**SOP: Future Use of Data and Specimens Obtained**

**for Research Purposes**

1. PURPOSE

When research participants agree to give their private health and social determinants information, blood, tissue or other biological specimen to a research project, they have a right to know about potential future uses of that information and material. This policy defines the types of choices that a research participant must be given when enrolling in studies.

1. REVISIONS FROM PREVIOUS VERSION
   1. None
2. POLICY

There are three distinct scenarios with respect to study benefit and the future use of research data and/or samples, each of which has its own PPHS/IRB requirements:

* 1. **Projects with no future uses not directly related to the research project (regardless of the prospect of direct benefit to participants):**
     1. The consent should include language, such as “The research team will never use or share your personal information (such as, name, address, date of birth, social security number), study data and/or samples (blood, tissue, urine, saliva, or any other body matter) that are collected as part of this study for future research, even if your identity is removed. Your data and/or samples will only be used to complete this study and then they will be destroyed.”
  2. **Projects WITHOUT the prospect of direct benefit to participants:**
     1. For the original project which DOES NOT hold the prospect of direct benefit to an individual research participant, the future use of research data and**/**or samples can be determined by the Principal Investigator (PI)/researcher and simply clarified for the participant at the time of informed consent. In other words, the future uses can be mandated as a condition of enrollment, and the prospective participant either agrees to it, or does not participate in the study.
     2. It is permissible for a researcher to ask permission for various types of future uses, and giving these choices may be preferable for recruitment or better reflect the personal preferences and beliefs of the researcher. However, if a PI does not wish to ask for permission for future use of research data and**/**or samples, the extent of the future use must be clear in the consent form and will need to state that in the future the information and material may be widely shared without any direct identifiers. It should be made clear if the future uses will be limited to explorations that are related to the original project or if they can be used widely for non-related uses. It will also be necessary to state if the uses will be for biomedical and health research, or if the research data and**/**or samples can be used for any scientific purpose, including non-medical uses such as determinations of ancestry, human migrations, the origin of the species, etc.
  3. **Projects WITH the prospect of direct benefit to participants:**
     1. For the original project which DOES hold out the prospect of direct benefit to an individual participant, the PI CANNOT mandate someone to agree to unrelated future uses of the research data and**/**or samples.
     2. The PPHS, with supporting correspondence from OHRP, believe that the probability is too high that a participant will feel unduly influenced to participate in unspecified/unrelated future research, as the price to pay to receive a direct health benefit now. In these consent forms, participants must be asked their preferences, and not placed in a take it or leave it position. The IRB has future use language in the consent template found in the electric IRB submission system Library that can be modified, or used as is, to meet this need.

1. RESPONSIBILITIES
   1. The principal investigator is responsible to ensure these procedures are carried out.
2. PROCEDURE
   1. Determine whether the study holds out the prospect for direct benefit to the participants.
   2. Determine whether the research data and/or samples will be used for future research, related or unrelated.
   3. Choose the appropriate language from the HRP-502 – TEMPLATE - Informed Consent Form to include in the study-specific consent form(s).
   4. Submit for official IRB review and approval.
3. MATERIALS
   1. HRP-502 - Informed consent form
4. REFERENCES
   1. 21 CFR §50.20, 50.25
   2. 45 CFR §46.116(b)(9)