GW OHR Guidance:

Blood Draws

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

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

The IRB focuses on the following when reviewing a chart review study:

1. Amount of blood drawn
2. Health and age of the study population
3. The minimal amount of blood needed to perform tests and/or banking is being collected

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 solely blood draws can be reviewed via expedited procedures.

Please see expedited category 2 below:

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.
Tip: A study can be minimal risk, but not qualify for expedited review. 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

If your study does not meet the requirements for expedited category 2, it will be assigned to a full board meeting for review. The risk level for studies assigned to a full board meeting will be determined by the full committee at the meeting.

CHECKLIST FOR BLOOD DRAW STUDIES

☐ The amount of blood is clearly listed in the IRB application, and consistently listed throughout the IRB application and informed consent form
☐ The consent form lists amount of blood in ml and tablespoons/teaspoons
☐ The consent form describes the method of blood draw (e.g. needlestick, finger prick, through a previously place IV, etc.)
☐ The consent form lists the risks of the blood draw and blood draw method
☐ Make sure all study personnel are listed consistently between sections 3 and 4 of the IRB application
☐ Make sure all study personnel are up to date on their CITI training
☐ Section 9.1 - Justify the amount of blood drawn in section
☐ Section 9.1 – Describe the health of the subjects
☐ Section 14.0 - Any risks to the subjects from the blood draw are described

If the study includes genetic analyses:

☐ Section 9.1 - Explain the type and extent of the genetic analyses
☐ Section 9.1 – Explain if subjects will be informed of the result of their genetic analyses and if so, what information will be shared with them and if any genetic counseling will be provided
☐ Sections 14.0 and 15.0 – Include any confidentiality or privacy concerns related to the genetic analyses or reporting and what steps will be taken to protect subjects
☐ The consent form includes GINA language (see consent form template)
☐ The consent form explains what genetic analyses will be performed and if/how results will be provided to subjects
Questions?

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References

1. 45 CFR 46.110
2. 21 CFR 56.110