

Does Your Project Require Submission for a Determination of "Not Human Subjects Research" or An Exemption from IRB Review?

For all NIH research initiated on or after January 21, 2019, formal determinations by OHSRP that NIH IRP research is **not human subjects research** will no longer be mandatory for research activities involving only use (including secondary use study or analysis) of coded or de-identified (not individually identifiable) human specimens or data. *This supersedes applicable sections of NIH HRPP SOP 5 NIH Research Activities with Human Data/Specimens, Sections 5.4.B.1 and 3, 5.7 and SOP 6 Determinations Made by the Office of Human Subjects Research Protections (OHSRP), Sections 6.4, and 6.6.*

- a. Investigators should assess whether their research meets the regulatory definition of human subjects research (see below). If an investigator is not certain, a request for a formal determination may be made through NIH iRIS, starting January 21, 2019.
- b. If a formal determination that an activity is not human subjects research is needed or desired, only OHSRP or the Office of IRB Operations (IRBO) can make a formal determination that an NIH IRP activity is not human subjects research.
- c. Importantly, activities with data and/or specimens that constitute human subjects research but may be exempt from IRB review under the pre-2018 Common Rule at 45CFR 46.101 (i.e., approved prior to January 21, 2019) or the 2018 Common Rule at 45 CFR 46.104 must still be submitted to OHSRP or IRBO for a formal exempt determination via NIH iRIS.
- d. This policy change does not supersede other NIH policies or requirements for the review of research, e.g., those involving human fetal tissue or human embryonic stem cells.

Not Human Subjects Research (NHSR) Determinations

Given that researchers are no longer required by NIH policy to obtain a formal NHSR determination as described in the policy statement above, researchers should carefully consider whether their work is human subjects research. If in doubt, researchers should contact the Office of IRB Operations or OHSRP for guidance. Researchers should consider the following when determining whether the research is NHSR.

- Is the activity research? See definition of research in footnote below.
 - If yes, consider further questions below. If no, no IRB review required.
- Do the specimens and/or data come from a living individual?
 - If yes, consider further questions below. If no, no IRB review required.
- Will you obtain specimens and/or data through an interaction or intervention with the subject? If yes to any of the questions below, IRB review may be required. Contact the OHSRP or IRBO.
 - Interaction includes communication or interpersonal contact between the investigator and subject.

17 January 2019

- Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- Will you obtain, use, study, analyze or generate identifiable private information (e.g. data) or identifiable specimens? If yes to any of the questions below, IRB review may be required. Contact the OHSRP or IRBO.
 - Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
 - Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
 - An identifiable specimen is a specimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Coded data and/or specimens should be considered identifiable if any member of the NIH research team has access to the code key. Additional information about coded specimens can be found at: HHS OHRP 's Coded Private Information or Specimens Use in Research, Guidance (2008).

Research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities."