**Tip Sheet for VU Investigators**

**Who to Contact**

* **For general questions: HRPP Main Line: 615-322-2918**

Please note: you must leave a voicemail with your name/contact information to receive a call back. All voicemails will be returned within 24 hours

* **For study-specific questions**: Contact the analyst who sent the pre-review or action letter
* **For other questions/concerns:**
	+ **ISC Team Leader:** Cliff Rhodes: louis.c.rhodes.1@vumc.org ; (615) 322-3049
	+ **Operations Manager:** Molly Shiflet: molly.a.shiflet@vumc.org ; (615) 875-4864

**Exempt Research: Informed Consent vs Information Sheet (HRPP Policy Reference: III.C.1)**

* Researchers must ensure prospective participants receive adequate information about the study to facilitate a truly informed choice. This ethical obligation exists for **ALL** research—exempt and non-exempt (standard/expedited).
* Exempt research is **NOT** subject to the federal regulations regarding informed consent requirements (e.g. not required to have all elements of consent, does not require a signature).
* Researchers are still required to provide information about the research to prospective participants (and their parent/legal guardian, when applicable) prior to their enrollment in the study. At minimum, this information should include:
	+ A statement that the activity involves research
	+ A description of the study procedures
	+ A statement that participation is voluntary
	+ Name and contact information for the researcher
	+ HRPP contact information; and/or
	+ There are adequate provisions to maintain the privacy interests of participants.
* Agreement to participate in Exempt Research should NOT include language stating the document is an informed consent document
* An “Information Sheet” should be submitted rather than an Informed Consent Document

**Performance Sites “Engaged” vs “Not Engaged” (HRPP Policy Reference: I.C)**

* **Performance Site:** A site where research is performed.
* **Performance Site(s) Engaged in Research:** A performance site becomes "engaged” in human subjects research when its employees or agents 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. Further, a performance site is considered to be "engaged” in human subjects research when it receives a direct federal award to support the research.
	+ **Required Documentation:** An IRB approval letter from the “engaged” performance site must be provided to the VUMC IRB before initiation of the research at the “engaged” research site.
* **Performance Sites Not Engaged in Research**: A performance site is "not engaged” in human subjects research if its employees or agents do not: 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. If a VU or VUMC Investigator or his/her staff, including site personnel contracted by VU or VUMC, performs all research related activities as well as screening, recruiting, or consenting at the performance site, the performance site would be considered "not engaged” in research, unless the non-VU or VUMC performance site releases identifiable private information to VU or VUMC researchers without first obtaining participants’ permission.
	+ **Required Documentation:**
	+ *When a “not engaged” performance site has its own established IRB 🡪*The Investigator must obtain approval to conduct the research at the "not engaged" site from the site’s IRB or provide documentation that the site’s IRB has determined that approval is not necessary for VU or VUMC to conduct the proposed research at the site.
	+ *When a “not engaged” performance site does NOT have its own IRB*🡪A letter of cooperation must be obtained demonstrating that the appropriate institutional officials are permitting the research to be conducted at the performance site.

**Resources and Tools**

* **HRPP Policies and Procedures**: <https://www.vumc.org/irb/policies-and-procedures>
	+ A word-searchable PDF version of HRPP policies is available in DISCOVRe and accessible to anyone who has a DISCOVRe account
* **DISCOVRe Manual**: <https://www.vumc.org/irb/node/29>
* **Social Behavioral Protocol template**: This is a recommended template for assistance with formatting the Protocol: <https://www.vumc.org/irb/applications-and-consents>
* **Social Behavioral Consent template**: Investigators are instructed to use this template for all investigator-initiated social behavioral research studies. Sponsor-initiated studies for which the Sponsor has its own consent template should use the Sponsor template: <https://www.vumc.org/irb/applications-and-consents>
* **Investigator’s Handbook:** This handbook was prepared to help Investigators comply with the Vanderbilt University and the Vanderbilt University Medical Center’s institutional policies, the HRPP policies and procedures, and the federal regulations**:** [**https://www.vumc.org/irb/tool-kit**](https://www.vumc.org/irb/tool-kit)

**Documents Required with New Study Submission (HRPP Policy Reference: III.D.1, III.E.2, X.G)**

* A completed IRB application
* Separate Protocol (for standard/expedited studies; not required for exempt research)
* Informed consent document(s) and assent forms (standard/expedited studies) OR Information Sheet (exempt studies)
* A copy of all forms of recruitment materials, in final form (e.g., flyers, posters, brochures, mass e-mail communications)
* A copy of all research related measures (e.g., surveys, questionnaires, tests, interview question outline)
* A copy of all participant facing materials, including screenshots of what a participant sees/interacts with when using an electronic application, device, etc.
* A copy of the grant face page/cover page
* All letters of cooperation or IRB approval letters, when appropriate, for performance sites not engaged in research
* All IRB letters of approval from performance sites engaged in research

