

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 research and will not be professional is a plan to provide intervention test/image/intervention should be documented results when the decision 4. If the research intervention the Investigator wishes must track which participants include a plan to provide follow up intervention o

¾ 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):

