

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 t 3. If the resear
 - and will not be profess is a plan to provide inte test/image/intervention should be documented results when the decisi
 - If the research interven the Investigator wishes must track which part include a plan to provid follow up intervention of

³/₄ 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):