**Recruitment vs. Screening (HRPP Policy Reference: IV.A, X.G)**

* Study screening procedures are frequently confused with study recruitment. The two activities may overlap but are distinctly different. Recruitment does not require the consent of the prospective participant whereas screening DOES
* **Recruitment:** includes all activities where information is provided to the prospective participant. This includes flyers, advertisements, and recruitment over the telephone
	+ Recruitment over the telephone: Provided the study team only gives information about the study and does not solicit or record information about the participant to determine eligibility, then this activity is considered recruitment and consent is not required.​
* **Screening**: includes obtaining information from prospective participants.
	+ Screening activities start the moment an investigator obtains information about a prospective participant to determine if they are eligible for the research study. ​
	+ Screening individuals to obtain and record information to determine eligibility involves obtaining identifiable private information and is considered human subjects research for research subject to 45 CFR 46. ​
	+ Example of screening activity: Asking participants questions or taking a medical history to determine if they meet study enrollment criteria (in person, via REDCap survey, or telephone).
	+ Information should not be solicited from the subject without first obtaining their consent.​
* **Screening Consent Requirements:** The consent form can be limited to only information about screening activities (e.g., a screening consent form) or it can include all study activities.​ All elements of consent are required for phone and REDCap screening activities.​ A waiver of documentation is required for phone consent where participants will not sign and return a consent form. (see HRPP Policy IV.A.2 for list of required elements)

**Quality Improvement Project (Non-Research) vs Research (HRPP Policy Reference: I.B, III.J)**

* Important definitions to take into consideration when determining whether a project qualifies as research or non-research:
	+ **Research**: Any systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.
	+ **Systematic Investigation**: Any activity that involves a prospective study plan including research development, testing, evaluation and data collection to answer a study question or hypothesis.
	+ **Generalizable Knowledge:** The HRPP defines this as information that is gathered by a research protocol or project that answers a research question (i.e., hypothesis). Resultant information should be able to be applied to the general population relative to the population targeted.
* Intent to publish a quality improvement project is not sufficient to require IRB review as a research study. Even though most QI activities aren't research, there is much to be learned from sharing descriptions of these non-research activities. For example, Case Reports are generally not considered to be research but provide a valuable addition to the medical literature.
* When a non-research application is submitted to the IRB, the application and accompanying materials should **NOT** use the phrase “research” to describe the project

**Single IRB (HRPP Policy Reference: I.G)**

* **Request Vanderbilt to be the Single IRB**
* For multi-site, federally funded projects with performance sites engaged in human subjects research, a reliance interest form must be completed ***prior*** to initiating a new study submission to determine whether or not a study qualifies for Single IRB (SIRB) review. The reliance interest form can be found on the HRPP website by clicking “Request to Use Vanderbilt as the Single IRB” under "Single IRB Help”.
* Once you receive an email confirmation that Vanderbilt is willing to serve as the SIRB, the PI and study coordinator must complete the required “SIRB Review at Vanderbilt” training. A link to the REDCAP training will be provided to the study team.
* Once these steps have been completed, the study team can proceed with submitting the study in DISCOVR-e.
* To streamline SIRB processes, the Vanderbilt IRB requires use of the 2-part consent form, located on the HRPP website under “Single IRB Help”.
* **Request Review by Another IRB for Vanderbilt Investigators**
* Vanderbilt will cede review for multi-site, non-exempt, federally funded projects with performance sites engaged in research.
* Once lead site approval from the IRB of Record has been extended, the lead site’s study team will provide to the Vanderbilt PI/study team with the IRB-approved documents reliance documents and local context forms.
* The Vanderbilt PI/study team will submit a “Request Review by Another IRB” application in DISCOVR-e along with IRB approved documents, reliance documents and local context forms provided by the lead study team. This should include a tracked copy of the consent form provided by the IRB of record with the Vanderbilt local context language inserted and standalone HIPAA forms if PHI will be used/disclosed.

**For reliance questions related to SIRB studies:**

**SIRB Operations Manager**: Tyler Hubbard: tyler.hubbard@vumc.org; 615-875-8716

**Research Conducted in Schools (HRPP Policy Reference: IV.C)**

* When conducing education research, it is often hard to determine what is standard practice in education and what is a research activity driven by the study. An activity is considered a “research activity” if this activity is being conducted by the research team for the purposes of the research study. If the activity is going to occur even if the study team does not plan to conduct the research study, then it is not research.
	+ Example: if a school decides to record a classroom instruction regardless of the involvement of the researchers, and the researchers only want to analyze this recorded session, the video recording itself would not be a research activity. The researchers’ analysis of this previously conducted activity by non-researchers would be the “research” that the IRB is responsible for reviewing.
* Video recording a child in a classroom for research purposes is a research activity that requires prospective parental consent UNLESS:
	+ The research qualifies for a waiver of consent. In order to qualify for a waiver of consent, the following 4 criteria must be met:
		- The research involves no more than minimal risk to the participant
		- The waiver or alteration will not adversely affect the rights and welfare of the participants
		- The research could not practicably be carried out without the waiver or alteration
		- *Please refer to the Secretary's Advisory Committee on Human Research Protections (SACHRP) guidance on “practicability” at:* [*https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-january-31-letter/index.html*](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-january-31-letter/index.html)
		- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

**International Research (HRPP Policy Reference: X.H)**

* Research studies are considered to have an international component when investigators travel abroad to collect data or investigators use or collect data from participants who are located outside of the U.S.
* Review and approval from a local (in-country) IRB or Ethics Committee must be obtained prior to initiation of the research
* VU investigators planning to conduct international research should consult with Liane Moneta-Koehler, the Assistant Provost for Research Integrity and Compliance, prior to submission of their study to the IRB. Liane’s contact information is:
	+ Liane Moneta-Koehler, PhD

liane.monetakoehler@vanderbilt.edu

(615) 322-2875