3.15 Managing Radiographic Incidental Findings in Human Subjects Research

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization’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.

2.0 Policy

- **2.1.** It is the policy of the Organization that all human subject research must include provisions for management of unexpected incidental findings.
- **2.2.** This policy applies to radiographs (including but not limited to MRI, fMRI, CT scan, ultrasound, nuclear medicine scans, PET scans, and plain radiographs) that are performed solely for research purposes, when there is not a formal radiologist’s report generated and saved in the medical record. This includes research scans performed as a screening procedure to determine whether a potential subject meets eligibility requirements for inclusion, or as a baseline evaluation prior to beginning the research intervention.

3.0 Definitions

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

4.0 Procedures

- **4.1.** Plan for Review and Disclosure of IFs to Subjects
  - **4.1.1.** The PI has an obligation to handle IFs responsibly and promptly. The time frame of the initial communication with the subject should be consistent with the suspected severity of the finding and the net benefit of the disclosure.

    - **4.1.2.** Prior to commencing the research, the PI must have a plan to validate any IF and confirm its importance for the health and wellbeing of the subject. If the researcher does not have the expertise to make this assessment, he/she must identify an individual who does have this competence. The plan and time course of the review must take into account the type and resolution of scans or tests performed (e.g., anatomic imaging more urgent than functional imaging), and the age and health status (and likelihood of an abnormality) of the subject population.
    - **4.1.3.** During the process of consent, the PI must explain the potential for discovering IFs, describe the steps researchers will follow to evaluate IFs, (including consultation with a qualified clinician), describe what types IFs the PI intends to disclose or withhold, describe the process of disclosure, and inform the prospective subject of their right to refuse to receive information regarding incidental findings
    - **4.1.4.** The PI has a responsibility for ensuring subjects are well informed regarding the potential risks and benefits of disclosure of incidental findings.
- **4.2.** When to Disclose IF Results
    - **4.2.1.** Whether IFs are disclosed to subjects will depend on the investigator's (and, if necessary, the consultant's) assessment of the "net benefit of disclosure."
        - **4.2.1.1.** ***Category A (Strong net benefit):*** (1) information revealing a condition likely to be life-threatening; or (2) information revealing a serious condition that can be avoided or ameliorated. Category A IFs must be disclosed, unless the subject explicitly refuses to receive the information.
        - **4.2.1.2.** ***Category B (Possible Net Benefit):*** (1) information revealing a nonfatal condition that is likely to be serious but that cannot be avoided or ameliorated, when a research participant is likely to deem that information important. Category B IFs may be disclosed, at the discretion of the investigator, unless the subject explicitly refuses to receive the information.
        - **4.2.1.3.** ***Category C (Unlikely Net Benefit):*** (1) information revealing a condition that is not likely to be of serious health importance; or (2) information whose likely health importance cannot be ascertained. Category C IFs should not be disclosed to subjects.
- **4.3.** Process of Disclosure to Subject
    - **4.3.1.** The time frame of the initial communication with the subject should be consistent with the suspected severity of the finding and the net benefit of the disclosure
    - **4.3.2.** Subjects may refuse to receive information regarding incidental findings. As appropriate, the PI is responsible for explaining to the subject the consequences of non-disclosure.
    - **4.3.3.** Disclosure of IFs should include a medical professional who is knowledgeable about the type of IF found and who is experienced in communicating sensitive medical information.
    - **4.3.4.** IFs should be disclosed directly to the research participant. Investigators may offer to disclose to the subject's PCP (in addition to, or in lieu of disclosure to subject), but this decision must be made by the subject.
- **4.4.** All IFs must be reported promptly to the IRB. All Category A IFs must be reported to the IRB as soon as possible. The report must include the plan to disclose the results to the subject (for categories A and B), or a description of how the results were disclosed if expeditious disclosure was warranted (for example, for a life-threatening finding).
- **4.5.** The PI generally has no obligation to affirmatively search for IFs. The goal of research is to seek generalizable knowledge, not to provide health information to individuals. Thus, in the context of imaging studies, the PI is not obligated to perform extra scans or modify

scans to provide clinical information.

- **4.6.** IFs in Pediatric and Adolescent Research Participants
  - **4.6.1.** If incidental findings detected in pediatric or adolescent subjects are to be disclosed (per section 4.2 above) disclosure should be made to parent or guardian.
  - **4.6.2.** If the disclosed minor subject has been judged mature enough to provide assent, then then offer of disclosure should also be made to the subject. These subjects may refuse to receive this information.
- **4.7.** IFs in Adult Research Participants without Decisional Capacity
  - **4.7.1.** If incidental findings detected subjects who lack decisional capacity are to be disclosed (per section 4.2 above) disclosure should be made to LAR.
  - **4.7.2.** If the subject has been judged competent enough to provide assent, then offer of disclosure should also be made to the subject. These subjects may refuse to receive this information.

5.0 Model CF Language

- **5.1.** The following information must appear in the consent forms where the determination is made to disclose IF (as indicated in Section 4.2 above):
  "In the course of this research, you will undergo [type of study or studies]. These tests are done for research purposes, and not to look for any specific abnormalities. The scans/tests are not the same as you might get to diagnose a medical condition. However, occasionally, scans/tests will find something unexpected which the research was not looking for. This is called an "incidental finding." Incidental findings may be nothing to worry about, or they may be significant or even life-threatening.
  If one of the researchers sees something on your test which he/she is concerned about, he/she may review the scan/test with an expert. The expert review will be supplied if needed with no cost to you. If the researcher and/or the expert thinks the finding may be of importance to you the researcher will tell you. You can refuse to get this information. If you agree he/she will also tell your doctor.
  There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are also risks. These include anxiety over a finding which may not be real or may not require treatment.
  You and/or your insurance company may be billed for follow-up to the incidental finding to see if the abnormality is real or a medical problem."

6.0 IRB Review

- **6.1.** Prior to approval of the research, the IRB must review:
  - **6.1.1.** The plan to validate any IF and confirm its importance for the health and well-being of the subject (per 4.1.2 above).
  - **6.1.2.** The criteria for deciding whether an IF will be disclosed to subjects
  - **6.1.3.** The proposed process of disclosure (per 4.3 above), including the qualifications of the persons who will be disclosing information to the subject
- **6.2.** All category A IFs must be reviewed by the full IRB. The IRB will determine whether the IF represents an unanticipated problem involving risk to the subject, whether the risk benefit relationship of the research is still acceptable, whether risks have been minimized,

and whether the CF is adequate

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