into the patient room. Eye protection equipment may be used when working closely with the patient or performing cough inducing procedures (suctioning, respiratory treatments)

- **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).

**Tuberculosis (TB) Control**

- 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 TB skin testing
- Cooperation with state and county health departments, including prompt case reporting, reporting nosocomial 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: 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 tuberculin skin test 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 skin test reaction equal to or greater than 5mm induration or with symptoms suggestive of active TB will receive a chest X-ray.

Additional Infection Control Measures

Blood Borne Pathogens
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, other body fluid or body tissues. These employees perform tasks that involve direct patient contact.
Examples: Nurses, Patient Care Aides, Aides, Phlebotomists

2. 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 blood, other body fluids or tissues.
Examples: Environmental Services, Bio-Medical Engineering, Laboratory, Central Processing

3. Category III
Employees whose tasks do not involve direct patient contact or the potential for exposure to blood and body fluids, or body tissues.
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.

Please review the bloodborne pathogen information included in this section.

Kaleida Health, as per OSHA 1910.1030 and 1910.141, is aware that hospital staff works 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. To protect our employees, the following designations are made.

**Keypoint:** 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 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.

Transmission Risks - 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 bloodborne 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:

- Made available at no cost to the employee at a reasonable time and place.
- Performed by or under the supervision of a licensed physician or licensed healthcare professional in conjunction with an accredited laboratory.
- 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:

- The employee has previously received the complete HBV vaccination series.
- The employee demonstrates antibody level indicating immunity to HBV (pre-screening prior to administration of HBV vaccine is not required).
- 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, then 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.
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.
I. Statement of Purpose

The purpose of precautions is to prevent the transmission of a communicable disease by direct or indirect contact to patients, personnel, volunteers, visitors and others.

Standard precautions apply to all patients.

Standard precautions are designed to reduce the risk of transmission of micro-organisms from both recognized and unrecognized sources of infection. Standard precautions apply to all contact with blood, all body fluids, secretions and excretions regardless of whether or not they contain visible blood, non-intact skin and mucous membranes.

Transmission based precautions of Airborne, Droplet, and Contact are always used in addition to standard precautions dependent upon the mode of transmission. Transmission-based precautions are used when specific communicable diseases or pathogens are suspected or identified. They are designed to contain highly transmissible agents and are based on the mode of transmission of the specific pathogen.

II. Audience

Patient care personnel

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

A. Standard Precautions

1. Hand hygiene is defined as using alcohol-based hand rub (ABHR) and rubbing all surfaces of the hands until dry; or washing hands with soap and water for 20 seconds scrubbing all surfaces of the hand with friction. If hands and other skin surfaces are visibly soiled, hand hygiene with soap and water is required. Hand hygiene must be performed between each patient contact.

2. Hand Hygiene must be performed before and after glove use.

3. 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.

4. 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.**

5. 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.
6. Gowns are to be worn during procedures that are likely to generate splashes of blood or other body fluids.

7. Gloves are to be worn to reduce the incidence of blood and/or body fluid contamination for:
   a. Touching blood, body fluids, mucous membranes or non-intact skin of all patients.
   b. Handling items and surfaces soiled with blood or body fluids.
   c. Performing venipuncture, phlebotomy or other vascular procedures.
   d. When the health care worker has cuts, scratches or other breaks in the skin.
   e. Gloves are changed after each patient contact and between procedures on the same patient and if they become torn or damaged.
   **Keypoint: Gloves are not a substitute for hand hygiene**

8. Surgical caps/hoods or shoe covers are required when gross contamination of the head or feet can be reasonably anticipated.

9. Specimens of blood and body fluid from all patients are considered infectious and the following precautions are to be followed:
   a. Care should be taken when collecting each specimen to avoid contaminating the outside of the container and the laboratory requisition accompanying the specimen.
   b. The container must be placed in a plastic biohazard bag.

10. Safe Injection Practices
   a. A single use needle and syringe must be used for each injection.
   b. Use single-use medication vials whenever possible.
   c. If a multi-dose vial is used, never reinsert a used needle in the multi-dose vial or solution.
   d. Used needles should NOT be recapped by hand, purposely bent or broken by hand, removed from disposable syringes or otherwise manipulated by hand. After they are used, all sharps are placed into puncture resistant containers for disposal.
   e. Needles, scalpels and other sharps must be handled with care to prevent injuries.
   f. All sharps must be secured in a locked storage unit/area.

