

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

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eSignature and Date:



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Purpose:

The purpose of this policy is to outline the process for adding Duke students, unpaid volunteers, and visiting trainees/interns to DUHS IRB study personnel.

In summary:

- 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](#), [Annual HIPAA Privacy and Security Training](#) module in LMS, and [New Workforce Member Policy Acknowledgement](#) module in LMS (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.

Definitions:

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 participating in an Academic Affiliation Agreement 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).

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.

Duke University undergraduate student: An undergraduate student whose home school is part of Duke University campus and is not considered part of the Duke Health covered entity.

Visiting trainees/interns: Students or trainees participating in a training or internship program through an Academic Affiliation Agreement between Duke and another academic institution.

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 another academic institution. Contact Susan Hayden in ORC: susan.hayden@duke.edu.
- **[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 undergraduate students who are engaged in the consent process. Contact Susan Hayden in ORC: susan.hayden@duke.edu.

Adult: an individual who is at least 18 years of age at the time of addition to a research study.

Procedure:

Review the section below that applies to the type of individual you want to add to your study team.

Requirements for adding visiting research scholars

For visiting research scholars, contact DOCR.help@dm.duke.edu.

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

1. Must be an adult.
2. Must complete all [Duke Health CITI modules](#), [Responsible Conduct of Research \(RCR\) training](#), LMS [Annual HIPAA Privacy and Security Training](#) module, and LMS [New Workforce Member Policy Acknowledgement](#) module (includes electronic signature for Confidentiality Agreement, Code of Conduct Attestation, and Secure System Usage Memorandum).
3. Listed as Key Personnel according to study role.

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
3. Must complete all [Duke Health CITI modules](#), [Responsible Conduct of Research \(RCR\) training](#), LMS [Annual HIPAA Privacy and Security Training](#) module, and LMS [New Workforce Member Policy Acknowledgement](#) module (includes electronic signature for Confidentiality Agreement, Code of Conduct Attestation, and Secure System Usage Memorandum).
4. Must be added under 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.

Requirements for adding Duke undergraduate students to Key Personnel (for studies under Expedited or Full Board IRB review)

1. Must be an adult
2. 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:
 - a. Documentation of completed [Duke Health CITI modules](#), [Responsible Conduct of Research \(RCR\) training](#), LMS [Annual HIPAA Privacy and Security Training](#) module, and LMS [New Workforce Member Policy Acknowledgement](#) module (includes electronic signature for Confidentiality Agreement, Code of Conduct Attestation, and Secure System Usage Memorandum).
 - b. Fully signed Agreement, as appropriate to the proposed activities (DUHS IRB volunteer agreement or DUHS IRB Duke Undergraduate student agreement for consent)
 - c. Email approval from the CRU/OO Director containing the following information:
 - i. PRO# of the study
 - ii. PI name
 - iii. 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.

Forward the CRU/OO Director's approval email with a copy of the fully signed DUHS IRB Agreement for each student to DOCR.help@dm.duke.edu.

- d. 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.
- e. Statement from the PI that the undergraduate will adhere to the following requirements:
 - i. They will not, under any circumstances, have access to Maestro Care

- ii. They will have access to Duke Health identifiable data only for recruitment and consenting purposes (if participating in recruitment or the consent process)
 - iii. Data access and storage as defined in Tables 1 and 2 at end of this document
 - iv. No copies or screen shots are made of the data
3. 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 and 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, and the student will remain on the study, the study team must submit an amendment to follow the process for unpaid undergraduates described above.

Requirements for adding Duke undergraduate students to Key Personnel (for studies being reviewed for Exemption by IRB)

- 1. Must be an adult
- 2. 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:
 - a. Documentation of completed [Duke Health CITI modules](#), [Responsible Conduct of Research \(RCR\) training](#), LMS [Annual HIPAA Privacy and Security Training](#) module, and LMS [New Workforce Member Policy Acknowledgement](#) module (includes electronic signature for Confidentiality Agreement, Code of Conduct Attestation, and Secure System Usage Memorandum).
 - b. Fully signed DUHS IRB volunteer agreement
 - i. **Forward a copy of the fully signed DUHS IRB Agreement for each student to DOCR.help@dm.duke.edu.**
 - c. Statement from the PI that the undergraduate will adhere to the following requirements:
 - i. They will not, under any circumstances, have access to Maestro Care or identifiable data.
 - ii. Data access and storage as defined in Tables 1 and 2 at end of this document
 - iii. No copies or screen shots are made of the data
- 3. 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 and 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, and the student will remain on the study, the study team must submit an amendment to follow the process for unpaid undergraduates described above.

