Non-Duke Health Employee Research Personnel

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Objectives

• Identify the basic types of non-Duke Health employee research personnel
• State how the Fair Labor Standards Act (FLSA) affect the use of non-Duke Health employee research personnel
• Identify IRB policies and processes regarding the use of non-employee research personnel
• Identify when non-Duke Health employee research personnel can have access to the electronic health record (Maestro Care) for research purposes
Key Personnel

“Key Personnel” for a research study are research personnel who are directly involved in conducting the research with human subjects through an interaction or intervention for research purposes, including participating in the consent process by either leading it or contributing to it; OR who are directly involved with recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting the research study.
Common types of Non-Duke Health Research Personnel

- Visiting Research Scholars
- Visiting Observers (non-physician)
- Graduate Students
- Duke Undergraduate Students
- Non-Duke Undergraduate Students
- Work Study Students
- Volunteers and Unpaid Interns
- Duke University faculty and employees
- Faculty and Staff who have left Duke
- Temporary Employees (Duke Temporary Services)
Visiting Research Scholars

• Often a fully trained MD who is in the US to assist a faculty member with his/her conduct of research
• Can be on key personnel
• Typically a non-paid status-therefore will not have access to the electronic medical record
Visiting Observers (non-physician)

• An individual 18 years of age or older, who attends a DUHS facility for a period of no more than 14 days in a 30 day period of time for the purpose of observing the performance of clinical and non-clinical duties, systems or processes

• Generally not appropriate to add to key personnel due to the brevity of the observation period and they cannot be involved in clinical activity

• Will not be allowed to have access to the electronic health record.
Graduate Students

• Graduate students often participate in human subjects research approved by the DUHS IRB. This includes all post-baccalaureate students in an academic program such as non-Duke Medical Students from another school completing a clinical rotation at Duke.
Undergraduate Students

• Duke undergraduate students (work-study, unpaid, or engaged in research for class credit) may participate in human subjects research:
  – Must be 18 years of age
  – If consenting, must meet all requirements of the Duke Undergraduate Engaged in Consent process on DUHS IRB protocols
  – If not being paid, must adhere to the Volunteer & Unpaid Intern Policy Guidelines
  – Do not get access to the electronic health records of Duke Health patients.
Undergraduate Students

• Non-Duke Undergraduate Students can participate in human subjects research approved by the DUHS IRB as a volunteer. The HR policy and the IRB policy for Unpaid Interns and Volunteers applies here.

• Non-Duke Undergraduate Students may not consent potential study participants

• Access to the electronic medical record is not provided by research
Work Study Students

• The DUHS IRB policies on Graduate and Undergraduate Students apply.

• Additionally, a Work Study Student may have access to the electronic health record since they are paid by Duke University.
Unpaid Interns or Volunteers

Definition of Volunteer

- Consistent with definitions and guidance from the U.S. Department of Labor, volunteers are "individuals who volunteer or donate their services, usually on a part-time basis, for public service, religious or humanitarian objectives, not as employees and without contemplation of pay, are not considered employees of the religious, charitable or similar non-profit organizations that receive their services."
- Volunteers are uncompensated and provide services without the expectation of pay from the volunteer activity and have no assurance or reason to expect that Duke will offer employment following the volunteer period. Volunteers are not eligible for any Duke benefits, including unemployment or workers' compensation benefits.
- To ensure that an individual performing volunteer services is not an employee for purposes of the Fair Labor Standards Act (FLSA), all of the following criteria must be satisfied in order for the individual to be approved as a volunteer:
  - The services are intended to be voluntary and to be rendered without compensation.
  - The services must constitute a bona fide effort of the individual to volunteer for humanitarian or public service purpose or for the benefit of education, training or professional experience.
  - Individuals volunteer their time for their own personal motives, without promise or expectation of compensation or employment.
  - Volunteers must not be used in ways that displace or replace regular employees in the performance of their normal duties.
Unpaid Volunteer or Intern

Definition of Unpaid Internship

• Individuals who wish to volunteer for the purposes of educational or professional interest as part of a formal or informal educational program must meet the following criteria:
  – The internship, even though it includes actual operation of the facilities of the employer, is similar to training that would be given in an educational environment.
  – The internship experience is for the benefit of the intern.
  – The intern does not displace regular employees, but works under close supervision of existing staff.
  – The employer that provides the training derives minimal or no immediate advantage from the activities of the intern and on occasion its operations may be temporarily impeded.
  – The intern is not necessarily entitled to a job at the conclusion of the internship.
  – The employer and the intern understand that the intern is not entitled to wages for the time spent on the internship.
  – If all of the factors listed above are met, an employment relationship does not exist under the FLSA, and the Act's minimum wage and overtime provisions do not apply to the unpaid intern. Further, the individual is not eligible for any Duke benefits, including unemployment or workers' compensation.
  – Examples:
    • High School students who are learning about research either as part of a project for which they are receiving class credit at their school or are learning more about it because they have an interest in it as a career field.
    • A college student who volunteers their time to increase their knowledge and skills through hands-on training when a part-time paid position or independent study (for credit) are not options.
Unpaid Intern and Volunteer

1. All unpaid interns and volunteers on research teams must be adults (18 yrs. or older).

2. All unpaid interns/volunteers must complete the CITI modules as do all other Duke researchers do.

3. All unpaid interns/volunteers must complete the DHRT (Duke Human Research Training) module.

4. A clean criminal background check must be obtained on each unpaid intern/volunteer. Note that the background check is not required for Duke students, because they were vetted during the Duke admissions process. However, the background check is required for students from all other schools.

