

# Return of Research Laboratory Test Results Procedure

## Scope

Applies to [Mayo Clinic](#) Human Research Protection Program (HRPP) when handling [laboratory](#) tests in Human Subjects Research for which [Mayo Clinic](#) Institutional Review Board (IRB) is the IRB of Record.

## Purpose

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 [Clinical Laboratory Improvement Amendments \(CLIA\)](#) certified or meets [CLIA](#) quality standards.

Specific only to [Mayo Clinic](#) research subjects:

- a. The results of such [laboratory](#) tests performed at or via [Mayo Clinic](#) shall be made available with other lab results in the Electronic Health Record (EHR) (or equivalent).
  - b. The investigator may request to withhold the results of such [laboratory](#) tests performed at or via [Mayo Clinic](#) from the EHR (or equivalent) only under certain circumstances, such as when necessary to maintain study blinding procedures or to protect sensitive information. The IRB must review and approve the request and clearly indicate the approval within the IRB minutes.
  - c. 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 EHR (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 first be provided to the investigator, who will then 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.

- a. 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.
  - b. 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.
3. 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 [[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

## Owner

[Tammy S. Neseth, M.A.](#) on behalf of Office for Human Research Protection

## Contact

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## Revision History

Date	Synopsis of Change
06/04/2021	Scheduled review. Transferred to standardized template. Updated Owner and Contact. Updated to Electronic Health Record (EHR) and minor changes.
01/24/2018	Scheduled review, updated to new procedure template. No other changes at this time due to AAHRPP Accreditation cycle.
09/21/2017	Minor revision. Updated the following definition per Glossary review: Mayo Clinic.
02/18/2016	Scheduled review - Added "Approved by" and "Revision History" sections
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