

Incidental Findings (HRPP 3.15)

Description:

This policy describes UNMC's requirements for disclosure, or nondisclosure, of radiographic incidental findings that may affect the management of a subject's current or future health or welfare.

Definitions:

Incidental Finding (IF): a finding concerning an individual research participant that has potential health implications and is discovered while conducting research but is beyond the aims of the study.

This policy applies to radiographs, including MRI, fMRI, CT scan, ultrasound, nuclear medicine scans, PET scans, and plan radiographs.

Review and Disclosure of IFs:

- The PI must have a plan to validate any IFs.
 - If they do not have the expertise to make the assessment, they must identify someone who does.
- The PI must explain the following during the informed consent process:
 - The potential of discovering IFs
 - What types of IFs the PI intends to disclose or withhold
 - The process of disclosure
 - Inform the subject of their right to refuse to receive information regarding IFs

When to Disclose IFs:

This depends on the "net benefit of disclosure":

- **Category A/Strong net benefit-** MUST be disclosed unless the subject explicitly refuses
 - The condition revealed is likely to be life threatening
 - Serious condition revealed that can be avoided or improved

- **Category B/Possible net benefit-** MAY be disclosed at the discretion of the investigator, unless the subject explicitly refuses
 - Nonfatal condition revealed that is likely to be serious but cannot be avoided or improved
- **Category C/Unlikely net benefit-** should NOT be disclosed to subjects
 - Condition revealed is not likely to be of serious health importance
 - Cannot be certain of likely health importance

Other Considerations:

All IFs should be promptly reported to the IRB.

All category A IFs MUST be reported and should include a plan to disclose to the subject.

IFs in **Pediatric and Adolescent Subjects:**

- Disclosure should be made to the parent/guardian.
- If the minor is old/mature enough to provide assent, then the offer of disclosure should be made to the subject.

IFs in **Adults Without Decisional Capacity:**

- Disclosure should be made to the LAR.
- If the subject is competent enough to provide assent, then the offer of disclosure should be made to the subject.

[CLICK HERE](#) for model ICF language.