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Department Research
Applicability Boston Children's Hospital- Policies & Procedures

Special Confidentiality Issues When Performing Research Related Imaging Policy/Procedure

Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

Policy Statements

This policy provides specifications and guidance for researchers when performing research related imaging procedures such as magnetic resonance imaging (MRI), computerized tomography (CT), ultrasound, radiographs, and echocardiography.

As part of a research protocol, images may be required from:

1. Patients undergoing images or sequences for research purposes.
2. Patients undergoing imaging for clinical care; however, the results of the scan may be also used for as research data.
3. Volunteers who are not Boston Children's Hospital patients and only having images taken because they are part of the research

Review for Incidental Findings

It is the policy of the IRB that all images obtained for research purposes are to be read by an appropriately qualified radiologist/clinician to determine if there are incidental findings. There is an ethical obligation to review these images because incidental findings may be of clinical significance.

All investigators are required to:

1. Implement a mechanism to ensure that images are reviewed by an appropriately trained clinician, and
2. Develop a plan for reporting incidental findings as part of their protocol application in a timely manner.
    a. It is often recommended that investigators consider whether adding a radiologist to the research protocol would assist in the review of images and reporting of information as necessary.
    b. Even when a radiologist is not part of the research team, investigators need to consider who receives information on incidental findings and how they will be reviewed and reported.
    c. In general, it is not acceptable to have research coordinators responsible for the receipt of such reports without the oversight and attention of the investigator or other qualified co-investigators.

Procedures

Scheduling for Research Imaging

In accordance with the policies of Boston Children's Hospital, research imaging research subjects must first be entered into the Boston Children's Hospital EPIC system.

1. For Boston Children's Hospital patients, scheduling accounts already exist.
2. For individuals who will only visit the hospital for research purposes, an EPIC account must first be established. In order to establish an EPIC account, there are specific fields of data that are requested.
    a. **Insurance**: One field is information regarding third party payers/medical insurance, even if insurance will not be billed and covered by the research. Insurance information is mandatory.
    b. **Primary Care Physician**: Another field requested is the research subject's primary care physician. This field may be left blank. Once again in accordance with Boston Children's policy, if a primary care physician is provided, this physician will be sent a copy of the report generated by the radiologist/clinician after it is reviewed for incidental findings.
        i. Investigators are urged to advise research subjects about reporting to primary care physicians and either allow subjects a choice or instruct them accordingly as to whether to provide this information

Medical Records of Research Imaging

Research images will be filed in either an existing medical record or a new medical record will be created, if one does not exist. The medical record will contain the actual image and the report that is generated by the radiologist/clinician.

Implications for Confidentiality

The requirements for scheduling, having a radiologist/clinician review the images and placing the images in a medical record impact confidentiality provisions for the research subject.

Subjects **cannot** be told that only the investigator and research team will have access to research results, since images and report results will be placed in their medical record. In addition, if a research report is released to a primary care physician, this also limits confidentiality provisions.

Informed Consent Template Language Suggestions

The IRB has developed template informed consent language that describes the potential creation of a medical record for participants that do not have a medical records, the inclusion of data, research scans/images in the consent and the potential for incidental findings. Investigators are responsible for including the template language as applicable for the study. Template language may be found on the IRB website.

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/25/2025
Steering Committee	Dwight Mayfield	2/25/2025
Required Departmental Review/Approval	August Cervini	1/17/2025
Committee Chair(s)	Susan Kornetsky: Manager	1/17/2025
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Applicability

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