Process for Adding Duke Students, Unpaid Volunteers, and Visiting Trainees/Interns to Study Personnel

For visiting research scholars, please contact DOCR-help@dm.duke.edu. Visiting Research Scholar: An individual coming to Duke to take part in research activities, whether funded or unfunded, who is not receiving payment from Duke or enrolled in any official Duke Coursework as part of their visit. Other roles for this individual may include, but are not limited to: affiliate, research scholar, postdoctoral fellow, visiting scientist, visiting graduate student, visiting undergraduate student (not including trainees/interns as defined below).

Definitions:

Duke University Schools of Medicine and Nursing graduate students: A Duke medical student, or any other Duke advanced degree student (e.g., Duke University School of Nursing ABSN students).

Duke University campus graduate student: A student who is not part of Schools of Medicine or Nursing graduate program. The student's home school is part of Duke University campus and is not considered part of the Duke Health covered entity.

Visiting trainees/interns: Students participating in a training or internship program for academic credit through an Academic Agreement between Duke and a local institution such as NCCU, Campbell, Durham Tech, etc.

Agreement: A document that must be fully executed between an official of the Duke Office of Research Contracts (ORC) and the individual student, academic program, or volunteer.

- DUHS/SOM academic affiliation agreement Academic Agreement between Duke and a local institution such as NCCU, Campbell, or Durham Tech.
- DUHS IRB Volunteer Agreement is for unpaid students or volunteers, including Duke undergraduate students, who are NOT engaged in the consent process.
- DUHS IRB Duke Undergraduate Student Agreement for Consent is for unpaid Duke undergraduates who are engaged in the consent process.
- Adult is an individual who is at least 18 years of age at the time of addition to a research study.

ESSENTIAL ELEMENTS OF THIS POLICY

- Unpaid Duke undergraduates and volunteers may not have access to the Epic Electronic Medical Record (EMR).
- Any external (non-Duke) personnel placed on study teams as unpaid volunteers, visiting students, or visiting trainee/interns must pass sanction and criminal background checks
and must complete all required Duke Health CITI modules, Responsible Conduct of Research (RCR) training, HIPAA for Researchers training, and LMS Workforce Policy Acknowledgment module (includes electronic signature for Confidentiality Agreement, Code of Conduct Attestation, and Secure System Usage Memorandum).

- All personnel are required to comply with all Duke Health policies and procedures, including privacy and security policies and procedures.

Please choose the section below that applies to the type of individual you want to add to your study team:

Requirements for adding Duke University Schools of Medicine and Nursing graduate students


2. Listed as Internal Key Personnel according to study role. Please note, data access and storage further defined in Tables 1 and 2 (below)

Requirements for adding Duke University campus graduate students to Key Personnel

1. Must be an adult
2. Activity on a research study is limited to conducting supervised clinical research activities that would normally be permitted as part of their clinical research training
4. Must be added under External Key Personnel in the role of Graduate Student

No background and sanction checks, CRU approvals, or Agreements are required for the addition of Duke University campus graduate students. However, their role must be described in the application.

Data access and storage further defined in Tables 1 and 2

Requirements for adding Duke undergraduate students to Key Personnel

- Must be an adult
- If unpaid (volunteer or receiving Duke course credit only), the following must be
uploaded into an external Key Personnel amendment to the study in iRIS:


2. Fully signed Agreement, as appropriate to the proposed activities (DUHS IRB volunteer agreement or DUHS IRB Duke Undergraduate student agreement for consent)

3. The email approval from the CRU/OO Director must contain the following information and include a copy to DOCR at: DOCR-help@dm.duke.edu
   - PRO# of the study
   - PI name
   - Specific description of the undergraduate student's role on the study, including whether or not the student will be participating in recruitment or the consent process

4. For undergraduate students taking part in the Informed Consent process, documentation of completed.

Informed Consent Process and Procedures for Clinical Research

Documentation of a clean criminal background and sanction check. To obtain a criminal background and sanction check:

A Duke faculty or staff member should email the HR Background Check Center at bgcc@duke.edu with the name and email address of the individual, the reason for the background and sanction check, and the fund code that the background and sanction check should be charged to. The Background Check Center will then send a link to the applicant to get the process started. The cost will be charged to the fund code provided.

