Office of Science and Research
Institutional Review Board
1 Park Avenue | 6th Floor | New York, NY 10016

Return of Incidental Findings from Research

This guidance indicates how Incidental Findings should be handled and disclosed when discovered in research conducted by or under the auspices of NYU Langone Health. As advances in imaging, genetic and genomic research technology make such discoveries more common, Principal Investigators (PIs) at NYU Langone Health must consider the possibility of such findings during the assessment of risks and benefits of subject participation, and have a plan for reporting these findings.

An **Incidental Finding** is a discovery concerning an individual research subject that:

(1) Is discovered in the course of research;
(2) Is **beyond or unrelated** to the results of the research required to achieve the primary aims of the study; and
(3) Has **potential** safety, health, reproductive, welfare, or psychiatric importance for the subject.

Return of findings applies to, but is not limited to, human subjects research in which data/specimens are collected from identifiable subjects for primary research, including:

- Genetic testing of human biospecimens (tissue, blood, etc.).
- Imaging (MRI, CT, PET, X-rays, etc.).
- Other procedures in which results/procedures could identify findings outside the aims of the research, that qualify for returning results to a subject.

Note: *This* ***does not apply*** *to use of de-identified data/specimens for which the PI and study team have no access to identifiers and no ability identify and contact subjects*

IRB Application and Informed Consent Requirements

If a study may generate Incidental Findings, the PI must include a comprehensive Incidental Finding plan in the **protocol** and statements in the **informed consent form** (ICF) regarding the possibility of discovering Incidental Findings. Both documents indicate how and when results will be disclosed to subjects. Elements for the protocol's incidental finding plan are listed below and in the policy, while the elements for the informed consent process and documentation can be found on the ICF templates on the IRB Operations Template Library webpage.

Protocol Incidental Finding Plan *must include:*

- Identifying and assessing Clinically Significant***** or Medically Actionable** incidental findings
- Type of results that may be returned
- Qualifications and training of the individual(s) disclosing the findings to the subject
- Timeframe and process for communicating Incidental Findings
- Recipients if the subject is a minor or an individual of diminished consent capacity
- Plan for sharing Incidental Findings with other investigators, if applicable
- Plan for allowing subjects to withdraw themselves, specimens, and data from future analysis/reporting
- Plan for further care for the subject after Incidental Findings are discovered

Disclosure Criteria and Process

The following **disclosure criteria** must be met to disclose an Incidental Findings to a research subject. Incidental Findings that do not meet all of the below criteria and do not receive an exception from the IRB must not be disclosed.

(1) The subject opted-in through the IRB-approved informed consent process to receive his/her individual results, unless the IRB has determined that an option to opt-out is not feasible (**opt-out is not an option for Incidental Findings discovered through Radiology Research**)
(2) The IRB-approved research informed consent form states that Incidental Findings may be returned to the subject
(3) Test result that produced the Incidental Finding is confirmed and reproducible **AND** is either:

- ***Clinically Significant* (affects a patient's diagnosis/treatment) **OR**
- ****Medically Actionable* (prompts clinical action by a medical provider due to interventions or other approaches that may change the clinical course of subject's disease)

(4) The IRB-approved disclosure plan, including applicable terms of the informed consent form, must comply with all applicable state and federal laws.

***Note**: Upon discovery of incidental finding via non-CLIA certified lab test result, PI should arrange for follow up testing to be done at a CLIA-certified clinical lab to validate the finding. Otherwise, the PI must submit to the IRB an explanation of why clinical validation is not appropriate or possible. If no clinically accepted standard for validating the result exists, the result cannot be returned to the subject.*

Disclosure Process

If a research test in a study uncovers a potential Incidental Finding that meets the above criteria, the finding should first be assessed consistent with the plan outlined in the study protocol, and with consultation by an expert as necessary. Before meeting with the subject, the PI should:

(1) Determine clinical implications of the result for the subject
(2) Re-evaluate the subject's medical history, family history, and physical examination in light of the finding, if appropriate
(3) Review the subject's preferences indicated at the time of the research informed consent
(4) Weigh potential harms and benefits of reporting the finding

The PI should notify the subject that initial results indicate a follow-up test is recommended, and refer the subject for testing by appropriate individual (including a genetic counselor in the case of genetic research). Results should remain de-identified while the test results are being analyzed. Only a licensed professional (consistent within the scope of the individual's licensure) may disclose Incidental Findings to subjects through the IRB-approved disclosure process. With IRB-approval, appropriately trained and supervised non-professional study personnel may communicate research test results with subjects. Upon notification, the Incidental Finding will be recorded in the subject's medical record.

Unexpected Incidental Findings

If an Incidental Finding is **unexpectedly identified**, and a plan was not included in the protocol, PIs should notify the IRB via a Reportable New Information (RNI) submission upon discovery. The submission should include (1) a recommendation on whether the Incidental Finding meets the criteria for disclosure and (2) a disclosure plan which meets the requirements of what needs to be included in the IRB application as indicated above. The IRB approval is required before disclosure.