

Section 5. Human Subject Research Determination

The responsibility for initial determination whether an activity constitutes human subject research rests with the investigator. The investigator should make this determination based on the definitions of “human subject” and “research” in Section 1.3. Because investigators are held responsible if the determination is not correct, investigators are urged to request confirmation that an activity does not constitute human subject research from the HRPP. **When research involves the use of coded private information or specimens, and the investigator makes an initial determination that the research does not include “human subjects,” the investigator must request confirmation following the procedures described below.** The request may be made by email or in writing. All requests must include sufficient description of the activity and the rationale for the investigator’s initial determination.

Determinations whether an activity constitutes human subject research are made according to the definitions in Section 1.3 using the *Human Subject Research Determination Checklist*. Determinations are made by the IRB chair or vice chair, who may refer the determination request to the convened IRB.

Documentation of all determinations made through HRPP and the IRB are recorded and maintained in HRPP/IRB records. Requests and responses are maintained in HRPP/IRB records.