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Not Human Subjects Research

Not Human Subjects Research Description

Procedures to Follow

Human Subjects Research Decision Tree [1]

Self-Certification Form [2]

Not Human Subjects Research Description

Under some circumstances [3], research involving only unidentifiable/de-identified or coded [4] private information or biological specimens is not human subjects research because investigators cannot readily ascertain the identities of the individuals to whom the data or samples belong.

In such cases, IRB review is not required. The PI makes and certifies this determination.

In order for your use of data and/or biological specimens to not meet the definition of a *human subject* [5], all of the following conditions must apply:

- The research is not FDA-regulated.
- The research team will not have access to identifiers or keys to link coded data (even temporarily).
- You are not conducting human stem cell research [6].

Note: If the project is not human subjects research, it does not matter whether or not the information or specimens existed or are collected before the study is proposed.

Examples of projects that do not qualify as human subjects research

Research with coded private information and biological specimens obtained from IRB-approved repositories that do not include any of the 18 Protected Health Identifiers [7] (e.g. Cancer Center Tissue Core, UCSF AIDS Specimen Bank, Neurosurgery Tissue Bank). This is not human subjects research because the IRB approved procedures the repository has but in place to provide specimens without identifiers.
Research with live tissue, i.e., surgical tissue that has been resected for clinical purposes and will otherwise be discarded is not considered human subjects if and only if an agreement exists between both parties that the individual providing the specimen will never provide the recipient with identifiable information.
A UCSF PI is analyzing coded data collected from a study being done at UCLA. The UCSF PI and the UCLA PI have entered into an agreement that prohibits the UCSF PI from receiving the key to the code.A UCSF researcher provides another investigator with coded data or biological specimens, and there is a written agreement between the UCSF researcher and the collaborator that the key or access to the identifying information will never be shared.
Proposed research with extra vials of identifiable or coded specimens from Pathology or Laboratory Medicine. The provider of the samples must remove the identifiable information prior to turning the samples over to the researcher.
Aggregate data that has been de-identified from its source and is provided to the PI, i.e. STOR provides PI with and aggregate data set or secondary data sets that do not contain any identifiers.

Procedures to Follow

1. If you are receiving data and/or specimens that are de-identified *or* coded with identifiers are kept separately, use the **Human Subjects Research Decision Tree** [3] to determine whether human subjects are involved in your proposed research study. Contact us [8] to discuss any unusual situations.

2. Fill out the **Self-Certification Form** [9] and keep it for your records. If necessary, submit the form to the Office of Sponsored Research for your funding agency. Do not submit the form to the IRB.

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Source URL: http://irb.ucsf.edu/not-human-subjects-research

Links
[1] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/decision-tree-human-subjects.pdf
[2] http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/self-certification-form.pdf
[3] http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/decision-tree-human-subjects.pdf
[4] http://irb.ucsf.edu/definitions
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