SOP 203: Incidental Findings

1 Summary

On rare occasions MRI research personnel may identify neurologic idiosyncracies, termed an 'unexpected observation', in data collected at the Notre Dame Human Neuroimaging Center (ND-HNC). This document establishes procedures for responding to such unexpected observations.

2 Scope

These policies apply to all investigators, research assistants, and staff who collect, review, or use MRI data collected at the ND-HNC.

3 Definitions

- **DICOM**: Digital Imaging and Communications in Medicine, a DICOM file consists of a header and image intensity data and is the foundational format for MRI data.
- **Incidental Finding**: A clinician's recommendation that an unexpected observation in research data warrants clinical follow-up.
- **IRB**: Institutional Review Board, an independent committee that reviews and approves research involving human subjects to protect their rights, safety, and welfare.
- **PI**: Principal Investigator, the lead researcher of the project that takes intellectual, fiscal, and administrative responsibility.
- **Operator**: MRI Technologist or Level 4 researcher, responsible for conducting research operations and maintaining equpiment. The Lead during emergency responses.

4 Policies & Procedures

The ND-HNC operates as a research facility focused on executing experimental MRI protocols for the purpose of scientific investigation. To this end, we provide personnel, infrastructure, and expertise that are appropriate to manage such research data. The ND-HNC is not a clinical facility and we are not organized to deploy clinical MRI protocols for the purpose of medical diagnosis. Given the volume of scans processed at the facility, however, research personnel will occasionally encounter idiosyncratic or anomalous anatomy.

Encountering such idiosyncracies introduces a number of responsibilities which the researcher must navigate to fulfill ethical and legal obligations. Namely, research personnel:

- do not normally use diagnostic MRI protocols nor hold the necessary qualifications to make medical diagnoses,
- must not cause harm to participants by *commission* (e.g. false alarm leading to undue stress or unnecessary medical expenses) or *omission* (e.g. withholding information which would have been medically relevant),
- are required to protect participant anonymity, and
- must adhere to IRB regulations of data usage and governance.

To help research personnel navigate these obligations, we provide an escalation protocol to be followed whenever unexpected observations occur. A description of these procedures should be included in any IRB application involving use of the ND-HNC MRI scanner. In short, the ND-HNC helps the Principal Investigator (PI) seek a recommendation from a qualified clinician.

4.1 Initial Review

Research personnel may notice something unexpected during the normal acquisition or use of the research data. When an unexpected observation occurs:

- Research personnel do not share their concerns with the individual who contributed the MRI data.
- Additional scans are not collected if the individual is present nor is the individual contacted for follow-up scans.
- The PI is contacted about the unexpected observation. The PI then coordinates with the MRI technologist for an External Review.
- The individual is not informed that the escalation process started.

4.2 External Review

The ND-HNC contracts with Radiology Inc.[1] for clinical review of unexpected observations. When a PI contacts ND-HNC staff to initiate an External Review:

- The MRI technologist copies the participant structural DICOM files to an encrypted flash drive. These DICOM files do not contain any Patient Health Information or identifiable information.
- The MRI technologist delivers the encrypted flash drive to Radiology Inc., and the decryption password is provided over e-mail.

- A radiologist reviews the data, writes a report, and provides a recommendation. Radiology Inc. does not store the DICOM files.
- The report and recommendation are e-mailed to the director (Aron Barbey: abarbey@nd.edu) and MRI technologist (Jeff Fox: jfox22@nd.edu).
- The MRI technologist retrieves the encrypted flash drive and deletes the copies of the DICOM files from the flash drive.

4.3 Follow-Up

The MRI technologist coordinates with the PI once a clinical review and recommendation is received; the director oversees this coordination. In cases where clinical follow-up is recommended, the role of PI is to communicate the clinician's recommendation.

If a clinical follow-up is **NOT** recommended:

- The MRI technologist relays this recommendation to the PI.
- No further action is necessary.

Whereas, if a clinical follow-up **IS** recommended:

- The MRI technologist e-mails the PI the review and recommendation with the subject title "ND-HNC Incidental Finding (secure)".
- The PI schedules a meeting with the participant to share the report and recommendation, referencing the following script:
    1. "Thank you for meeting with me today."
    2. "You recently participated in research at the Notre Dame Human Neuroimaging Center and part of the data you contributed were MRI scans."
    3. "While the data were collected for research purposes, something unexpected showed up in your scans."
    4. "Per our Standard Operating Procedures, your scans were referred to a radiologist for interpretation."
    5. Provide the radiologists review and recommendation. Refrain from interpretation or providing guidance.
    6. If the participant has questions, reinforce the PI role in this matter: "I am not a physician, so it is not appropriate for me to answer any questions about the radiologist's report or provide any advice."

5 Figures

None.

References

[1] https://www.rad-inc.com