New Staff Orientation and Training revised: 02-24-2017

1. Register with CITI
CITI contains modules on topics like informed consent, vulnerable populations, ethical principles and IRB regulations. If you need to create a new account, please register by clicking "Register" and follow the subsequent steps (affiliate with UNC). Once your account is created, please select the required training mentioned below.
https://www.citiprogram.org/

2. Human Subjects Protection- Affiliate with UNC Chapel Hill – *updated every 3 years*
CITI contains modules on topics like informed consent, vulnerable populations, ethical principles and IRB regulations. Please follow the link below to access the HSP training. If you need to create a new account, please register by clicking "Register" and follow the subsequent steps (affiliate with UNC). Once your account is created, please select the Human Subjects Protection training. Each module has a short quiz at the end to assess understanding. Complete module for Biomedical Research.
Please print certificate of completion.
https://www.citiprogram.org/

3. Good Clinical Practices (GCP)- Affiliate with DAIDS - *updated every 3 years*
CITI contains modules on topics like informed consent, vulnerable populations, ethical principles and IRB regulations. Please follow the link below to access the GCP training and affiliate with DAIDS instead of UNC to complete sponsor required modules not accessible through UNC. Your main account will not be affected by this course affiliation change.
The Office of Clinical Trials usually has an Education Workshop entitled "Introduction to Good Clinical Practice". Workshop should be taken within a year of hire.
While waiting on a workshop, GCP training must be completed online at:
https://www.citiprogram.org/

Once affiliated with DAIDS do the following:
Question 1: Answer "No, I am NOT required to complete the basic HSP course at this time"
Question 2: Answer "No, I am not interested at this time, maybe later."
Question 3: Answer "No."
Question 4: Answer if you would like to complete the course in Spanish or Portuguese"
Question 5: Answer "Yes, I am required to complete the GCP course at this time"
Question 6: Answer "Not at this time."

***If you have any problems, please refer to this link for more detailed instructions on how to register and enroll in a course:**
https://www.citiprogram.org/citidocuments/citiinstructions.htm

4. Curriculum Vitae – *updated annually*
On your CV, please indicate your current UNC work address
Sign and date the front page

5. Confidentiality/HIPAA – *updated annually*
To complete the on-line SOM HIPAA training go to the following link:

http://www.med.unc.edu/security/hipaa

Please complete the required modules. Please print certificate after completion.

6. University Required Health and Safety
http://ehs.unc.edu/training/self-study/joint-commission-and-emergency-preparedness/
This course is designed to meet the annual general safety training required by the Joint Commission for personnel working in a Healthcare environment.
Please print certification after taking the test

7. IGHID Confidentiality Contract

See attached form. Print name, sign, and date the second page.

Please complete all items and submit documentation to:

Felicia Barriga Munante
Regulatory Documents Specialist, Institute for Global Health and Infectious Diseases
University of North Carolina at Chapel Hill
Bioinformatics Building 2160-H * 130 Mason Farm Rd. * Chapel Hill, NC 27599-7215

Institute for Global Health and Infectious Diseases
Employee, Volunteer and Visitor Confidentiality Contract

Purpose:

The purpose of the "Employee, Volunteer and Visitor Confidentiality Contract" is to heighten the awareness and accountability of all employees other associated staff, volunteers and visitors in adhering to the strict confidentiality guidelines required by our mission. Individuals who participate in clinical trials are assured that their medical information will be protected to the extent possible as described in the informed consent document. It is imperative to fulfill this responsibility. A breach of confidentiality, intentional or not, can jeopardize participants' livelihood, safety, and relationships with others in the community. Since such a breach can occur at any point in the process of clinical trials and other research projects, confidentially must be upheld throughout the department. Compliance with all HIPAA regulations is required.

Responsibility:

All employees, volunteers and visitors regardless of position, are responsible for reviewing and signing the contract, as well as fulfilling the obligations detailed therein. Employees are responsible for immediately reporting any breach of confidentiality or a situation which could potentially result in such occurrence. Disclosure of any participant information by UNC staff and affiliated site staff, volunteers or visitors without the consent, preferably in writing, of the participant will be grounds for disciplinary action, which may include dismissal of current position.

