**UConn Health Students Engaging in Research**

**External to UConn Health**

**INTRODUCTION**:

The purpose of these guidelines is to provide guidance to faculty and students regarding when student involvement in external human subjects research as a member of the research team engages UConn Health in the research and thus requires interaction with the IRB office. These guidelines represent common scenarios that are presented to the IRB office, not all possible scenarios. When unsure whether a situation would engage UConn Health in research, faculty and students should contact the IRB at irb@uchc.edu. Students should not participate in research activities prior to reviewing this guidance and ensuring required steps at UConn Health have been completed.

For purposes of this guidance, the terms 'student' and 'UConn student' are inclusive of students in the UConn School of Medicine, Dental Medicine or Graduate School of Public Health. For other UConn students, refer to UConn Storrs IRB guidance.

**DEFINITIONS:**

**Agents:** For purposes of these guidelines, an institution's employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. 'Agents' may be covered under an institution's FWA when their purpose is to carry out some aspect of a research study on behalf of the engaged institution holding an FWA.

**Engagement in Research:** In general, an institution is considered engaged in a particular human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

Institutions that receive an award through a grant, contract, or cooperative agreement directly from a federal department or agency ('awardee institutions' or 'prime awardees') for a human subjects research project are also considered engaged, even when all activities involving human subjects are carried out by employees or agents of another institution(s) unless the federal Office for Human Research Protections (OHRP) or another appropriate agency has determined otherwise.

**GUIDELINES**:

1. When the research is **student-driven** (e.g., designed by the student for the purposes of undergraduate research or a thesis, dissertation, or capstone) and takes place at an external organization, the student **is** acting as an agent of UConn Health.

   **What is needed for UConn Health IRB?**
   **If the research is taking place at a local institution** (e.g., Hartford Hospital, CCMC, Trinity Health/St. Francis) ***and*** that institution's IRB has deemed the research to be exempt or approved through expedited review, the IRB may elect to follow a streamlined process[1] to enter the study into

IRIS. If you have not already been notified by the UConn Health IRB that the study has been entered and accepted in the IRIS system, send the external institution's IRB approval letter to irb@uchc.edu to request a streamlined process[1].

**If the research is taking place at another external institution**, or the streamlined process[1] is not an option, a submission to the UConn Health IRB in IRIS will be required for UConn Health IRB review, determination of exempt status, or IRB reliance. Please note that establishing a reliance agreement can take several weeks, please contact the IRB at irb@uchc.edu as early in the process as possible**.**

2. When the research is being conducted at or by the external organization, **and the research will be modified** (e.g., additional survey questions, additional experiments, new or modified objectives) **for the purposes of the student** (e.g., for the student's thesis), the student **is** acting as an agent of UConn Health.

   **What is needed for UConn Health IRB?**
   **If the research is taking place at a local institution** (e.g., Hartford Hospital, CCMC, Trinity Health/St. Francis) and that institution's IRB has deemed the research to be exempt or approved through expedited review, the IRB may elect to follow a streamlined process[1] to enter the study into IRIS (HSPP policy 2011-009.15.b ). If you have not already been notified by the UConn Health IRB that the study has been entered and accepted in the IRIS system, send the external institution's IRB approval letter to irb@uchc.edu to request a streamlined process[1].

   **If the research is taking place at another external institution**, or the streamlined process[1] is not an option, a submission to the UConn Health IRB in IRIS will be required for UConn Health IRB review, determination of exempt status, or IRB reliance. Please note that establishing a reliance agreement can take several weeks, please contact the IRB at irb@uchc.edu as early in the process as possible**.**

3. When the research is **being conducted at or by the external organization**, and the UConn Health student is being added as research staff without the research being modified for the purposes of the student (e.g., additional survey questions, additional experiments, new or modified objectives), the student **is not** acting as an agent of UConn Health. This is true even when the experience will result in course credit or otherwise count towards the student's degree progression.

   **What is needed for UConn Health IRB?** Submission to the UConn Health IRB is not required. If documentation of this is needed for the external organization or for the student's record, please provide a copy of these guidelines. If additional documentation is required, please contact irb@uchc.edu.

4. When UConn Health is the **prime awardee** on a federal grant, contract or agreement, **UConn Health is engaged in human subjects research** even when all activities involving human subjects are carried out by employees or agents of another institution(s) unless an exception has been granted by OHRP or another appropriate agency.

   **What is needed for UConn Health IRB?** A submission to the UConn Health IRB in IRIS will be required for UConn Health IRB review, determination of exempt status, or IRB reliance. The application will either request UConn Health to serve as the IRB or request facilitated review with

UConn Health relying on the external institution where the research is being conducted. Please note that establishing a reliance agreement can take several weeks, please contact irb@uchc.edu as early in the process as possible.

Engagement can be influenced by situational considerations, if unsure whether UConn Health would be considered engaged in external research that a UConn student would like to be involved in, please contact the IRB at irb@uchc.edu.

[1]*Streamlined process (see HSPP Policy 2011-009.15b) may be followed when a local neighboring IRB approves the research through expedited review or issues an exemption determination, and the research only involves a student. The UConn Health IRB may elect to accept the approval letter of the other IRB as notification and not require a formal submission in IRIS. When this happens, the UConn Health IRB will send notification to the student through IRIS correspondence indicating the study has been entered and accepted by the UConn Health IRB. No further action on the part of the student will be required. This often occurs after the local IRB has copied the UConn Health IRB on the IRB's approval or exemption letter directly.*

**REFERENCES:**


1. OHRP Guidance: Engagement of Institutions in Human Subjects Research (2008). Retrieved on March 4th, 2024.
2. SACHRP Recommendations: A New Interpretation of the "Engaged in Research" Standard. Retrieved on March 4th, 2024.
3. Email Correspondence between HRP Consulting Group and OHRP: Question related to Engagement dated November 30th, 2023. (Available from HRPP/IRB office upon request.)