



## **Special Confidentiality Issues When Performing Research Related Imaging**

### **Policy**

This policy applies to imaging procedures such as MRI, ultrasound, radiographs and echocardiography

Imaging is often performed as part of a research protocol. Images may be required from

- patients undergoing additional images or sequences for research purposes,
- patients undergoing imaging for clinical care, however the results of the scan scans may be also used for as research data.
- volunteers who are not Children's 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 in order 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 must have a mechanism to insure that images are reviewed by an appropriately trained clinician and investigators must develop a plan for reporting incidental findings as part of their protocol application. .

#### **Scheduling for Research Imaging**

In accordance with the policies of Children's Hospital ,research imaging research subjects must first be entered into the Children's Hospital EPIC system. For research subjects who are already CH patients, scheduling accounts already exist. However 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 required. 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.

Another field requested is the research subject's primary care physician. This field may be left blank. Once again in accordance with Children's policies, 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. Investigators are urged to

# The Clinical Investigation Policy and Procedure Manual



Children's Hospital Boston

Document: CIPP 081.030

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 impacts 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. Since informed consent documents must discuss confidentiality, it is important that correct information be disseminated to the research subjects. Please note some of the specific language required to address research imaging will be different from template language about confidentiality for other types of research assessments and procedures.

## **Informed consent template suggestions**

The following templates may be used by investigators for various scenarios. Since each protocol will be different, it is impossible to provide templates for each possibility. It is the investigator's responsibility to determine which issues apply to your research and to include the appropriate information in the consent document. You should feel free to adapt these templates as deemed necessary.

### **Incidental Findings When Scans Images Performed only for Research:**

*When imaging subjects there is always the risk of discovering a potential abnormality. We emphasize that the (insert type of image/ scan) being performed for this study are designed to answer specific research questions and they are not designed to be used for any medical diagnoses of conditions that may or may not exist. The research images, as such, are not substitutes for what a doctor would order and so may not show problems that might be picked up by clinically indicated medical images. Your research images will, however, be examined by a trained radiologist or clinician within one week of the exam. If the radiologist/clinician believes that the research study may show an unexpected abnormality, he/she may request that you return for additional imaging or recommend that you contact your physician for further follow-up. Information generated from the research imaging will become part of your medical record. It is possible that by participating in this research study you could become unnecessarily worried if an abnormality was suspected but later ruled out by further tests.*

### **Incidental Findings When More Frequent or Additional Scans/Images Performed only Subjects who are patients at Children's.**

# The Clinical Investigation Policy and Procedure Manual



Children's Hospital Boston

Document: CIPP 081.030

*When imaging subjects there is always the risk of discovering a potential abnormality. We emphasize that the (insert type of image) being performed for this study are designed to answer specific research questions. The research images, as such, are not substitutes for what a doctor would order and so may not show problems that might be picked up by clinically indicated medical/imaging. However because there are more frequent (or additional) images being performed than would be routinely required for your care, they still will, be examined by a trained radiologist/clinician within one week of the exam. If the radiologist/clinician believes that the research study may show an unexpected abnormality, he/she may request that you return for additional imaging or recommend that you contact your physician for further follow-up. Information generated from the research/imaging will become part of your medical record. It is possible that by participating in this research study you could become unnecessarily worried if an abnormality was suspected but later ruled out by further tests*

## **What will happen with the information obtained as part of this research study? What about confidentiality?**

*In order to perform imaging for this research, you/your child will need to have an appointment scheduled through the hospital systems. If you are already a patient at the hospital your information is already on file. However if you are not a current Children's Hospital patient, the hospital is required to obtain certain types of information in the event it was ever required for your care. You will be asked for insurance /third party payer information even if the research will cover the costs of these tests. In addition you will be asked for the name of your primary care provider. You may decide whether or not to provide your primary care providers name.. If you do provide this information a report about imaging will be sent to the provider.*

*Medical information collected during this study will become part of your/your child's hospital record. Medical records are considered permanent records. Therefore, materials cannot be deleted from the record. Medical records are available to health care professionals at Children's Hospital and may be reviewed by Hospital staff in the course of carrying out their responsibilities. However, they are required to maintain confidentiality in accordance with applicable laws and Hospital policies. Information contained in your/your child's medical record may not be given to anyone unaffiliated with Children's Hospital in a way that could identify you/your child without written consent, except as required or permitted by law. Information collected during the study that does not become part of your/your child's medical record will be stored in separate research files maintained by the investigator. If you/your child withdraw from the research study, information that has already been collected will become part of the research data. However, you/your child will not be identified.*

# The Clinical Investigation Policy and Procedure Manual



Children's Hospital Boston

Document: CIPP 081.030

## Document Attributes

<b>Title</b>			
<b>Author</b>	<b>Susan Kornetsky</b>	<b>Dates Reviewed/ Revised</b>	06/21/2010
<b>Reviewed/ Revised by</b>	Susan Kornetsky	<b>Last Modified</b>	06/21/2010
<b>Copyright</b>	©Children's Hospital Boston, 2012		
<b>Approved</b>	Susan Kornetsky Director of Clinical Research Compliance  Carleen Brunelli, MBA, PhD Vice President for Research Administration		