

## **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. For guidance on whether an activity constitutes human subjects research, investigators should use the Determination of Human Subjects Research Form on the IRB-HSR website or IRB-SBS research portal. Because they will be held responsible if the determination is not correct, investigators are must submit the required documentation for confirmation that an activity does not constitute human subject research from the IRB office if the determination is not clear. 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 by submitting the completed Determination of Human Subject Research Form to the appropriate IRB office. 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 will be made according to the definitions in Section 1.3 using the Determination of Human Subject Research Determination Form. Determinations regarding activities that are either clearly human subject research or clearly not human subject research, may be made by an experienced IRB staff member. Determinations regarding less clear-cut activities will be referred to the IRB Chair, sub-committee or IO.

Documentation of all determinations made through the IRB Office will be recorded and maintained in the IRB Office. Email and other written requests will be responded to in writing and a copy of the submitted materials and determination letter/email will be kept on file.