**Guidance for Investigators Using the SMART IRB Initiative (** https://smartirb.org/**)**

**When UConn Health is Deferring IRB Oversight for**

**Participation in a Multi-Center Trial or Collaborative Research Project**

Note:Multi-center research means each site implements the complete protocol independent of other sites and all sites report the data to a central coordinating facility. Collaborative research means each site implements a part of the same protocol and the sites work together sharing information. UConn Health **does not intend** to act as the IRB of Record for NIH funded/supported multi-center clinical trials. Whether UConn Health will act as the reviewing IRB for collaborative research with other members of the SMART IRB initiative will be determined on a case-by-case basis. However when collaborative research involves multiple sites from other States the preference will likely be to utilize one of the commercial IRBs that also participate in the SMART IRB Initiative (e.g. Quorum, Advarra, Western). If UConn Health is the reviewing IRB normal submission requirements pertain.

The following guidance for deferring IRB oversight may be used when UConn Health is participating in research with another institution that is also a member of the SMART IRB Initiative when either that institution’s IRB will be the IRB of Record; or a commercial IRB that is also a member of SMART IRB (e.g. Quorum Review IRB, Advarra, Western IRB) will act as the IRB of Record. This guidance reflects the steps that should occur at UConn Health. It is not an instructional document for using the SMART IRB platform. For instructions regarding the SMART IRB platform, please refer to the SMART IRB web site (<https://smartirb.org/investigators/> )

**Regardless of the specific steps in the process, a study for which an institution participating in the SMART IRB initiative will act as the IRB of Record cannot commence until the IRB of the other institution has issued the final approval AND UConn Health has issued the Final Letter of Acceptance of that IRB as the IRB of Record**. UConn Health will not issue the final letter of acceptance until all other local requirements are met (e.g. training, HIPAA etc.). After initial acceptance, changes to UConn Health study personnel will continue to require administrative review by the local IRB in addition to any requirements for review by the IRB of Record.

**1. Notifying UConn Health IRB**

* The investigator submits a request for facilitated review to the UConn Health IRB through the iRIS system. The initial request will serve as an administrative action to inform the UConn Health IRB that approval for a specific study will be sought from an institution participating in the SMART IRB Initiative.
  + The investigator (or designee) creates a new application in iRIS
  + The application at UConn Health must name all key study personnel individually and be routed to them for sign-off.
  + The type of review requested is facilitated
  + The question that asks if the submission is an industry sponsored or NIH multi-center study is answered “yes”
  + The participating site that will act as the IRB of record is noted as the requested IRB of Record.
  + The application form is the only required document at this time.**\***
* The UConn Health IRB will issue the letter of contingent acceptance of that IRB as the IRB of record. Because this is an administrative acknowledgement, a Regulatory Specialist within the IRB may grant the contingent acceptance.
  + This letter may be provide to the reviewing IRB.

**2. Obtaining Final Acceptance from UConn Health**

* After obtaining approval from the IRB of Record, the investigator returns to the UConn Health iRIS system and provides responses to the previous contingent acceptance of the other IRB as the IRB of Record and attaches all required documents as noted on the UConn Health submission checklist for facilitated review.
* UConn Health will follow its procedures for conducting facilitated reviews.
* When all local requirements are met UConn Health will issue the Final Acceptance of the SMART IRB member institution’s IRB as the IRB of Record and send the letter to PI with copy to the reviewing IRB.

**NOTES:**

* The process described above is the method preferred by the UConn Health IRB. However, if the reviewing IRB requires local review first, all relevant documents may be submitted in step 1 of the process. Once all documents are considered acceptable by the UConn Health IRB a letter indicating contingent acceptance of the external IRB will be issued. The remaining contingency will be to submit the evidence of final approval from the reviewing IRB.
* UConn Health requires **a separate HIPAA Authorization form**. Be sure to submit the authorization and that the consent form does not contain HIPAA language.
* UConn Health does not intend to act as the IRB of Record for other sites under the SMART IRB Initiative and individuals are encouraged to utilize the services of participating commercial IRBs or an IRB at an institution that is a participant in the study and in the SMART initiative and that agrees to serve as the study’s reviewing IRB.
* UConn Health IRB application will ask the PI to indicate whether the IRB of record is accredited by AAHRPP (The Association for Accreditation of Human Research Protection Programs). If unsure, please contact the IRB at that institutions or ask the collaborators at that site to determine. *AAHRPP is an independent, non-profit accrediting body that works to protect the rights and welfare of research participants and promotes high-quality research through an accreditation process.  AAHRPP’s accreditation standards meet or exceed U.S. federal regulatory requirements and the International Committee on Harmonisation –Good Clinical Practice (E6) guideline for protection, and are reasonable, attainable, and representative of current best practices. UConn Health’s Human Subjects Protection Program (HSPP) achieved AAHRPP accreditation in 2006.*

\* - Investigators may opt to submit other ancillary documents (e.g. pharmacy review, conflict disclosures) to the UConn Health IRB with the initial request, at the time the final acceptance is requested or by responding to the initial contingent acceptance while the IRB of Record is processing its review. The study specific documents (e.g. consent, protocol etc.) should not be submitted until after approval from the IRB of Record is obtained. The preference of UConn Health IRB is that all documents are submitted when seeking the final acceptance from UConn Health.