**IRB Guidance to Researchers for Studies Involving Blood Draws from Human Participants for Research**

# **Subject**

[IRB policy #19](https://www.irb.cornell.edu/documents/IRB%20Policy%2019.pdf) describes the IRB’s policies, considerations and institutional requirements for conducting biomedical procedures with human participants on the Ithaca campus. Researchers should familiarize themselves with the policy before they consider conducting any such procedures. We highly recommend that any on- campus blood draws be conducted by clinical professionals at the Ley Lab at the Gannett Health Services or in the HMRU.

If neither of these are viable options and if research cannot be conducted at outside clinical facilities, blood draws at other locations on campus can be done under very specific conditions.

Any request to draw blood for research at Cornell campus locations other than the HMRU and the Gannett Health Services, or by professionals not employed by these two entities, will require extensive review by the Cornell Occupational Medicine, University Biosafety and the IRB.

Below we describe the process to follow for each option for blood draw.

**What would you like to do? (Click on the link below for details of each, or you can browse each option starting on the next page)**

# **[Blood draw at Gannett Health Services (GHS) (highly recommended)](#_Blood_draw_at_5)**

# [**Blood draw at the Human Metabolic Research Unit (HMRU)**](#_Blood_draw_at_4) **(recommended)**

# **[Blood draw at an off campus location](#_Blood_draw_Off-campus)**

# [**Blood draw at a CU-Ithaca location other than GHS or HMRU**](#_Blood_draw_at_3) **(not recommended)**

# **Blood draw at Gannett Health Services**

Blood draw services provided by [Gannett Health Services (GHS)](http://www.gannett.cornell.edu/) are strongly recommended for drawing blood on the CU Ithaca campus. GHS can provide appointments for drawing blood from participants with prior arrangement and for a fee. [Details of this service are available here.](https://webhost068.hosting.cornell.edu:8443/irb/documents/Gannett%20procedures%20venipuncture%202016.docx)

Studies involving blood draws are likely to undergo Full Board review at the [Cornell IRB](https://www.irb.cornell.edu/documents/Secondary%20Data%20Analyses%20Review.pdf). Plan for a 4-6 week turnaround time for approval. In completing the [application](https://www.irb.cornell.edu/documents/Blank%20Protocol%20Approval%20Request%20Application.pdf), make sure that you address the following questions in reference to the blood draws:

1. **Participant demographics:** Are you planning to recruit healthy adults or do you need to get blood from older (65+) adults, children, pregnant women, persons with certain conditions or those whose autonomy may be limited in some way. Make sure to list any exclusion or inclusion criteria: (any specific health or demographic profile that you are looking for, or wish to avoid. For example individuals with BMI less or more than a certain number, women or men under a certain age or involved in athletics or sports activities, etc.)
2. **Procedures:** Amount of blood to be drawn, which part of the body it will be drawn from, frequency and interval between each blood draw.
3. **Informed consent form** – The general requirements for consent are included in [this template consent form](https://webhost068.hosting.cornell.edu:8443/irb/documents/Template%20venipuncture%20Consent%20Form%202016.docx). The IRB has approved the language in this consent form. You may modify the form to include specifics for your study, but we suggest not changing any of the language in the other sections, as it might add to the review time for your application. Any changes you make will be visible to the reviewers in “track changes” mode. Attach this consent form with your application to the IRB.
4. **Take home information sheet:** A template “take home” or follow up note for participants for taking care of the venipuncture site is provided with the SOP document. Please make any changes pertinent to your study and include it with your application.
5. **Transportation and storage:** All blood samples must be transported using the following procedure. Please note this in your IRB application:

* Use triple packaging consisting of a leak-proof primary receptacle (e.g. a blood tube), a leak-proof secondary package (e.g. sealable plastic bag), and an outer package (e.g. cardboard box or cooler if you are transporting it yourself)
* Place absorbent materials between the primary receptacle and the secondary packaging and be sure to make sure there is no contact between primary receptacles if they are placed in the same sealable plastic bag
* Secure the secondary packaging with cushioning material (e.g. bubble wrap)
* When you are done, the package should be able to withstand a drop from about four feet
* Samples must be clearly labeled with Biohazard sign below
* Laboratory Contact information must be in or on the outer container.
* Contact the [University Biosafety Office](mailto:askehs@cornell.edu) for more information.



