UCI Office of Research

Institutional Review Board
Human Research Protections (HRP)

When UCI Serves as the IRB of Record for Cooperative Research: A Streamlined Process

Version Dated April 13, 2020

HRP has streamlined the reliance processes for when UCI serves as the IRB of record for cooperative research[1]. These changes take effect immediately and apply to all situations where UCI will serve as the IRB of record, including where the UC Reliance Registry or CHOC-Memorial Health-UCI Agreements were previously utilized.

1. **Appendix U: This new appendix captures key information from the relying lead researcher / site. This appendix must be completed when UCI will serve as the IRB of record. A single Appendix U is required for each relying entity.**

2. **SMART IRB: For cooperative sites with an IRB, the UCI IRB will utilize the SMART IRB agreement. The SMART IRB is freely available for institutions and investigators and enables IRB reliance for multisite studies across the nation, regardless of funding status. *SMART IRB is not an IRB* – it is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy.**

3. **Other Agreements: For independent collaborators or institutions without an IRB, either an Individual Investigator Agreement or Institutional Authorization Agreement (with or without HIPAA) must be completed.**

4. **UCI IRB Documentation: In addition to Appendix U, the UCI Protocol Narrative must be updated to specify any difference in study procedures at the cooperative site/s. The relying researcher is responsible for his/her study team and ensuring compliance with UCI policy. This includes tracking educational tutorials for study team members. (Note: The UCI IRB no longer tracks completion of educational tutorials for non-UCI study team members.)**

5. **HRP seeks your feedback on this new process! For questions or to provide feedback, please reach out to the HRP Staff. Also, please be sure to review the HRP Webpage on this topic: Human Research Activities Performed at Other Institutions.**

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[1] **sIRB Mandate Effective January 20, 2020:**
UCI will follow the single IRB requirement for new cooperative research studies that are:
1. Conducted or supported by an agency that has signed on to the 2018 Common Rule
2. Conducted or supported by the NIH
3. Conducted in the USA only
4. Non-exempt* level of IRB review

* *For dual affiliated researchers only, the UCI IRB may make an exception to serve as the IRB of record for exempt research.*