

LESSONS LEARNED FROM PREVIOUS CQI ASSESSMENTS

Discrepancies Between...

1. iStar application vs. conduct of study
2. IRB policies vs. conduct of study
3. Informed consent vs. conduct of study (IC promise/commitment vs/ reality)

Study Personnel Issues

1. Consent document listed study personnel but omitted one researcher
2. Amendment approved to add study personnel but original iStar application was not updated
3. Study personnel list in IRB application out-of-date
4. Study personnel listed as authorized to obtain consent in application was incomplete
5. Lack of study personnel oversight
6. Lack of study personnel training

Recruitment Issues

1. Exclusion of 18-20 yrs olds when inclusion criteria stated “adult population” was included
2. IRB application did not specify that USC students would be recruited for the study
3. Professor recruiting subjects from his/her classroom
4. No documentation that subject met inclusion or exclusion criteria
5. Inclusion/exclusion violations

fMRI Users Issues

1. Study team unfamiliar with Dornsife policy
 - a. No documentation that CR-rom of scan was provided to subjects, as required by policy
 - b. Study team believed all scans are sent to a USC Radiologist for review, yet informed consent indicated only scans with suspected anomaly would be sent to USC Radiologist
 - c. “jpeg” images of scans were emailed to subjects which was not consistent with the informed consent document or iStar application.
2. CD-roms with subject fMRI scans that contained the subjects ID number were stored with the informed consent documents identifying subjects’ CDs. It is suggested these CD roms be stored in a separate location to add another level of data protection.

Incidental Findings

1. iStar application did not include a plan for “incidental findings” related to abnormal brain images. The Dornsife policy on incidental findings must be employed and documented.

Adverse Events

1. Coordinating Center: No plan in place to communicate Adverse Events and Unanticipated Problems arising at the research site to the coordinating center.

Funding

1. Gift used to fund study was not disclosed in iStar and PI held the funds in his personal checking account.
2. Application indicated study was not funded yet subjects were compensated. IRB applications must indicate where study funds come from (e.g., PI’s personal funds, gift account, etc...).

HIPAA Issues

1. Use of HIPAA forms though not required for study (study team did not serve as a health care provider and no PHI was collected/shared)

Consent Issues

1. Not using an approved IRB-stamped consent document
2. Use of strikethrough, edited consent (no IRB stamp!)
3. Using one consent document to consent more than one subject
4. Subjects asked to sign a consent form for each visit to the imaging facility
5. Missing an entry such as subject's name (or signature), subject date, PI signature, PI date
6. No documentation of consent
7. Use of an expired consent