Return of Research Laboratory Test Results Procedure

Scope
Mayo Clinic Human Research Protection Program
Research for which Mayo Clinic IRB is the IRB of Record

Purpose
The purpose of this procedure is to provide criteria under which the results of laboratory tests performed for research purposes as approved by the Mayo Clinic Institutional Review Board (IRB) may/may not be returned to individuals. This procedure does not apply to activities which have not been reviewed and approved by the Mayo Clinic IRB or to products labeled as Research Use Only (RUO) or Investigational Use Only (IUO).

Equipment/Supplies
N/A

Procedure
1. The results of clinically-available tests performed for research purposes may be returned to individual research subjects only when the test is performed in a laboratory which is CLIA certified or meets CLIA quality standards.

   Specific to Mayo Clinic research subjects:
   - The results of such laboratory tests performed at or via Mayo Clinic shall be made available with other lab results in the Electronic Medical Record (EMR) (or equivalent).
   - The investigator may request to withhold the results of such laboratory tests performed at or via Mayo Clinic from the EMR (or equivalent), such as when necessary to maintain study blinding procedures or protect sensitive information. The IRB must review and approve the request and clearly indicate the approval within the IRB minutes.
   - The results of laboratory tests performed in a CLIA certified laboratory at an institution outside of Mayo Clinic shall be documented in that institution's record. When the results are returned to the research team, the team may, but is not required to, upload the results into the Mayo EMR (or equivalent).

2. The results of tests performed for study purposes in a research lab or in a clinical laboratory on samples that do not meet CLIA quality standards shall not be returned to individual research subjects nor made available in the subject's medical record. The information will be provided to the investigator, who will follow the IRB-approved plan for use of the information which may include sharing the information with research participants and entering a narrative note in the subject's medical record.

   - If the test is available in the clinical setting and, in the opinion of the investigator, returning the test result would be in the best interest of the research subject, the investigator may suggest the subject have the test performed in a CLIA certified lab. The IRB may require genetic counseling for the research subject for the return of a genetic test result. The research subject has the option to either choose or decline to learn the result.
When possible and in agreement with the research subject, the investigator should inform the subject-identified primary care provider with recommendations regarding testing.

- If the test is not available in the clinical setting and, in the opinion of the investigator, returning the test result would be in the best interest of the research subject, the investigator must obtain IRB approval before returning the result. The return of such a result may be approved by the IRB if it is deemed to be in the best interest of the research subject, have a high degree of validity, and be actionable. The IRB may require genetic counseling for the research subject for the return of a genetic test result. The research subject has the options to either choose or decline to learn the result. When the IRB approves a request, the result shall be documented in a provider note rather than included with other lab results.

Investigators remain obligated to inform research subjects of study findings which may change the balance of risks and benefits and/or relate to the subject's willingness to continue participation [45 CFR 46.116(b)(5)]. This is different from providing test results specific to the individual research subject.

**Troubleshooting**
N/A

**Procedural Notes**
N/A

**Related Documents**
N/A

**Definitions**

**Clinical Laboratory Improvement Amendments of 1988 (CLIA):** Established quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed.

**Laboratory (as defined by CLIA):** Any facility that does laboratory testing on specimens derived from humans to give information for the diagnosis, prevention, treatment of disease, or assessment of health.

**Mayo Clinic:** Mayo Clinic refers to Mayo Clinic in Arizona, Florida, and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

**References**
N/A

**Owner**
Pam Kwon on behalf of Office for Human Research Protection

**Contact**
Michelle Daiss
## Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Synopsis of Change</th>
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<tbody>
<tr>
<td>January 24, 2018</td>
<td>Scheduled review, updated to new procedure template. No other changes at this time due to AAHRPP Accreditation cycle.</td>
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<tr>
<td>9/21/2017</td>
<td>Minor revision. Updated the following definition per Glossary review: Mayo Clinic.</td>
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<tr>
<td>2/18/2016</td>
<td>Scheduled review - Added &quot;Approved by&quot; and &quot;Revision History&quot; sections</td>
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