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Research
Administration

NIH Genomic Data Sharing Policy

Published August 27, 2014

Effective January 25, 2015

Scope

- ❖ Non-human Genomic Data Sharing Plans
- ❖ Human Genomic Data Sharing Plans
- NIH expects all funded investigators to adhere to the GDS Policy, and compliance with this Policy will become a special term and condition in the Notice of Award or the Contract Award.
- NIH expects investigators and their institutions to provide basic plans for following this Policy in the “Genomic Data Sharing Plan” located in the Resource Sharing Plan section of funding applications and proposals.

De-Identification and Confidentiality

- Investigators should de-identify human genomic data that they submit to NIH-designated data repositories
 - Follow HHS Regulations for the Protection of Human Subjects
 - Follow HIPAA
- Although de-identified, NIH has obtained a Certificate of Confidentiality as an additional precaution
- NIH encourages investigators and institutions submitting datasets to NIH-designated data repositories to seek a Certificate of Confidentiality as an additional safeguard.

National Human Genome Research Institute

According to the current definition of "human subject" in the Common Rule informed consent for use of de-identified samples and data (such as those that are often stored in biobanks and data repositories for unspecified future research use), or for stored samples and data from people who are deceased is not required.

GDS Policy Position

- ❖ For some research, while informed consent is not required by federal regulations, ... NIH, under the NIH Genomic Data Sharing (GDS) policy, expects that after the effective date of the GDS Policy, researchers generating large-scale human genomic data use specimens or cell lines for which consent was obtained for future research purposes and broad sharing.
- ❖ Additionally, research on information from deceased individuals who did not provide consent before death is legally permissible under HIPAA and the Common Rule. ... It is important to consider whether prior consent or consent from surrogates can and should be sought, even if not explicitly required by regulations, and how the interests of participants and surviving relatives will be protected if informed consent cannot be obtained.

dbGaP Approved User Code of Conduct

- ❖ The following is the Code of Conduct that research investigators agree to abide by as Approved Users of data received through the database of Genotypes and Phenotypes (dbGaP). Failure to abide by any term within this Code of Conduct may result in revocation of approved access to any or all datasets obtained through dbGaP.
- ❖ Investigator(s) will make no attempt to identify or contact individual participants from whom these data were collected without appropriate approvals from the relevant IRBs;
- ❖ Investigator(s) will not distribute these data to any entity or individual beyond those specified in the approved Data Access Request;

Guidance from OHRP

- ❖ ... OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems. For example, OHRP does not consider research involving **only** coded private information or specimens to involve human subjects as defined under 45 CFR 46.102(f) if the following conditions are both met:
 1. the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
 2. the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
 - the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
 - there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; ...

Requirement for Informed Consent

- ❖ For studies proposing to use genomic data from cell lines or clinical specimens that were created or collected after the effective date of the Policy, NIH expects that informed consent for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified.
- ❖ If there are compelling scientific reasons that necessitate the use of genomic data from cell lines or clinical specimens that were created or collected after the effective date of this Policy and that lack consent for research use and data sharing, investigators should provide a justification in the funding request for their use.