

## **WU IRB Return of Results Guidance: Genetic/Genomic Data**

### General principles

- Only results obtained in an environment certified as analytically valid (e.g., CLIA-certified) may be used for clinical decision-making. Results generated in a non-certified lab may be returned to participants under certain conditions, but the results must be verified in a certified lab before they are used for clinical decision-making.
- The implications and limitations of the results must be presented to participants. The investigator should provide the opportunity for the participant to discuss the findings with a licensed health care provider. This individual must have sufficient expertise to be able to explain the significance of the information and to address the participant's questions and concerns.
- Participants should have the option to decline receiving genetic results.
- The IRB must review and approve the return of results plan, including any written communications sent to participants to notify them of their results.

### Return of primary findings

Primary findings are an anticipated outcome of the study. As such, the study team should have a detailed plan for returning results to participants.

If the primary findings are not obtained in a certified analytically valid lab, the limitations of the results should be clearly and completely explained in the consent form. Results must be verified in a certified lab before they are used for clinical decision-making.

Regardless of the lab generating the results, the consent should include explanations of (1) the significance of the findings and (2) the limitations of the information. Participants should be given an option not to receive results, unless receipt of results is integral to the study design. Consultation with a genetic counselor may be offered or required.

### Return of secondary (a.k.a., incidental) findings

Before returning secondary findings, the study team should confirm that the participant consents to receive genetic results.

If the findings are not obtained in a certified lab, they should be confirmed in a certified lab before returning them to the participant, if possible. If the findings are not confirmed in a certified lab, they should be returned only after explaining the limitations clearly and completely. Results that are not analytically valid may not be used for clinical decision-making.

Return of results that are not clinically valid and actionable is discouraged. If results with uncertain clinical validity and utility are identified, consultation with the IRB is required before notification of the participant. The IRB, in consultation with experts, will weigh the risks and benefits of returning a secondary result of unclear significance to a participant.

## Requirements for Informed Consent

All studies that include genetic/genomic research and return of results should include the following in the informed consent document:

1. A definition of "genetic testing" in lay terms along with any other terms related to the genetic testing in lay terms. (DNA, RNA, etc.).
2. A description of the planned testing and what data will be generated in lay terms. For example, specific mutation testing required by the protocol, sequencing of specific candidate genes only, whole genome sequencing, whole exome sequencing, or creation of cell lines if these lines will be used as a future source of genetic material.
3. Risks associated with genetic information, including re-identification.
4. A statement describing any protections for genomic findings, i.e. GINA.
5. A statement describing plans for data and sample sharing. If the research is funded by NIH, language describing deposition into dbGaP is required. It is highly recommended that the informed consent specifically state that the sequence data will be shared for general biomedical use, and not impose restrictions for the type of future research that is permissible. Please refer to the NIH Genomic Data Sharing policy (<http://gds.nih.gov/index.html>).
6. If secondary (incidental) findings are possible, a statement that explains this possibility and describes what secondary findings are in lay terms. It should be stated whether or not secondary findings will be returned to the participant.
7. If the investigator intends to return results, including primary and/or secondary findings, the participant must be given the option to choose whether or not they wish to receive the results, unless receiving the results is integral to the scientific aim of the study. This choice should be indicated clearly on the consent document by way of a yes/no area to initial.

If the investigator plans to return primary research results, the following additional elements are required:

1. If primary research results are not generated in a way that can be determined to be analytically valid, this must be clearly indicated in the consent document. The limitations associated with the results must be clearly explained in lay terms.
2. A statement describing the clinical utility of the result; in particular, if the result is not from or has not been confirmed by an FDA approved test, a statement that these results may not be appropriate to use for the diagnosis, treatment, or prevention of a disease or condition
3. A clear description of how the results will be returned, including who will return the results, what type of information they will receive, and what mechanism will be used to return the results
4. A clear description of the timeframe in which the participant should expect any results