

GW OHR Guidance:

Research Involving Blood Collection

This guidance document will outline general best practices and requirements for conducting research that involves blood collection from research participants. This document should be used by investigators and research team members who are planning a study that will involve blood collection.

What does the IRB look for when reviewing a study that involves blood collection?

The IRB focuses on the following when reviewing a study that involves blood collection:

- Amount of blood collected
- Frequency of blood collected
- Health and age of the study population
- The minimal amount of blood needed to perform tests and/or banking is being collected
- Whether or not the blood is being collected as part of standard of care (occurring regardless of the research) or solely for research purposes. If leftover/excess blood samples obtained from standard of care are being used in research, please indicate this.
- How blood samples are being securely handled, transported, and stored

How does the IRB determine if the study is minimal or high risk?

The Federal regulations define specific categories of research that may be reviewed through the expedited review process under 45 CFR 46.110 and 21 CFR 56.110. The IRB uses the expedited review category 2 to determine if a study that involves blood collection can be reviewed via expedited procedures (minimal risk). If your research exceeds the criteria in expedited category 2, it will be assigned to an IRB convened committee meeting for review. The risk level for studies assigned to a full board meeting will be determined by the full committee at the meeting.

EXPEDITED CATEGORY 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amount drawn may not exceed 550ml in an 8 week period and collection may not occur more frequently than 2 times per week;
- **or**
- b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Note: If you believe your study is minimal risk, but does not meet the requirements of expedited category 2, please contact us at ohrirb@gwu.edu.

CHECKLIST : RESEARCH INVOLVING BLOOD COLLECTION

- “Research Study Personnel” sections of the IRB Application
 - Make sure all study personnel are listed
 - Make sure all study personnel are up-to-date on their CITI training
- “Study Details” section of IRB Application
 - Specify the amount of blood (ml and tablespoons/teaspoons) that will be obtained; make sure this is consistent between the IRB application and study documents (e.g., informed consent form, recruitment materials, etc.)
 - Justify the amount of blood drawn
 - Describe the age and health of the research participants
 - Describe how the blood collection will occur (i.e., who will perform it, how it will be performed, duration, where, frequency, etc.)
 - Describe whether or not the blood collection is occurring as part of the standard of care procedures or solely for research purposes
- “Risks to Subjects” section of IRB Application
 - Describe risks to the participants from the blood collection
- “Privacy and Confidentiality” section of the IRB Application
 - Describe in detail how blood samples will be securely handled, transported, and stored
- “Informed Consent Form”
 - Specify the amount of blood in ml and tablespoons/teaspoons
 - Describe how the blood collection will occur (i.e., who will perform it, how it will be performed (e.g. needlestick, finger prick, through a previously placed IV, etc.), duration, where, frequency, etc.)
 - List the risks of the blood draw and blood collection method

If the research includes genetic testing and/or analyses:

- “Study Details” section of IRB Application
 - Explain the type and extent of the genetic testing and/or analyses
 - Explain if participants will be informed of the result of their genetic testing/analyses; if so, how, what information will be shared with them, and if any genetic counseling will be provided
 - Specify which aspects of this is part of the standard of care (what participants would experience regardless of the research) or occurring solely for research purposes
- “Privacy and Confidentiality” section of IRB Application
 - Include any confidentiality or privacy concerns related to the genetic analyses or reporting and what steps will be taken to protect participants
- “Informed Consent Form”
 - Include the GINA language (see GW OHR’s informed consent form template)
 - Explain what genetic testing/analyses will be performed and if/how results will be provided to participants; specify which aspects of this is part of the standard of care (what participants would experience regardless of the research) or occurring solely for research purposes

Questions?

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References

1. 45 CFR 46.110
2. 21 CFR 56.110