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

12. Equipment Cleaning
    Refer to the Hospital Equipment Cleaning Policy (IC.25)

13. Clothing and personal effects
    a. Clothing contaminated with blood/body fluids will be placed in a clear plastic bag and sent home with the family.
    b. Personal toys are permitted in the patient room and should be sent home with the patient/family upon discharge.
    c. Refer to the hospital Toy Cleaning Policy (IC.17)
d. For patients with skin related infestation such as scabies or lice, personal clothing and other personal items should be placed in a clear plastic bag which is tied in a single/goose neck knot.
e. Refer to the Pest Prevention / Bed Bug Policy (IC.8)

14. Laundry/Linen/Waste will be placed in designated bags. Dispose of waste according to hospital policy.

B. Transmission Based Precautions

Transmission Based Precautions include Contact Precautions, Droplet Precautions and Airborne Precautions

1. Initiating and Care of the Patient on Transmission Based Precautions

When an infection/infectious organism is suspected or identified, precautions should be initiated based on the CDC Guidelines for Precautions: Prevention of Infectious Agents in Healthcare Settings Appendix A.

a. Transmission Based Precautions will be initiated by the Infection Preventionist, Providers, or Nursing Staff.
b. All personnel are responsible for complying with Transmission Based Precautions.
c. The appropriate hospital approved sign is immediately placed on the patient’s door.
d. PPE will be readily available immediately outside of the patient room.
e. The patient and family are advised regarding the need for precautions and the specific actions necessary. Patients and visitors will be instructed on proper hand hygiene.
f. Do not take unnecessary items into the patient room

g. Designate the use of non-critical patient care equipment to a single room

Dedicated disposable thermometer, blood pressure cuff and stethoscope will be used and will remain in the patient room to reduce the risk of transmission of infection to other patients.
h. Reusable equipment, including but not limited to glucometer, pulse oximeter, portable x-ray; will be appropriately cleaned and decontaminated with an approved disinfectant immediately after each patient use.

**Keypoint: Protective equipment must be removed prior to leaving the patient room.

2. Charting

a. Do not take the patient’s paper medical records into the room
b. When transporting the patient, store the medical record in an area where it will not be contaminated by the patient, patient hands, clothing or linens.
c. Workstations/ Computers on wheels, Medication Carts may be brought into the patient room and must be wiped with the hospital approved disinfectant upon leaving the room

**Keypoint: For emerging infectious diseases consult the Infectious Diseases Service or the Infection Preventionist immediately.
3. **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. Place the patient in a single/private room
      1) Any cohorting of patients will be under direction of the Infection Preventionist.
      2) The door to the patient room may remain open.
   b. **Contact Precautions** signage must be posted prominently outside the room/on the patient door. If the organism is C-diff, norovirus, diarrheal illness, or candida auris- check the box on the sign to indicate bleach-based disinfectants must be used for equipment and environmental cleaning.
   c. **Wear a gown and gloves** (clean, non-sterile) on entry into the room
      1) Remove gown immediately prior to leaving the room.
      2) Remove gloves immediately prior to leaving patient room. Always perform hand hygiene immediately upon removal of gloves/between glove changes.
   d. Handle patient care equipment and instruments/devices according to Standard Precautions and the hospital Equipment Cleaning Policy.
   e. Use additional PPE as necessary, consistent with Standard Precautions.

4. **Transporting Patients on Contact Precautions**
   a. Transporting of patients should be limited to essential purposes only.
   b. Prior to transport, transport services and the receiving department or facility must be notified that the patient is on Contact Precautions.
   c. Any wounds or lesions will be covered with a dressing.
   d. Patients with a respiratory source requiring Contact Precautions will be provided with a surgical/procedure mask or tissues and provided with instructions on respiratory etiquette.
   e. Incontinent patients with diarrhea will be provided with an adult brief/diaper or incontinent pad.
   f. Out of room participation in physical and occupational therapy activities for a patient on Contact Isolation may conflict with recommended transmission-based precautions. The therapy team, in collaboration with nursing staff and infection prevention, must determine patient appropriateness for specific treatments and ensure prevention of infection transmission.

**Keypoint: Contact the Infection Preventionist for discontinuation of Contact Precautions**

5. **Droplet Precautions**
   Use Droplet Precautions to prevent transmission of diseases caused by respiratory droplets that are generated by coughing, sneezing or talking. Droplet transmission involves contact of the conjunctivae or mucous membranes of the nose or mouth of a susceptible person with large-particle droplets. These droplets because of their larger size travel short distances before dropping to the ground.
a. Place the patient in a single/private room
   1) Any cohorting of patients will be under direction of the Infection Preventionist
   2) The door to the patient room may remain open

b. **Droplet Precautions** signage must be posted prominently outside the room/on the patient door

c. **Wear surgical/procedure mask upon entry into the patient room**
   Eye protection equipment may be used when working closely with the patient or performing cough inducing procedures (suctioning, respiratory treatments).

d. Use additional PPE as necessary, consistent with Standard Precautions.

