



# Study Participant Supervision Policy

## I. PURPOSE

- A. This Study Participant Supervision Policy has been established to provide a minimum level of supervision required for a safe environment for participants in research studies within the IIBIS imaging areas.

## II. SCOPE

- A. This policy covers all IIBIS facilities located at R2 building and within Goodman Hall in regards to the supervision of all human study participants for any imaging modality.

## III. EXCEPTIONS

- A. Any exception to this policy requires the approval of the Director of IIBIS.

## IV. DEFINITIONS

- A. IIBIS: Indiana Institute for Biomedical Imaging Sciences
- B. Study Personnel: Personnel supplied by the Principal Investigator responsible for the participant while in the IIBIS suite.

## V. POLICY STATEMENTS

- A. There are many potential risks that require patients to be supervised while in the imaging area. It is imperative that study personnel and IIBIS imaging staff communicate to assure a safe and successful imaging study.

## VI. PROCEDURES

- A. Study Personnel:
  - o Study personnel are responsible for arriving with study participants at the research imaging check in station. Routine exams performed for research purposes may be waived of this requirement by the Director.
  - o Study personnel who cannot stay for the entirety of the imaging procedure must complete a Study Participant Intake Form and verify the study personnel contact phone number(s) where they can be reached during the imaging procedure.
  - o Study personnel with tasks associated with the study imaging procedure or are required to stay for the duration of those tasks.



- Study personnel with scheduled exams that extend beyond regular business hours may be required to stay for the imaging exam pending imaging staff levels.
  - Study personnel without tasks related to the imaging procedure should use their own discretion in determining whether to stay for the imaging procedure.
  - Study personnel must provide study participants detailed instructions for where to go after the imaging procedure is completed.
  - Study personnel must remain with study participants who are severely cognitively impaired throughout the entire imaging procedure.
  - Study personnel must remain with study participants who are minors, or arrange for a responsible guardian to be present, throughout the entire imaging procedure.
- B. IIBIS Staff:
- IIBIS staff may contact the study coordinator via the supplied contact number as needed during the visit. If the study personnel cannot be reached with the provided contact number or if time does not permit, IIBIS staff will use best practice guidelines to determine whether to continue the imaging procedure.
  - IIBIS staff are not responsible for making study imaging protocol judgement decisions in the event study personnel are unavailable.
  - IIBIS staff are not responsible for study participants once they have left the designated research-imaging suite.

**Indiana Institute for Biomedical Imaging Sciences  
Department of Radiology and Imaging Science**



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