Standards:

- Access to participant information is on a "Need to Know" basis. Only those personnel directly involved with the research participants, consulting, or monitoring for QA purposes will have access to the participants' charts and EPIC information. Access and review of records must be limited to the extent needed to reasonably perform assigned duties. Participants' names and other identifying information must be excluded when presenting clinical case reviews, SAEs, or other educational discourse. Interview of participants must also be limited to questions needed to reasonably perform assigned duties.

  Violations of this policy include:

  - accessing confidential information that is not within the scope of your duties, including your own medical record;
  - misusing, disclosing without proper authorization, or altering confidential information;
  - disclosing to another person your sign-on code and/or password for accessing electronic confidential information or for physical access to restricted areas;
  - using another person's sign-on code and/or password for accessing electronic confidential information or for physical access to restricted areas;
  - intentional or negligent mishandling or destruction of confidential information;
  - leaving a workstation unattended without locking the screen
  - Attempting to access a secured application or restricted area without proper authorization or for purposes other than official UNC-Chapel Hill or UNCHCS business.

- No sensitive information should be stored on computer hard drives (internal or external) including individual desktop or USB thumb drives. Sensitive information must be stored on approved network storage such at the shared drive (J:\ID) Storage media (DVD, CD, thumb drives) must be placed in a shred box for disposal. ID IT must be consulted before sending any hard drives to surplus, as the hard drive will need to be wiped before disposal. Storing sensitive information by other means (e.g encrypted thumb drive) requires advance approval from ID IT and the project principle investigator.

Institute for Global Health and Infectious Diseases
Employee, Volunteer and Visitor Confidentiality Contract

- All personnel (i.e., research associates, research assistants, coordinators, administrative assistants, and pharmacy staff) are responsible for examining all mail, packages, faxes, or other outgoing items for identifying information containing such words as AIDS, HIV, or any other infectious disease—and omitting such references before sending them to study participants or outside sources. All electronic correspondence including scanned document attachments must be examined prior to emailing. This includes visual examination of the scanned documents once uploaded.

- All records containing participant information must be kept in a discreet place when not being worked upon. If an individual steps away from their workspace, folders must be closed or information turned over to hide identifiers.

- Individuals must have computer passwords enabled and must lock computers when stepping away from their work space.

- Sensitive information must not be stored on personal devices such as tablets or mobile devices. Access to email and other applications on personal devices likely to contain sensitive data must be approved by the supervisor and set up by ID IT. Prior to an individual's departure, it is the individual's responsibility to meet with ID IT and have access to all applications deactivated on personal devices.

- All identifiers must be removed, shredded, or obliterated from participant records prior to discarding.

- Discretion must be used when encountering participants in the outside community, and in social media.

- Discussion of specific participants in areas where there is a risk of being overheard by unauthorized individuals must be avoided. This includes, but is not limited to, hospital and clinic hallways, elevators, stairwells, cafeterias, and any public places.

- Extreme discretion must be used when contacting or attempting to contact participants by phone. If messages are left, they must be of a general nature only. No reference to AIDS, ID, Clinical Trials or other potentially sensitive areas must be made on voicemail or to anyone other than the patient. (e.g. family members or friends who might answer the phone)

- Additional standards included in mandatory HIPAA and CITI training will also be observed.

- Any suspected privacy breaches must be reported to an employee's supervisor and to the Regulatory Director. Privacy breaches may be reported to UNC IRB Compliance and UNC HIPAA Privacy Officer. As applicable to roles and responsibilities, all employees, volunteers and visitors will also be expected to follow the confidentiality statements currently in use by the UNC School of Medicine and UNC Health Care.

All staff and volunteers will sign an annual confidentiality statement to be kept in their personnel files.
I have read and agree to comply with the requirements of this Confidentiality Contract.

Print Name	**Signature**	**Date**