1. Send the completed Initial Approval Request form and all attachments to the Cornell IRB office [irbhp@cornell.edu](mailto:irbhp@cornell.edu).
2. Once the protocol, consent, SOP and all other study documents have been reviewed and approved by the IRB, the IRB office will send a written confirmation with approval of your protocol, and stamped copies of the consent form. When you have this information, you can begin your study.

# **Blood draw at the Human Metabolic Research Unit (HMRU)**

The [HMRU](http://www.human.cornell.edu/dns/hmru/) is an approved campus location for venipuncture and certain other biomedical procedures for research. HMRU provides phlebotomy services with prior arrangement and for a fee. Details of this service are available [here](http://www.human.cornell.edu/dns/hmru/policiesand-standardoperatingprocedures.cfm). Contact the HMRU Manager [Erica Bender](mailto:eb572@cornell.edu) for a consultation and more information about their services. If you choose to use the services offered by the HMRU, include a letter of support from Ms. Bender with your IRB application; this will speed up the IRB review process.

Studies involving blood draws are likely to undergo Full Board review at the Cornell IRB. Plan for a 4-6 week turnaround time for approval. In completing the [application](https://www.irb.cornell.edu/documents/Blank%20Protocol%20Approval%20Request%20Application.pdf), make sure that you address the following questions in reference to the blood draws:

1. **Participant demographics:** Are you planning to recruit healthy adults or do you need to get blood from older (65+) adults, children, pregnant women, persons with certain conditions or those whose autonomy may be limited in some way. List any exclusion or inclusion criteria: (any specific health or demographic profile that you are looking for, or wish to avoid. For example individuals with BMI less or more than a certain number, women or men under a certain age or involved in athletics or sports activities, etc.)
2. **Procedures:** Amount of blood to be drawn, which part of the body will it be drawn from, frequency and interval between each blood draw
3. **Informed consent form** – The [HMRU](http://www.human.cornell.edu/dns/hmru/) has a standard consent form for blood draws. The IRB has approved the language in this consent form. You may modify the form to include specifics for your study, but we suggest not changing any of the language in the other sections, as it might add to the review time for your application. Contact the HMRU for the consent template, or you can use [this](https://webhost068.hosting.cornell.edu:8443/irb/documents/Template%20venipuncture%20Consent%20Form%202016.docx) one as a start.
4. **Take home information sheet:** The HMRU provides a template “take home” or follow up note for participants for taking care of the venipuncture site. Please consult with Erica to make any changes pertinent to your study and include the document with your application.
5. **Transportation and storage:** All blood samples must be transported using the packaging provided by the HMRU for the samples. Confirm that:

* Samples are clearly labeled with Biohazard sign below
* Laboratory Contact information is in or on the outer container

Contact the [University Biosafety Office](mailto:askehs@cornell.edu) for more information.



1. Send the completed Initial Approval Request form and all attachments, including the letter of support from the [HMRU](http://www.human.cornell.edu/dns/hmru/), to the Cornell IRB office [irbhp@cornell.edu](mailto:irbhp@cornell.edu).
2. The IRB will review the materials and may have questions or may issue approval. Once the protocol is approved and you have a stamped copy of the consent form, contact [Ms. Bender](mailto:eb572@cornell.edu) from the HMRU to schedule your study procedures.

# **Blood draw at an Off-campus location**

You may engage the services of phlebotomists at off campus clinical or other facilities that are approved to draw blood. In your IRB application, provide information about the details and credentials of the facility where the work will be done, and the personnel who will be conducting the procedures. Attach a letter of support from the facility describing the clinical set up of the facility and who will draw blood.

