1. **Purpose**
   This SOP establishes the process where possible institutional conflicts of interests (ICOI) related to UNC-Chapel Hill human subjects research are identified and coordination with the UNC COI Office regarding such interests is delineated to ensure timely, appropriate reviews with related management of such ICOIs are conveyed to the OHRE.

2. **Definitions**

   **Institutional Conflict of Interest (ICOI):**
   For the purposes of this SOP, an institutional conflict of interest may exist when one or more of the following might affect the design, conduct or reporting of human studies research:
   - Known equity interests of the University
   - Intellectual Property (IP) which has been licensed or optioned, which includes potential or actual royalties
   - When the University is the manufacturer of a study treatment

3. **Procedures**

   **Identification at Initial Review**

   **PI Form:** On the individual Conflict for Interest form for Principal Investigators, there are three questions specifically focusing on University/Institutional Interests touching upon three areas in the definition above. A positive response for any of these questions will route the form to the COI Office for review.

   **Database:** The UNC Office of Technology and Commercialization (OTC) is responsible for maintaining a list of entities in which the University holds equity as part of a licensing arrangement or if the IP is licensed/optioned. The OTC reflects this information in a real-time fashion into a database.

   As a back-up step to assist in the identification of human studies for which there may be an institutional interest, OHRE staff are able to see, through a database flag, any known licensing (L) or equity interest ($) of an entity directly in the IRBIS system.

   If results for PI COI review and the informed consent text do not indicate a University interest, but there is an interest indicated via the database flag, the OHRE shall refer a proposed human research project to the COI Office for assessment.

   **Review**

   Pursuant to the Policy on Institutional Conflict of Interests, the COI Officer maintains the authority for conducting an initial assessment to determine whether a possible ICOI is present
and if, in accordance with applicable COI Office standard operating procedures, the human study case may be referred to the ICOI Committee for review.

For those human studies where the ICOI Committee has determined an ICOI is present and management is applicable, the recommendations of the ICOI Committee are made to and approved by the Chancellor of the University.

This Chancellor-approved recommendation letter is sent to the PI of the human study with a copy to the OHRE Director or designee. Additionally, this letter is referenced in the Principal Investigator’s COI Finalization letter, requiring it to be uploaded in the IRBIS human study file; also in the COI Finalization letter is the minimum required disclosure text for the informed consent. Per standard practice, this PI COI Finalization letter is reflected from the COI Office’s online system into IRBIS and must be provided to the IRB of record as per SOP 901.

**Identification After Initial Review**

In the event that the OHRE/IRB is made aware that IP is licensed after a human study has been initiated at UNC-Chapel Hill and is under the oversight of the UNC-Chapel Hill IRB, the PI of the human study will be advised by OHRE to contact the COI office, and the COI office will be included in this notification to the PI. The process for review and notification will be conducted as listed.

**ICOI Management**

Management of ICOIs related to UNC-Chapel Hill human subjects research shall include the guideline the research cannot be reviewed by the UNC-Chapel Hill IRB or, for ongoing research, shall be transferred to the oversight of an external IRB. In such cases, the Director of OHRE, or designee, shall communicate with the UNC investigator to facilitate transfer of the research to an external IRB.

External IRBs providing oversight for UNC research with related ICOIs may require additional management controls (e.g. Clinical Trials Quality Assurance monitoring). If such additional controls are required by a reviewing IRB, they will be communicated to OHRE as per the applicable reliance agreement (IRB authorization agreement) and OHRE will then communicate to the COI Office.