1. PURPOSE
   1. This guidance describes the obligations of investigators concerning <Incidental Findings> when conducting <Human Research> overseen by this [Organization’s] local IRB.
   2. For research overseen by an IRB other than [Organization’s] local IRB, investigators should follow the requirements of that IRB.
2. Background
   1. “Incidental Findings” are:
      1. Findings that concern an individual research subject that has potential health or reproductive importance and is discovered in the course of screening for, conducting, or analyzing results from research, and is beyond the aims of the study, i.e., occurring from variables not directly under study.
   2. Federal regulations [45 CFR 46.111(a)(6)] require that studies have adequate provisions for enrollment screening and data monitoring to ensure the safety of research subjects. In the course of carrying out the applicable research, information that is secondary to the goals of the research may be identified which may impact the current and future safety and/or wellbeing of the participants.
   3. It is the policy of the Temple University’s Institutional Review Board (IRB) that a research protocol which will include genomic and other laboratory testing and/or imaging procedures must include the following elements:
      1. A statement on whether or not radiologic procedures conducted as part of the research will be of clinical quality.
      2. A statement that speaks to the whether a subject’s cellular material will be used for current and/or potential future genomic testing or biobanking.
      3. A statement that addresses the use of the subject’s associated personal health information and/or the subject’s identity with any future genomic testing or biobanking.
      4. A plan for managing incidental findings.
3. Guidance
   1. Researchers should:
      1. Develop a plan for managing anticipated and unanticipated incidental findings, even if the plan is *not* to disclose any secondary or incidental findings.
      2. Clearly communicate the plan to the IRB.
      3. Clearly communicate the plan to subjects during the informed consent process. The provided plan should be sufficient to inform individuals that they must affirmatively agree to participate in research if they are so inclined; or choose *not* to participate in research if they are uncomfortable with the management plan.
         1. **Example language to use in the consent document for potential incidental findings that *may be* communicated to the participant**:

“This (provide imaging procedure (e.g. MRI)) is done for research purposes rather than for diagnosis. The (provide procedure) will not be routinely examined by health professionals for potential structural and functional clinical abnormalities. However, in the event an abnormality is detected by the investigators or the (administer of the procedure (e.g. MRI technician)), the (named procedure) will be further examined by a (name appropriate clinician (e.g. a radiologist)) and the investigator may encourage you to consult your physician.” [add below language if applicable]

[The blood, saliva, tissue that is obtained from you will be tested and/or stored for future use and potential laboratory, genomic and proteomic studies. The material will have your name, medical record number and other identifying information associated with it. Please indicate if you wish to be contacted in the future regarding any test results that may be obtained.]

* + - 1. **Example language to use in the consent document for potential incidental findings that *will not* communicated to the participant**: “The *(named procedure)* we collect are for research purposes only and we cannot provide a (*name* *appropriate clinician)* clinical interpretation of the results. However, if your healthcare provider would like to use the *(type of data e.g. scans)* for comparison with another clinical *(applicable types of data)* that has already been obtained or may be obtained in the future, they may request these *(type of data)* if they are still available.” [add the below language if applicable]

[The blood, saliva, tissue that is obtained will be tested and/or stored for future use and potential genomic and proteomic studies. However, the material will be de-identified (will not have your name, medical record number or other identifying information associated with it. Therefore, we will not be able to contact you in the future regarding any test results that may be obtained]

1. REFERENCES
   1. 45 CFR 46.111(a)(6)