

## **University of Texas Health Science Center at Houston Behavioral Science Imaging Center**

### **Incidental Findings Policy (Draft v2.)**

Date: 10/03/2024

The imaging data collected at the University of Texas Health Science Center at Houston Behavioral Sciences Imaging Center (BSIC) are intended for research use only. Most of the imaging protocols used at the center are based on research sequences that are not FDA approved for diagnostic purposes, distributed for research use only, and are not meant for diagnostic evaluation. Therefore, the imaging data will not be sent for clinical reading.

Investigative teams are expected to have a policy and a clinical evaluation in place to screen participants for any neurological abnormalities as part of the consenting process.

It is the responsibility of investigative teams to convey the limitations of research imaging data to the participants in IRB approved consent documents. The following are examples of such languages from different UTH-approved IRB protocols. The purpose is to convey to the participants that the imaging data collected by this project are for research purposes only and are not meant or appropriate for clinical read and/or search for evidence of clinical diagnoses that have or have not been suspected by a doctor. Each participant should be informed and consented accordingly prior to imaging. Investigators have the option to use, modify, or not use these languages.

Investigative teams may opt to obtain clinical read for diagnostic purpose for their participants. Such an imaging protocol must include FDA-approved sequences. We recommend that the consent form includes languages that clearly state this and inform the participant of the pros and cons of having their images read for diagnostic purposes and receiving incidental findings, if any, that are not based on prior clinical evidence.

Examples of such text include:

#### Example I

##### *“Incidental Findings*

*The investigators for this project are not trained to perform radiological diagnosis, and the MRI scans performed in this study are not designed to find abnormalities and are being conducted only for research purposes. If the investigators notice a finding on an MRI scan that seems abnormal, the scan will be shared with a licensed radiologist for further evaluation. Should this occur, a neuroradiologist would be consulted and the MRI scan will be sent to Baylor College of Medicine and/or UTHealth Houston. If the neuroradiologist thinks that further investigation of the finding is called for, you will be contacted about the finding and next steps. You will also receive a copy of the radiology report for your records. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The images collected in this study are not meant or approved for diagnosis or treatment of any disorder and do not comprise a clinical MRI study. These images will not be made available for diagnostic purposes.”*

Or

Example II

*“The tests here are for research purposes only and are not the type used to look for problems like a tumor or to make a diagnosis. It will not be routinely reviewed for these sorts of problems. However, sometimes MRI and other tests may show what could be an abnormal finding. Should this occur, we may seek a specialized physician’s opinion, or you will be referred to the proper expert(s).”*

If any staff and faculty in viewing or processing their research imaging data collected at BSIC identifies any potentially clinically meaningful findings at any time, BSIC can assist transfer of the images to a radiologist or other experts that the PI designated for evaluation. The Center has a routine service using American Radiology, which is an online service for reading, typically by a neuroradiologist. They usually provide a report within hours but typically within a day. They currently charge \$50 per read. If you choose this option, BSIC staff can assist the transfer of the images to American Radiology and obtain the report for the PI.