

Multiple Institutional Review Board (IRB) Review: Protocols for various Healthcare sites

Review by the UC Merced IRB is required when UC Merced researchers are engaged in human subjects research. Many hospitals, universities and other organizations also require their own IRB review if recruiting from subject populations associated with their institution. One of the goals of the UC Merced IRB is to minimize multiple IRB reviews, which causes a delay in the research process.

Please always take the following steps when planning to engage in research accessing patient samples (see Engagement Guidance for more information on determining who is engaged in human subjects research: <http://www.hhs.gov/ohrp/policy/engage08.html>):

1. **Contact the UC Merced IRB** (Leslie Teixeira at 209-228-4613 or lteixeira@ucmerced.edu) and explain your study and strategy for data collection and analysis.
 - a. If you or your co-investigators will intervene or interact with patients (human subjects) and/or identifiable private data, this will require approval of at least one IRB.
2. **Contact HSRI** (Erin Gaab at egaab@ucmerced.edu) and / or **the healthcare providing organization** to find out;
 - a. If they have their own IRB and what their procedures are to apply for review,
 - b. if a relationship has been established with external (other universities, UCs, etc.) researchers and how that process previously worked, and
 - c. if you will need to include an individual associated with the healthcare provider as a Principal or Co-investigator on your protocol.
3. Relay this information to Leslie Teixeira to **create a plan** for IRB review by one or all organizations involved.

There are a number of routes a research study may take when under IRB review (which is determined on a case-by-case basis and depends entirely on the details of the study and the requirements of all IRB's involved):

- A. **Review by the UC Merced IRB only.** This may be most appropriate when the other institution does not have their own IRB, such as in the case of George Mark Children's House, a small, independent facility for children receiving pediatric palliative care. This is the case when the other institution and their personnel are determined to not be engaged in the research. An agreement/permission to access the patient population may be necessary.
- B. **Review by the other healthcare-providing institution's IRB and acceptance by "reliance" by the UC Merced IRB.** This may be appropriate when the sample of participants is coming from the other institution (which has its own IRB), such as in the case of Children's Hospital and Research Center Oakland, an established medical research facility. The UC Merced IRB has a regulatory obligation to the Federal

government to know the patient population. Since the IRB of the healthcare providing site has more experience dealing with their patients and is responsible for their patient population, healthcare providing sites may require internal IRB review. The UC Merced IRB may then rely on the review of the healthcare providing site IRB.

- C. **Review by another University of California IRB.** When a researcher is accessing a patient population at a UC-Affiliated hospital (such as the UC Davis Hospital), the protocol may be reviewed by that UC's (UC Davis') IRB. The UC system has an agreement in place that allows for reliance on the review of another UC IRB.
- D. **Review by multiple IRBs.** This may be required by some institutions which do not accept "Reliance" or "Individual Investigator Agreements*."

When researchers have to apply for review by the UCM IRB and another institution's IRB, this is called multiple IRB review, or dual IRB review. Review by multiple IRBs:

- can result in delays, and
- requires additional administrative time completing applications for IRB review at multiple institutions, and
- can lead to compliance violations (for example, if researchers do not maintain a single consent form approved by both IRBs, and do not obtain approval from both IRBs prior to making changes in research), and
- can delay the start of industry-sponsored research and cause sponsors to withdraw research, or reduce the number of participants that can be enrolled at the local site

The UC Merced IRB has set out some guidance when working with outside institutions. You can find this information at the following link:

<http://webtest20.ucmerced.edu/2.asp?uc=1&lvl2=43&lvl3=43&lvl4=51&contentid=36>

Please note that many of the healthcare-providing institutions in the Central Valley have not dealt with researchers from universities or external organizations before. Therefore, relationships and agreements may not have been established. Please be patient and flexible in your approach and understand that if you are going to have access to patients and identifiable private data, the healthcare institution wants to make sure that their patients are safe.

*In some cases, you may be asked to submit an Individual Investigator's Agreement (IIA). IIAs lay out the terms and condition under which personnel from an external organization (healthcare providers outside UCM, etc.) will be engaged in the research project (such as by translating, interviewing, etc.). The "Individual Investigator" is the actual person who will be assisting you. This may be required when the organization does not have its own IRB or an Assurance for human subjects research from the Federal Government. Both of these things are required for UC Merced to do human subjects research according to UC policy and federal regulations. This agreement extends our Assurance to the external individual for the purposes of each individual study (please see <http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html> for guidance regarding the IIA).