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UNIVERSITY

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CSI Policy and Procedures for Technical Development (TD) Studies on Imaging Equipment

Currently, there are three categories of imaging studies performed at the Center for Systems Imaging (CSI): (i) funded CSI Core studies, (ii) pilot studies, and (iii) technical development (“TD”) studies. The purpose of this document is to define “technical development” studies that may take place at the CSI and to further outline standard operating procedures for such studies.

Definition of Technical Development Studies

Technical development studies are studies performed by CSI core faculty that are done explicitly to either: (i) develop, validate, or refine methodology for the express purpose of creating an imaging service or methodology that can then be applied to expand or enhance CSI core services, (ii) test new hardware or software on a core device that will be implemented for use in funded CSI core studies. TD studies may involve simulations, tissue specimens, phantom models, or occasionally human or animal subjects. These studies would typically generate data that would **not** be specifically intended for use in research papers or as preliminary data for grant applications. For case (ii) above when no human or animal studies are involved, the program director for the appropriate modality/service may approve the study

For case (i) above or when human or animal subjects are involved, TD studies should also be:

1. of minimal risk
2. typically include fewer than 5 subjects
3. performed under the review of the appropriate Program Director and with advance written approval of the CSI Director

Those eligible to conduct TD studies include the CSI program directors and all other CSI core faculty. Technical development studies must conform to all other CSI policy guidelines including all necessary safety training of involved personnel. All TD studies must be scheduled in advance and individuals using CSI equipment must appropriately sign in and sign out (see below).

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Scheduling of Technical Development Studies

Scheduling of TD studies must be done using the normal CSI scheduling and screening procedures, including recording of the investigator and time required. It should be noted that funded CSI studies may take priority over TD studies and may occasionally require their rescheduling. Every effort will be made to minimize inconvenience and a minimum guideline of 24 hours prior to the scheduled hour is recommended. Additionally, TD studies should preferentially be scheduled at less busy core service hours, e.g., early or late in the day.



July 24, 2009

Director, CSI

Date