   Please contact:
   3-D Background Screening
   Tel. 1-866-293-6486
   The cost is approximately $20-30 per person.

5. One of two agreement letters must be completed by the study team and signed by the unpaid intern/volunteer. The volunteer agreement letter is intended for unpaid interns or volunteers, including Duke undergraduate students, who are NOT engaged in conducting the consent process. The agreement letter for Duke undergraduates engaged in the consent process is intended for only unpaid, undergraduate Duke students engaged in the consent process.
6. An email must be sent to your CRU medical director/Oversight Organization director/Dept. Chair if not part of a CRU) containing the following:
   - Unpaid Intern/Volunteer Name
   - Pro# of study
   - PI
   - Specific description of the individual’s role on the study (including whether consent will take place (Duke undergraduate students only) and expected time on study team
   - Please ask the CRU medical director or Oversight Organization director (or designee) to respond with an approval via email.

7. A personnel amendment must be submitted in the eIRB to add the unpaid intern/volunteer to **external key personnel** for each study on which he/she participates. The amendment must contain copies of:
   - The appropriate signed volunteer agreement letter
   - Approval (email) from CRU Medical Director or Oversight Organization Director
   - CITI module completion report
   - DHRT (Duke Human Research Training) (and, if appropriate, the Undergraduate Student Informed consent workshop)
   - Completion report Statement from the PI that a clean criminal background check has been obtained for non-Duke student
   - Once the IRB has approved the personnel amendment, the unpaid intern/volunteer may join the study team.
8. Unpaid interns/volunteers will not have access under any circumstances to a subject’s or patient’s electronic medical record.

9. Unpaid interns/volunteers may be granted Duke email accounts and access to shared drives specified by the PI. However, all work by the unpaid intern/volunteer must be conducted on-site under the supervision of the PI or other designated study team members. In addition, all work by the unpaid intern/volunteer must be conducted on Duke computers and servers. Remote access to Duke servers will not be permitted. Use of personal electronics by the unpaid intern/volunteer for storage/analysis/receipt of information involving Duke research studies is not permitted.
Unpaid Interns or Volunteer

Prohibited Activities

• Volunteers or Unpaid Interns cannot replace or be substituted for current employees or perform work that would otherwise require another individual to be employed. Volunteer services are generally limited to educational training (normally for unpaid interns), humanitarian, charitable or public service purposes and normally are rendered on a part-time and temporary nature.

• University Volunteers and Unpaid Interns are also prohibited from performing the following activities:
  – Operating heavy equipment, including vehicles
  – Working with stored energy (e.g. steam, electricity, hydraulics)
  – Activity considered inappropriate for any employee
  – Entering into any contract on behalf of the University
  – Being present in a clinical setting or working with Protected Health Information (PHI), except in accordance with Duke IRB policies and procedures, or Duke University Health System policies and procedures as applicable
  – Performing any activities not approved or outlined by the minimum safety guidelines established by the Occupational & Environmental Safety Office (OESO)
VISA Status

**H-1B Employee:** The H-1B classification is for an employer who wishes to sponsor a professional worker in a “specialty occupation.” A “specialty occupation” means an occupation that requires the theoretical and practical application of a body of highly specialized knowledge considered to be equivalent to the attainment of a United States Bachelor’s degree or foreign equivalent, in a specific field. Jobs which have a minimum hiring requirement of a United States Bachelor's degree, or foreign equivalent, in a specific field generally qualify for the H-1B classification. The person for whom the employer is filing the H-1B petition must be able to prove s/he meets all the minimum hiring requirements of the position, including the degree(s) in the appropriate field, license, etc., and must prove with an equivalency evaluation that any foreign degree is equivalent to the required United States degree.

**J-1 Visiting Scholar (non-trainee):** The J-1 was created to promote academic, cultural, and scientific exchange between the visitor and the host country. J-1 exchange visitor visa status is available to scholars to engage in educational and cultural programs in the United States, and then return to their home countries to share their experiences, as well as encouraging their colleagues in the United States to participate in educational and cultural programs abroad. J-1 scholar status refers to a variety of specialized categories. Duke University is authorized by the Exchange Visitor Program to accept students, researchers, professors, short-term scholars and specialists. Depending on the category, these programs can be valid for multi-week to multi-year periods, but regardless of the duration of the program, scholars must focus on the specific goals of the program for the duration of their stay in J-1 status.

[https://visaservices.duke.edu/category/index.php](https://visaservices.duke.edu/category/index.php)
Duke University (Non Duke Health) Faculty and Employees

• Treated like Duke Health Faculty and Employees on DUHS IRB approved protocols

• They are not considered part of the covered entity for Duke Health-therefore no access to the electronic health record
Faculty/Staff who have left Duke

- Move to Key personnel external to Duke
- They do not have access to the electronic health record
- Access to the research information is identified in the executed Date Use Agreement or the Material Transfer Agreement (for specimen information)
- Depending on whether identifiers are being received and how the external personnel are accessing this info, either an IRB authorization agreement (IAA) or individual investigator agreement (IIA) may also be needed.
Temporary Staffing

- Hired through Duke Temporary Services fill an immediate need
- Can be placed as key personnel and have access to the electronic medical record if that is the job hired for (CRC)
- Must meet all research requirements (CITI and DHRT)

Request Temporary Staffing
Complete the Job Order Request to submit an order for temporary staffing.
Panel Discussion