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 result concerning an individual research participant that:

- Has potential health or clinical significance, and
- Is discovered in the course of conducting research, but
- Falls outside the stated aims or objectives of the study

Ex. A brain MRI conducted for a cognitive neuroscience study reveals a previously undiagnosed brain tumor

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

Procedures:

Plan for Review and Disclosure:

- 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
- **During consent:** subjects must be informed about:
  - The possibility of discovering IFs
  - What types of IFs the PI intends to disclose or withhold
  - The process of disclosure
  - Their right to refuse information regarding IFs

When to Disclose IFs:

Disclosure decisions are categorized by net benefit:

- **Category A: Strong Net Benefit**
  - Condition likely life-threatening or can be avoided or improved
  - **Must be disclosed,** unless subject opts out
- **Category B: Possible Net Benefit**
  - Serious but untreatable conditions
  - **May be disclosed,** at PIs discretion unless declined by subject
- **Category C: Unlikely Net Benefit**
  - Condition not likely to be of serious health importance, or cannot be certain of likely health importance
  - **Should not be disclosed**

IRB Reporting:

- **All IFs must be reported to the IRB**
- **Category A IFs:** Report as soon as possible, with disclosure plan or post-disclosure summary

Other Considerations:

There is no obligation to proactively search for IFs beyond the research aims *(e.g. there is no need for additional imaging solely to detect clinical abnormalities).*

Pediatric/Adolescent Participants:

- Disclosure to parents/guardians is required
- Assent-capable minors must be offered results and may refuse disclosure

Adults Lacking Decisional Capacity:

- Disclosure to LAR (Legally Authorized Representative) is required
- Assent-capable subjects should be offered disclosure and can refuse

CLICK HERE for model ICF language.