VANDERBILT UNIVERSITY

PRACTICAL TIPS WHEN SUBMITTING TO THE VU IRB

Below are practical tips to facilitate the most efficient IRB review. Following these helpful tips will streamline the IRB review process for both the research team and IRB reviewers. This document is intended for Vanderbilt University (VU) researchers submitting their human research to the VU Social, Behavioral, Educational Institutional Review Board (IRB) for review.

TABLE OF CONTENTS

Know if your research meets the regulatory definition of human subjects research. If you are unsure, use the VU *HRPP Determination Tool* to get an initial determination regarding whether your project meets the regulatory definition of human subjects research and if so, which IRB should be reviewing the research study (VU IRB or VUMC IRB). The VU HRPP staff are available for consultations. It is recommended to initially utilize the tool.

Review the Investigator Manual and relevant policies/guidance documents available on the VU HRPP website.

For multi-site research, determine if external research collaborators (individuals and/or organizations) are engaged in human subjects research. If VU will be the IRB of Record (where external sites will rely on VU) reach out to the VU HRPP at irb@vanderbilt.edu with questions.

Determine if anyone on the research team has a conflict of interest (refer to the *Vanderbilt University Conflict of Interest and Commitment Policy*) and include this information in the submission. A copy of the COI determination and/or approved COI management plan should be attached to the submission to the VU IRB.

Ensure all research personnel have completed the required human research protection training through the **CITI Program** before submitting to the VU IRB. When submitting to the VU IRB, the research team does not need to submit CITI training completion certificates as part of their submission, unless specifically directed to do so by the VU HRPP.

Identify a qualified Principal Investigator (PI). The PI should be someone who can develop, execute, and support the research in an ethical and compliant manner. The PI is responsible for the protection of research participants' health and well-being throughout the research lifecycle. VU Faculty, staff, postdocs, and PhD students who have Oracle accounts can serve as the Principal Investigator (PI) of a study. Other students will need their faculty advisors to serve as the PI on a study and should be included as key study personnel when submitting in the electronic IRB system. PhD students serving as a PI must have a *Faculty Advisor Responsibilities Form* attached to the submission.

Submit your research in a timely manner. In addition to your own research timeline, be sure to account for the IRB review process (and any additional necessary reviews) in the research life cycle. Note that review times may vary based on several factors. These include but are not limited to: additional reviews that may be necessary for the research

(e.g., international research, multi-site research where VU IRB is the IRB of record, consultant review); the volume of submissions being reviewed by the VU HRPP at any given time; and, a short timeframe for human research to occur (e.g., research start/end date is contingent upon a school semester start/end dates or a tight funding timeline).

- *Minimal Risk Research*: Plan to submit a few weeks prior to the start of the research to provide enough time for the intake, review by a Compliance Analyst/IRB Designee, and processing of the submission.

- *IRB Committee Review (Expedited or Greater Than Minimal Risk)*: The VU SBER IRB Committee convenes the first Tuesday of each month to review research that qualifies for full board review. Plan to accommodate for the intake of the submission, review by a Compliance Analyst and individual IRB reviewers, IRB committee review at a monthly convened meeting, and processing of the submission.

Ensure all appropriate permissions and additional ethical reviews are obtained prior to start of the research.

- School district approval and site permission(s) from schools are typically required when conducting human research in K-12 schools.
- Human research studies involving Tribal communities require Tribal IRB or Tribal Council approval.
- Studies involving biological materials or invasive devices may require the Institutional Biosafety Committee and/or the Radiation Safety Committee review.
- Some countries where international research is occurring may require a local ethics committee review.

Use VU HRPP templates. A completed protocol template is required to submit for all human research being reviewed by the VU IRB. Researchers are encouraged to use VU HRPP consent templates as they include regulatory required elements of consent. All templates and forms are found on VU HRPP's website.

Label documents clearly when submitting them.