Requirements for adding other unpaid volunteers, visiting trainees/interns to Key Personnel

1. Must be an adult
2. The following must be uploaded into an external Key Personnel amendment to the study in iRIS:
 - a. Documentation of completed [Duke Health CITI modules](#), [Responsible Conduct of Research \(RCR\) training](#), LMS [Annual HIPAA Privacy and Security Training](#) module, and LMS [New Workforce Member Policy Acknowledgement](#) module (includes electronic signature for Confidentiality Agreement, Code of Conduct Attestation, and Secure System Usage Memorandum).
 - b. Fully signed DUHS IRB volunteer agreement
 - c. Email approval from the CRU/OO Director containing the following information:
 - i. PRO# of the study
 - ii. PI name
 - iii. Specific description of the volunteer's role on the study

Forward the CRU/OO Director's approval email with a copy of the fully signed DUHS IRB Agreement for each volunteer or trainee/intern to DOCR.help@dm.duke.edu.

- d. 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.
- e. **For Volunteer:** Statement from the PI that the volunteer will adhere to the following requirements:
 - i. They will not, under any circumstances, have access to Maestro Care
 - ii. Data access and storage as defined in Tables 1 and 2 at end of this document
 - iii. No copies or screen shots are made of the data

For Trainee/Intern: Statement from the PI that the trainee/intern will adhere to the following requirements:

- i. Data access and storage as defined in Tables 1 and 2 at end of this document
- ii. No copies or screen shots are made of the data

Tables:

Table 1: Consented Clinical Research Data

Table 2: Non-Consented Clinical Research 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 ¹ : PACE, REDCap, Duke Box, Duke Health Department Shared Drive supported by DHTS					
		Required Agreements			Allowable Activities	
Research Role Type	DUHS/ SOM academic affiliation agreement	DUHS IRB volunteer agreement	DUHS IRB Duke undergraduate student agreement for consent	Role-based access to Epic EMR	Access to identifiable data	Access to de- identified data
Duke Schools of Medicine and Nursing graduate students	No	No	No	Yes	Yes	Yes
Duke University campus graduate students	No	No	No	Yes	Yes	Yes
Duke undergraduate students (unpaid)	No	Yes ²	Yes ²	No	Yes	Yes
Duke undergraduate students (employed or work study of Duke Health Dept working on DUHS IRB approved protocol)	No	No	No	Yes	Yes	Yes
Duke undergraduate students for academic credit research project (unpaid)	No	Yes ²	Yes ²	No	Yes	Yes
Volunteer – not Duke Health affiliated (unpaid)	No	Yes	No	No	No	Yes
Visiting trainee/intern (formalized Academic Agreement)	Yes	Yes	No	Yes	Yes	Yes

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.

² Unpaid Duke undergraduates must sign *either* the DUHS IRB volunteer agreement *or* the DUHS IRB Duke undergraduate student agreement for consent, depending on proposed activities.

Table 2	<p align="center">Non-Consented Clinical Research Data</p> <p>Below are roles and requirements for access to non-consented clinical data.</p> <p><u>Definition:</u> 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.</p> <p><u>Approved Data Access and Storage Locations for Identifiable Data</u>³: PACE</p>						
	Required Agreements			Allowable Activities			
Research Role Type	DUHS/ SOM academic affiliation agreement	DUHS IRB volunteer agreement	DUHS IRB Duke undergraduate student agreement for consent	Role- based access to Epic EMR	Access to Duke Health identifiable data	Access to Duke Health identifiable data for recruitment and consenting purposes only	Access to de- identified data
Duke Schools of Medicine and Nursing graduate students	No	No	No	Yes	Yes	Yes	Yes
Duke University campus graduate students	No	No	No	Yes	Yes	Yes	Yes
Duke undergraduate students (unpaid)	No	Yes ⁴	Yes ⁴	No	No	Yes	Yes
Duke undergraduate students (hired & paid by Duke Health Dept working on DUHS IRB approved protocol)	No	No	No	Yes	Yes	Yes	Yes
Duke undergraduate students for academic credit research project (unpaid)	No	Yes ⁴	Yes ⁴	No	No	Yes	Yes
Volunteer – not Duke Health affiliated (unpaid)	No	Yes	No	No	No	No	Yes
Visiting trainee /intern (formalized Academic Agreement)	Yes	Yes	No	Yes	Yes	Yes	Yes

³ 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.

⁴ Unpaid Duke undergraduates must sign *either* the DUHS IRB volunteer agreement *or* the DUHS IRB Duke undergraduate student agreement for consent, depending on proposed activities.

Policy Owner:	Duke Office of Clinical Research
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