

# Series 403 Non Human Subjects Research | Institutional Review Board

## Determinations of Non Human Subjects Research from Series 403 of the Standard Operating Procedures

### I. Authority to Determine

The Institutional Review Board at Utah State University is the only entity that can provide an official determination that a project is or is not human subjects research as defined in USU Policy 584. It may do so in a meeting of the Convened IRB or via delegated review actions as outlined in SOP 402.

### II. Process to Obtain a Determination

The only method for obtaining a determination of whether a project is “research” with “human subjects” is via a submission in the USU IRB’s electronic protocol management system, Kuali Protocols, available at [Kuali Protocols](#). That submission, a Determination of Non Human Subjects Research (NHSR Determination), will receive a submission ID and will receive an official determination within a reasonable time following submission and any necessary clarifications by the research team. NHSR Determinations may not be made via phone call, email, in-person discussion, or other informal means. Only a member of the IRB or the Institutional Official (IO) may render such a determination in that system.

The IRB (or individual rendering the determination) should, in most cases, complete that determination process within three business days. Special circumstances may extend that time frame.

### III. Substance of a NHSR Determination

Upon receipt of a completed NHSR Determination via Kuali Protocols, the IRB member rendering a determination shall consider whether the project meets the definition of research, and if so, whether it also involves a human subject. The definitions in USU Policy 584 shall guide these determinations, except in the case of a protocol where a federal sponsor of that project defines it differently.

USU Policy 584 defines “research” as a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge. “Research” does not include public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance, including: (i) the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority; (ii) trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products; and (iii) those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). “Research” also does not include collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. Finally, “research” does not include authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, or other national security missions.

That same Policy defines a “human subject” as a living individual about whom an investigator or other USU Affiliate (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Many of the terms contained in those definitions have their own specialized definitions in the context of human subjects research. To aid investigator understanding of those specialized terms, definitions, guidance, and examples (where appropriate) are provided in the CITI Module on Identifying Human Subjects Research, as well as in the NHSR Determination form within Quali Protocols.

#### **IV. Outcome of a NHSR Determination**

After review of a NHSR Determination submission by a qualified member of the IRB or the IO, the submitting investigator shall be notified of the outcome of the Determination process. Notifications shall be in writing and accessible to the members of the research team. The IRB shall keep a copy of this determination in its records for at least one year, or through an appropriate time frame based on the details of the underlying project.

A NHSR Determination will receive one of two determinations: either the project is not human subjects research, or the project is human subjects research and requires further review by the IRB. If appropriate and clear based on the information provided, the individual or entity rendering a determination should provide guidance regarding the level of IRB review that will be necessary.