Incidental Findings

Purpose

This page details the procedures to be followed when incidental findings are discovered in a human research scan.

Introduction

Occasionally, previously unknown abnormalities are noted in MRI scans of unsuspecting research subjects that are otherwise normal. When this happens, the level 2 researcher on duty shall strictly follow these procedures.

Procedures:

1. The researcher will run the pseudo-clinical imaging protocol on the scanner. This protocol takes about ten minutes to run and is designed to simulate a clinical study for the identification of most abnormalities. If there is insufficient time remaining in the reserved experiment time to complete the study and run the extra protocol, the study shall be immediately terminated, and the extra "pseudo-clinical" protocol will be run instead. The researcher should ensure that the study is anonymous; no identifying information should be included in the MR study metadata.
2. At the conclusion of the study, the researchers must not indicate any suspicion of an adverse finding. The study should end as usual, and the researcher should confirm the subject’s contact information before being permitted to leave. If the subject specifically asks if the researcher observed anything out of the ordinary, the researcher should inform the subject that their images will be read by a qualified radiologist, and if anything is noted, they will be contacted.
3. As soon as possible after the subject leaves the control room, the researcher should download and fill out Section 1 of the BIC’s Incidental Findings Log using Adobe Acrobat Pro or Adobe Acrobat Reader. VERY IMPORTANT: Do not use a substitute PDF reader (e.g. Apple Preview or Foxit) to fill out the form. Also, do not print out the form, fill it in by hand, and scan it. All BIC computers have Adobe Acrobat Reader installed for your use.
4. The researcher should e-mail the log form with only Section 1 completed to bic-medical@utlists.utexas.edu. Do not CC or BCC anyone else on this e-mail.
5. The BIC Safety Panel listed below will process the form and coordinate any contact between the subject and Medical Director as necessary. Once all the procedures have been completed, the PI of the study will be notified IF the findings are medically significant.

Implementation and Update of Active IRB Protocols

These procedures became effective on September 28, 2015, upon notice of unanimous consensus approval by the University of Texas at Austin Institutional Review Board. All active IRB protocols that involve MR imaging in the BIC are considered to be automatically updated to include these procedures. All previous versions of these procedures are obsolete. Do not use them.

Currently active IRB protocols should list this change in their continuing renewal, and specifically reference this wiki page as a comprehensive list of the current procedures.

New IRB protocols should simply reference this wiki page as a comprehensive list of the current procedures.

BIC Safety Panel

Doug Befroy, BIC Facilities Director
J. Neal Rutledge, BIC Medical Director
Don Nolting, BIC Facilities Manager