KENNESAW STATE UNIVERSITY
OFFICE OF RESEARCH
Research Compliance

IRB Guidance:
Incidental Findings

Things to consider when interventions for research have the potential to show unexpected, incidental findings,
in general:

1. If the intervention is done for research as well as for standard clinical care and the interpretation of the results would occur anyway, the results should be disclosed to the participant and/or participant's physician. The PI is responsible for disclosing results.
2. If the research intervention is not approved for use clinically, the findings should not be disclosed to the participant. This should clearly be outlined in the consent form.
3. If the research intervention is approved clinically, but done solely for research purposes and will not be professionally interpreted, the results should not be disclosed unless there is a plan to provide interpretation by the appropriate person (i.e. qualified to interpret the test/image/intervention) and a plan for follow up intervention or discussion. This plan should be documented in the protocol/IRB application. The PI is responsible for disclosing results when the decision to disclose is made.
4. If the research intervention is approved clinically but done solely for research purposes and the Investigator wishes to give the participant the option to get results, the Investigator must track which participants want and which do not want results. This option must include a plan to provide interpretation by the appropriate qualified person and a plan for follow up intervention or discussion. The PI remains responsible for disclosing the results.

- Incidental findings, including formal interpretation of research images, tests, etc. should be maintained in the research record unless requested by the participant to be included in his/her medical record.

Examples of language to use in the consent document:

For potential IFs that may be communicated to the participant (#3 and #4):

> "This (MRI) is done for research purposes rather than for diagnosis. The (scans) will not be routinely examined by health professionals for potential abnormalities. However, in the event an abnormality is detected by the investigators or the (MRI technologist), the (scans) will be further examined by a (radiologist) and the investigator may encourage you to consult your physician."

For potential IFs that will not be communicated to the participant (#2):

> "The (neuropsychological) tests are completed for research purposes only. They are not administered by a licensed (clinical psychologist) and thus, we are not able to provide a clinical interpretation of the results."

OR

> "The (MRI images) we collect are for research purposes only and we cannot provide a (radiologist's) clinical interpretation of the results. However, if your healthcare provider would like to use the (scan images) for comparison with another clinical (scan) that has already been obtained or may obtain in the future, they may request these (scans) if they are still available."

When no mention of incidental findings has been included in the consent document, the following can be used as a general guide for when to disclose the findings to the research participant:

Disclose to research participants as an incidental finding:

- Any information that has been collected through a clinically accepted method (e.g., a CLIA certified lab); AND any of a-e below
  a. Any information that reveals a condition that is likely to be life-threatening; OR
  b. Any information that reveals a condition that is likely to be grave that can be avoided or ameliorated; OR
  c. Any information that reveal a significant risk of a condition likely to be life-threatening; OR
  d. Any information that reveals genetic information that can be used to avoid or ameliorate a condition likely to be grave; OR
  e. Any information that reveals genetic information that can be used in reproductive decision-making: (1) to avoid significant risk for offspring of a condition likely to be life-threatening or grave or (2) to ameliorate a condition likely to be life-threatening or grave.

ALSO: Consider and discuss with the participant additional treatment options or communication with other providers, genetic counselors, etc., as well as the potential costs associated.

It is the Investigator's responsibility to arrange a process for disclosing results in the event it is decided that results should be disclosed.

Do not disclose to research participants as an incidental finding:

- Any information that has NOT been collected through a clinically accepted method (e.g., a CLIA certified lab); AND/OR
- Any information that reveals a condition that is not likely to be of serious health or reproductive importance; or
- Any information that reveals a condition or information that the importance of which cannot be ascertained.