- Examples: *Protocol*, *Recruitment Email for Teachers*, *Social Media Recruitment Posting for Community Members*, *Spanish Consent Form for Adults*, *Interview Questions for Key Informants, Site Permission XYZ Organization*

Maintain consistency and transparency in all information within research study submission materials. Study details should match across all documents (e.g. participant numbers, data collection methods, duration of procedures, number of research visits, etc.). For transparency purposes for the IRB review, if using deception/incomplete

disclosure, explain why it is necessary, at what point participants will be informed of the deception/incomplete disclosure, and whether and how debriefing will occur.

Provide a detailed description of research procedures in lay terms in the protocol and relevant study materials. Please do not copy the content directly from a grant proposal or dissertation proposal into the protocol template. Simplify the detailed description of research procedures to facilitate a more efficient review. The reviewers should be able to clearly understand what researchers and participants are experiencing throughout the entire study. Some pointers are included below.

- *Recruitment.* Recruitment procedures (how potential participants will be recruited) must be fully described (e.g., flyers, emails, social media). Additionally, consider how privacy of targeted audiences for recruitment will be protected (e.g., permission to email group listservs, 3rd party access to information associated with social media recruitment postings).

- *Study Population(s).* Make specific considerations for protected populations (e.g., children, pregnant women, prisoners) or other vulnerable populations. Additionally, if you plan to exclude or include a certain population, there should be a justification for it (e.g., pregnant women are excluded due to dietary restrictions that may pose unknown risks to fetal development or pregnant women are included as they may benefit from dietary consultations).

- *Consent.* Keep in mind that consent is a process not simply a form. Explain the entire consent process to the IRB in the submission. The consent materials should provide detailed information about the study so a participant or their legally authorized representative (LAR) can make an informed decision to voluntarily participate in the research. There are specific elements of consent that must be included in the consent document for non-exempt research per the federal regulations. Researchers are encouraged to utilize the VU HRPP consent templates, which have these required elements built into them. If waivers are requested, ensure to include justifications for all required criteria (e.g. in large scale retrospective or secondary data analysis studies, it would be logistically impractical obtain consent).

- *Risks.* Research-related risks and a risk minimization plan should be clearly explained in the study protocol and consent forms (e.g. data confidentiality concerns will be mitigated using data encryption and use of a code link, emotional/psychological risks will be managed by offering mental health resources).

- *Benefits*. Benefits of the research for research participants should be clearly described in the IRB submission and the consent form. If there is no direct benefit to participants, state this. Compensation is not considered a benefit.

- *Privacy and Confidentiality.* It is important for the IRB to know how the research team will implement adequate privacy and confidentiality protections for participants and their data throughout the research cycle. This pertains to privacy and confidentiality throughout the recruitment, consent, data collection, and data reporting aspects of the research. For example, collecting the minimum amount of personally identifiable information (PII) and the use of a code link are a couple of best practices to safeguard the confidentiality of the data. Also, the researcher is responsible to ensure compliance with relevant VU policies (such as IT/Cybersecurity policies around appropriate cloud storage, use of transcription services, etc.).

Directly answer the questions that are being asked. The protocol has separate questions addressing different aspects of the research life cycle. For instance, when asked about recruitment procedures, provide a response only pertaining to recruitment procedures (not the consent process or data collection procedures). This is to streamline the information for a smoother IRB review.

Ensure the submission is complete. Review all questions to make sure they are answered in the VERA Smart Form and study protocol, even if the answer is not applicable or no. Check that all study documents are attached (preferably in Word format).

Identify if additional regulations apply to your research. Researchers should account for additional regulations that apply to their research (FDA, HIPAA, FERPA, PPRA, GDPR, PIPL, etc.) which may affect the design of the research. Inform the IRB in your submission of any additional regulations that may apply to your research.

Expect revisions or clarification questions from the VU IRB during the review of your submission. It is common for researchers to receive revisions or clarification questions from the IRB before approving a research study. Requests for revisions may range from being minor or major in nature. The IRB review is a joint effort between the research team and the VU HRPP/IRB. Contact the HRPP staff at irb@vanderbilt.edu for assistance anytime during the review process.