Studies involving blood draws are likely to undergo Full Board review at the Cornell IRB. Plan for a 4-6 week turnaround time for approval. In completing the [application](https://www.irb.cornell.edu/documents/Blank%20Protocol%20Approval%20Request%20Application.pdf), make sure that you address the following questions in reference to the blood draws:

* 1. **Participant demographics:** Are you planning to recruit healthy adults or do you need to get blood from older (65+) adults, children, pregnant women, persons with certain conditions or those whose autonomy may be limited in some way. List any exclusion or inclusion criteria: (any specific health or demographic profile that you are looking for, or wish to avoid. For example individuals with BMI less or more than a certain number, women or men under a certain age or involved in athletics or sports activities, etc.)
  2. **Procedures:** Amount of blood to be drawn, which part of the body will it be drawn from, frequency and interval between each blood draw
  3. **Informed consent form** –The IRB has approved the language in [this template consent form](https://webhost068.hosting.cornell.edu:8443/irb/documents/Template%20venipuncture%20Consent%20Form%202016.docx). In case that the facility that you are working with, may have its own consent form that you will need to use please ensure that it has the components included in this consent form. To the extent possible we suggest using this consent form and modifying it to accommodate specifics for your study.
  4. **Take home information sheet:** We highly recommend a “take home” or follow up note for participants for taking care of the venipuncture site. The template SOP document includes this sample take home sheet. Please make any changes pertinent to your study and include it with your application.
  5. **Transportation and storage:** All blood samples must be transported using standard biosafety practices. Guidelines are provided below; however we understand that the facility that you are working with may have its own standard procedures. In your application please describe how you will transport blood samples and where they will be stored.
* Use triple packaging consisting of a leak-proof primary receptacle (e.g. a blood tube), a leak-proof secondary package (e.g. sealable plastic bag), and an outer package (e.g. cardboard box or cooler if you are transporting it yourself)
* Place absorbent materials between the primary receptacle and the secondary packaging and be sure to make sure there is no contact between primary receptacles if they are placed in the same sealable plastic bag
* Secure the secondary packaging with cushioning material (e.g. bubble wrap)
* When you are done, the package should be able to withstand a drop from about four feet
* Samples must be clearly labeled with Biohazard sign below
* Laboratory Contact information must be in or on the outer container.
* Contact the [University Biosafety Office](mailto:askehs@cornell.edu) for more information.



* 1. Send the completed Initial Approval Request form and all attachments, including the letter of support from the outside clinic, to the Cornell IRB office [irbhp@cornell.edu](mailto:irbhp@cornell.edu).
  2. In addition to the Cornell IRB approval, the outside facility may have its own system of checks and balances. Researchers are responsible for making sure that all such procedures are complied with, in addition to any Cornell requirements.

# **Blood draw at other locations on CU-Ithaca campus**

To the extent possible, on-campus blood draws should be done at either [GHS](https://www.gannett.cornell.edu/) or the [HMRU](http://www.human.cornell.edu/dns/hmru/). This is because the HMRU and GHS have the infrastructure, personnel and necessary institutional approvals to conduct these procedures in a manner that assures the adequate protection of employees, participants and the institution. Alternatively researchers may engage outside clinical facilities to collect blood.

**If it is necessary to conduct blood draws at other campus locations, researchers must justify this in their research protocols to the IRB. The process of getting these alternative locations and personnel approved is likely to take time. Here is how to get started:**