5. Statement from the PI that the undergraduate will adhere to the following requirements:
   - a. They will not, under any circumstances, have access to Maestro Care
   - b. They will have access to Duke Health identifiable data only for recruitment and consenting purposes
   - c. Data access and storage further defined in Tables 1 and 2
   - d. Activities will be conducted under supervision of the study team as documented as part of Return to Research plan provided to CRU/OO and described in IRB plan
   - e. No copies or screen shots are made of the data

- If paid by Duke, in full, in part, or as work-study, the undergraduate incurs the Duke Health employee training, confidentiality and behavioral responsibilities and compliance with Duke Health policies & procedures and may be added to internal Key Personnel in the same manner, and with the same requirements, as any other Duke employee. However, if the student's employee status is terminated at any time, the study team must submit an amendment to follow the process for unpaid undergraduates described
Requirements for adding other unpaid volunteers, visiting trainees/interns to Key Personnel

- Must be an adult
- The following must be uploaded into an external Key Personnel amendment to the study in iRIS:
  1. Documentation of completed Duke Health CITI modules, Responsible Conduct of Research (RCR) training, HIPAA for Researchers training and LMS Workforce Policy Acknowledgment module (includes electronic signature for Confidentiality Agreement, Code of Conduct Attestation, and Secure System
  2. Fully signed DUHS IRB volunteer agreement
  3. The email approval from the CRU/OO Director must contain the following information and include a copy to DOCR at: DOCR-help@dm.duke.edu
     - PRO# of the study
     - PI name
     - Specific description of the volunteer’s role on the study
  4. Documentation of a clean criminal background and sanction check
     1. To obtain a criminal background and sanction check: A Duke faculty or staff member should email the HR Background Check Center at bgcc@duke.edu with the name and email address of the individual, the reason for the background and sanction check, and the fund code that the background and sanction check should be charged to. The Background Check Center will then send a link to the applicant to get the process started. The cost will be charged to the fund code provided.
  5. Statement from the PI that the undergraduate will adhere to the following requirements:
     1. They will not, under any circumstances, have access to Maestro Care
     2. Data access and storage further defined in Tables 1 and 2
     3. Activities will be conducted under supervision of the study team as documented as part of Return to Research plan provided to CRU/OO and described in IRB plan
     4. No copies or screen shots are made of the data
**Table 1: Consented Clinical Research Data**

Below are roles and requirements for access to consented clinical research data.

**Definition:** Consented clinical research data are data belonging to participants who have consented to participate in a DUHS IRB approved research protocol.

Approved Data Access and Storage Locations for Identifiable Data:
- PACE, REDCap, Duke Box, Duke Health Dept
- Shared Drive supported by DHTS

<table>
<thead>
<tr>
<th>Research Role Type</th>
<th>Required Agreements</th>
<th>Allowable Activities</th>
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<tbody>
<tr>
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<td>DUHS/SOM academic affiliation agreement</td>
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<td>Duke undergraduate students for academic credit research project (unpaid)</td>
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<td>No</td>
<td>Yes</td>
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<tr>
<td>Visiting trainee/intern (training rotation for credit)</td>
<td>Yes</td>
<td>Yes</td>
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1Consented data must be maintained in accordance with the DUHS IRB-approved protocol. If working remotely, personal devices may be used, but DHTS & DOCR Remote Work Guidance must be followed, including use of VPN & Citrix. If a user by virtue of research role may access protected health information (PHI), then no removal of PHI from Duke Health Enterprise servers and/or environments is permitted.
Non-consented identifiable data must be maintained in PACE only. If working remotely, personal devices may be used, but DHTS & DOCR Remote Work Guidance must be followed, including use of VPN & Citrix. If a user by virtue of research role may access non-consented PHI to perform recruitment and consenting, then all PHI must be maintained in PACE.

### Table 2: Non-Consented Clinical Research Data

Below are roles and requirements for access to non-consented clinical data.

**Definition**: Non-consented data are clinical patient data that are often used in research prior to obtaining informed consent (e.g., Epic clinical patient data captured as part of a retrospective chart review). These clinical data often are accessible only under a waiver of informed consent and are considered accessible only by approved roles in the DUHS Covered Entity.

Approved Data Access and Storage Locations for Identifiable Data: PACE

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<td>Duke undergraduate students (hired &amp; paid by Duke Health Dept working on DUHS IRB approved protocol)</td>
<td>No</td>
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<td>Yes</td>
<td>Yes</td>
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2 Non-consented identifiable data must be maintained in PACE only. If working remotely, personal devices may be used, but DHTS & DOCR Remote Work Guidance must be followed, including use of VPN & Citrix. If a user by virtue of research role may access non-consented PHI to perform recruitment and consenting, then all PHI must be maintained in PACE.