6. **Transporting Patients on Droplet Precautions**
   a. Transporting of patients should be limited to essential purposes only.
   b. Prior to transport, transport services and the receiving department or facility must be notified that the patient is on Droplet Precautions.
   c. If transport is necessary, the patient will be instructed to wear a surgical/procedure mask and will be provided with instructions on respiratory etiquette.
      No mask is required for the persons transporting the patient.
   d. If the patient is unable to wear a surgical/procedure mask, the patient must be supplied with tissue and instruction in respiratory etiquette.
      The transport staff and receiving staff must wear a mask.

   **Keypoint: Contact the Infection Preventionist for discontinuation of Droplet Precautions**

7. **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).

   a. Place the patient in a single/private room with Negative Air Pressure
      1) Notify Plant Operations and communicate the need for smoke testing
      2) **The door to the patient room must remain closed** to maintain negative pressure
      3) The air pressure is monitored daily by Plant Operations when a negative pressure room is in use for a patient on airborne precautions.

   b. **Airborne Precautions** signage should be posted prominently outside the room/on the patient door (See also IC.9 – Tuberculosis Control Plan)
   c. Wear a fit tested NIOSH (National Institute of Occupational Safety and Health) N95 respirator or PAPR (Powered Air Purifying Respirator) upon entry into the patient room
   d. Handle items contaminated with respiratory secretions with gloves
   e. 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 smallpox if other immune personnel are available.

8. **Transporting Patients on Airborne Precautions**
   a. Transporting of patients should be limited to essential purposes only. Contact the Infection Preventionist to further proceed with any transporting of the patient.
      1) If transport of a patient from the negative pressure room is necessary, instruct the patient to wear a surgical mask.
      2) If the patient cannot wear a mask for transport, contact the Infection Preventionist for guidelines.
      3) Prior to transport, transport services and the receiving department or facility must be notified that the patient is on Airborne Precautions.

IV. **Approved by** - (Include date)
   - Chief Quality & Patient Safety Officer 5/18
   - Hospital Epidemiologist 5/18
   - Clinical Interdisciplinary Approval Committee 6/20/18

V. **References** (Include evidence based research, Kaleida Health policy, and regulation as applicable)
   - Appendix A - Type and Duration of Precautions Recommended for Selected Infections and Conditions
     - IC.8 – Bed Bug Control
     - IC.9 – Tuberculosis Control Plan
     - IC.17 – Toy and Play Equipment Cleaning and Management Guidelines
     - IC.25 – Cleaning and Equipment Classification for Patient Use/ Department Specific Equipment
     - IC.26 – Multi-Drug Resistant Organism (MDRO)

**Version History:**

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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 11/29/2018 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.

Revised October 2018
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
• 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.

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.

Revised October 2018
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

Revised October 2018
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
- Email 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.*
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.):
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

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**

- 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
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.

**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**

<table>
<thead>
<tr>
<th>Approver</th>
<th>Date</th>
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<tbody>
<tr>
<td>John Tomaszewski, MD: Clinical Service Director</td>
<td>05/2018</td>
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<tr>
<td>Keith Krabill, MD: Laboratory Medical Director, Flint &amp; OCH</td>
<td>05/2018</td>
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<tr>
<td>Lucia Balos, MD: Medical Lab Director Anatomic Pathology</td>
<td>05/2018</td>
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<tr>
<td>Marianne Gehen: Manager Site Laboratory</td>
<td>05/2018</td>
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<tr>
<td>Elizabeth Marchetti Korangy: Medical Laboratory Director, Suburban</td>
<td>05/2018</td>
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<tr>
<td>Hassan Nakhla, MD: Medical Lab Director, BGMC and DMH</td>
<td>05/2018</td>
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<tr>
<td>Barbara Roach: Manager Site Laboratory</td>
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<td>Marianne Gehen: Manager Site Laboratory</td>
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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
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 Jennifer Edmonds at 626-7916.

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

Enclosure
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  
Research Request for Anatomic Pathology Support  
Involving Human Subjects

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

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<th>STUDY INFORMATION</th>
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<td>Principal Investigator:</td>
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<td>Associate Investigator:</td>
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<td>IRB Review Complete? YES / NO  IRB Approval: Informed Consent or Exempt</td>
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<td>Note: Please forward copies of the following if applicable – Protocol, IRB Approval, stamped Informed Consent Form</td>
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<td>Does IRB Approval include Chart Review? YES / NO</td>
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<td>HSIRB Protocol # :__________ Expected Start Date:__________</td>
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  ___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 ______
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

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| Copy of Research Protocol Attached: Yes/No  ____ |

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