* **Call the** [**IRB office**](https://www.irb.cornell.edu/) **to discuss your project, the location, and details of the study.**
* **Determine first if you can get a phlebotomist from GHS or HMRU to draw blood at the campus location.** Contact [GHS](https://www.gannett.cornell.edu/) or the [HMRU](http://www.human.cornell.edu/dns/hmru/) to find out details about pricing, schedules etc. If you prefer to have some other member of the research team or another phlebotomist draw blood, please see Appendix A of this document for the credentialing requirements for someone to draw blood at the CU-Ithaca campus. You will need to contact Gannett Health Services [Occupational Medicine](http://www.gannett.cornell.edu/services/occupational/) to begin the process.
* **Location:** Any location where blood is drawn must meet biosafety standards for blood borne pathogens and must have sufficient privacy and safety safeguards for participants. For example, having a hand washing sink, phone for emergency contact, floor and surfaces than can easily be cleaned in case of a spill, a chair with back support, etc. Contact the [University Biosafety Office](mailto:askehs@cornell.edu) to start the facility review and approval process.
* **IRB Approval:** Studies involving blood draws are likely to undergo Full Board review at the Cornell IRB. Plan for a 4-6 week turnaround time for approval. In completing the [application](https://www.irb.cornell.edu/documents/Blank%20Protocol%20Approval%20Request%20Application.pdf), the IRB will pay particular attention to:
  1. **Participant demographics:** Exclusion or inclusion criteria: (any specific health or demographic profile that you are looking for, or wish to avoid. For example individuals with BMI less or more than a certain number, women or men under a certain age or involved in athletics or sports activities, etc.)
  2. **Procedures:** Amount of blood to be drawn, which part of the body will it be drawn from, frequency and interval between each blood draw
  3. **Informed Consent**–The IRB has approved the elements of [this consent form.](https://webhost068.hosting.cornell.edu:8443/irb/documents/Template%20venipuncture%20Consent%20Form%202016.docx) We recommend using this form to the extent possible, with changes only to provide details about your study. Please adapt this form to your study and include this with your application
  4. **Take home information sheet:** A template “take home” or follow up note for participants for taking care of the venipuncture site is provided with the SOP document. Please make any changes pertinent to your study and include it with your application.
  5. **Standard operating procedures (SOP):** The IRB has approved [this SOP](https://webhost068.hosting.cornell.edu:8443/irb/documents/Editable%20SOP%20for%20Venipuncture%202016.docx) for blood draws. If you follow this SOP to conduct these procedures without making any changes (highly recommended), you can provide a link to this SOP in your protocol application. If you wish to make changes to the procedures outlined in the document, wish to develop your own or use an existing SOP used elsewhere, attach it to your application. The SOP will be reviewed by [Occupational Medicine](http://www.gannett.cornell.edu/services/occupational/) and the [IRB](https://www.irb.cornell.edu/) for appropriateness and may require modifications.
  6. **Transportation and storage: All blood samples must be transported using the following procedure:**
* Use triple packaging consisting of a leak-proof primary receptacle (e.g. a blood tube), a leak-proof secondary package (e.g. sealable plastic bag), and an outer package (e.g. cardboard box or cooler if you are transporting it yourself)
* Place absorbent materials between the primary receptacle and the secondary packaging and be sure to make sure there is no contact between primary receptacles if they are placed in the same sealable plastic bag
* Secure the secondary packaging with cushioning material (e.g. bubble wrap)
* When you are done, the package should be able to withstand a drop from about four feet
* Samples must be clearly labeled with Biohazard sign below
* Laboratory Contact information must be in or on the outer container.
* Provide the Room and building number of the location where blood samples will be stored
* Contact the [University Biosafety Office](mailto:askehs@cornell.edu) for more information.



* 1. **When can you start: when you receive a written letter of approval from the IRB office and stamped consent form, you may begin your study.**

**Appendix A**

QUALIFICATIONS TO CONDUCT BIOMEDICAL PROCEDURES FOR RESEARCH: VENIPUNCTURE

1. Training/Experience/Certification
   1. Training. Diploma from a Gannett Health Services Occupational Medicine approved phlebotomy training program that includes at least 20 hours of class training including the performance of venipuncture on humans

OR

* 1. Work experience. Letter of reference, or other suitable evidence, verifying work for at least one year in a health care setting in a position with venipuncture duties in job description. Consideration may be given to experience gained through an education/ training program in a health care or clinical research setting.

OR

* 1. Certification from a GHS-OM approved phlebotomy certification organization.
     1. Current certificate from one of the following: American Medical Technologists, American Society of Clinical Pathologists, National Center for Competency Testing, or National Health Career Association.
     2. Verification by employer/supervisor of the provision of the following venipuncture training components:
        + Medical law and ethics
        + Anatomy and physiology
        + Medical terminology
        + Asepsis and infection control
        + Venipuncture equipment and procedure
        + Specimen integrity, handling, and transport

OR

* 1. Health care professional. Current New York State license as an MD, DO, PA, NP, RN, or LPN.

1. Skills Assessment. Successful demonstration of good/excellent venipuncture skills on at least 5 individuals during a Gannett-administered skills assessment.
2. Bloodborne Pathogen Training. Current bloodborne pathogen training provided by Environmental Health and Safety.
3. First Aid Certification. Current First Aid certification obtained through hands-on training.
4. CPR/AED Certification. Current CPR/AED certification obtained through hands-on training.