



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Returning Research and/or Incidental Findings

The following questions and definitions/examples should be considered when determining whether a study includes the possible discovery of relevant research/incidental findings, and if so, describing the procedures associated with discovering and returning these findings to the participant.

After considering whether the study includes the possible discovery of relevant research/incidental findings, it is the responsibility of the PI to include appropriate language in the consent/permission/assent form(s) advising subjects/parents whether relevant research/incidental findings will be returned, what types of findings are expected, to whom and how the findings will be provided, what and when the findings will be provided, costs, etc. and provision for allowing the subject/parent to indicate whether they want to receive such findings. Sample language can be found below.

1. Will Clinically Relevant Research/Incidental Findings Be Discovered on this Study?

- a) Does the study include a reasonable possibility of the discovery of clinically relevant research/incidental findings? If so, how likely? If not, why not?
- b) On what data/information is the likelihood based?

2. Definition of a Research Finding

- a) Three types of findings
 1. Baseline finding
 - a) A finding that is the result of information collected at the beginning of a subject's participation in the study such as tests done to address inclusion/exclusion criteria. These findings could include results from routine lab tests, memory tests, IQ tests, etc.
 2. In-study finding
 - a) A findings that is generated during the progress of the research. These findings could include blood pressure and vital sing measurements, lab tests, etc.
 3. End-of-Study finding
 - a) A finding that is collected or collated or interpreted after the study has ended and analysis of all participant data is complete.

3. Definition of an Incidental Finding

- a) An incidental finding is a finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of research but is *beyond the aims of the study* including the following:
 1. A finding that is known to be associated with a test or procedure being done in the course of the study. Examples include the following:
 - a) MRI studies that may find an unexpected mass
 - b) Aneurysm, malformation and evidence of current or past trauma to the brain

- c) Studies that include CT scans such as colonography that may find extracolonic findings in the torso or colonic findings;
 - d) Studies with EEGs done for cognitive mapping where epileptic patterns are discovered
 - e) An erythropoietin study where testing complete blood count for hemoglobin discovers a high white blood cell count
 - f) Unexpected psychotic symptoms endorsed on a validated rating form by a research participant or unexpectedly low memory scores on a validated instrument in a control participant
 - g) Discovery of misattributed paternity
 - h) Detection of markers for Huntington's Disease or APOE.
2. A finding that was not anticipated given the current state of scientific knowledge. An example includes whole genome sequencing that as science progresses may reveal information that was unanticipated at the time of consenting.
 3. A finding that is actively sought by a researcher when doing so is recommended by an expert body, organization or professional society guidance, or by a consensus of researchers, as ethically and medically appropriate. An example includes recommendations found on the [American College of Medical Genetics and Genomics \(ACMG\) list](#).

4. How, When and What Relevant Research/Incidental Findings could be Discovered?

- a) During which procedure(s) could research/incidental findings be discovered?
- b) When in the course of the study could research/incidental findings be discovered?
- c) What are some examples of research/incidental findings that could be discovered?

5. What is the Basis for Returning Findings?

- a) What should be returned?
 1. Level of confidence in the findings
 - a) Does the PI and/or co-investigators has/have the expertise to evaluate the findings or should additional expertise be used in the evaluation and determination?
 - b) If the findings are based on tests of biological specimens, have the findings been validated by a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA) or conducted using devices or assays that have regulatory approval from the FDA?
 2. Guidelines for returning – Determination made by the PI –based on recommendations from SACHRP
 - a) Should be returned – findings that are validated and actionable. Actionable findings include the following:
 1. Findings determined to be clinically significant
 2. Finding that reveal a condition that is likely life-threatening or grave that has an available course of action to treat the condition, or make the condition better or more tolerable
 3. Finding that may be useful for reproductive decision making to avoid significant risk, make better or more tolerable to an offspring a condition likely to be life-threatening or grave.
 - b) Should consider returning – findings that are not validated but could be actionable

1. Non-validated results should be followed up with validated testing to help provide certainty but there will not be approved or validated tests available.
 - c) Should consider returning – findings that are validated but not actionable
 1. Findings that may become clinically actionable at a later date.
 - d) Should consider not returning – findings that are neither validated nor clinically actionable
 1. Findings that are experimental results in basic science studies.
- 6. To Whom Will Findings Be Returned and What is the Justification for this Decision?**
- a) Subject only?
 - b) Subject and Subject’s physician?
 - c) Subject’s physician only?
 - d) Subject’s family members including parents and siblings?
- 7. How Will Findings be Returned and What is the Justification for this Decision?**
- a) Face-to-Face?
 - b) With “experts” present such as appropriate clinician, specialist, genetic counselor?
 - c) With provision of educational information or advice on how to seek care from a clinician or specialist?
- 8. When Will Findings be Returned?**
- a) When during the course of the study will the findings be returned?
 - b) What, if any, risk is there to the validity of the research by returning findings during that time such as to the potential of “unblinding” the subject/researcher
- 9. What are the Costs Associated with Finding/Returning Research/Incidental Findings?**
- a) How will any costs with finding/returning research/incidental findings be billed?

Sample consent document wording

[If the PI will be returning research and/or incidental findings to the subject/parent, please describe the procedures associated with providing the findings including to whom they will be returned, how when, and what findings/information will be returned, costs associated with returning the findings, etc., as described in the Research Plan, in lay terms. This wording should also include a means for the subject/parent to indicate whether or not they wish to receive incidental findings such as by the use of “Yes/No” boxes.]

This study may include a reasonable possibility of the discovery of incidental findings. An incidental finding is a finding concerning an individual research participant that has potential health or reproductive importance and is discovered while conducting the research but is not directly associated with the purpose of the research. Incidental findings include findings that a) are known to be associated with a test or procedure that is being done as part of the research; b) were not anticipated given the current state of scientific knowledge; and/or c) are actively sought by a researcher when doing so is recommended by an expert body or by a consensus of researchers, as ethically and medically appropriate.

There are risks and benefits associated with returning incidental findings to you. Potential benefits include informing you of a clinically significant or life-threatening condition. Potential risks include providing information that may cause unwarranted tests, anxiety, or distress without corresponding benefit.

You should not enroll in this study if you do not wish to be provided with findings that we determine a) to be clinically significant, b) a course of action is available to treat, make better, or more tolerable a condition that is likely to be life-threatening or grave, or c) can be used for reproductive decision making to avoid significant risk or make better or more tolerable to an offspring a condition likely to be life-threatening or grave.