Research Investigator Audits and Inspections

"How to be prepared and avoid violations"

There are 2 levels of inspection for research compliance which include:

1) Federal
    - FDA and the OHRP (office for human research protection)
2) Local
    - IRB (institutional review board)
    - OPRS (office for the protection of research subjects)

If you are selected for an audit it will likely be led by the USC OPRS with the findings submitted to the USC IRB. Inconsistencies and omissions in your research practices that are acknowledged by or reported to the IRB may initiate an audit but the OPRS also randomly selects investigators to audit based on the type and volume of research conducted. Below is a list of common problem areas identified during audits that will help you in correcting and maintaining appropriate research compliance. For more information and guidelines, refer to USC Human Subjects Protection Program (HSPP) Policies & Procedures: https://oprs.usc.edu/files/2012/11/PnPs-Final.pdf

The most common deficiencies found are:

- **Use of expired consent/wrong version or no consent obtained**
- **IRB application does not accurately reflect study procedures/personnel**
- **HIPAA form not obtained**
- **Protocol non-compliance**
- **Lack of documentation**
- **Unsecure data storage and management/organization**

More specific deficiencies are listed below by category:

Consent and HIPAA Form Issues:

- no documentation of consent
- use of unapproved consent
- missing subject name, signature, or signature date
- missing PI signature
- use of wrong HIPAA form
- HIPAA form not signed by subjects
- required fields not completed in HIPAA form

IRB Application Discrepancies:

- discrepancies between IRB application and study procedures
- unable to locate approved documents in iStar
- study personnel different from those in application
- personnel obtaining consent is different from that in application

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Lack of Documentation:

- no documentation of subjects meeting inclusion/exclusion criteria
- no regulatory binder or substantial documentation missing

Personnel-Related Issues:

- no GCP or Human Subjects training
- lack of personnel
- insufficient personnel oversight

Lack of Communication with IRB:

- done in untimely manner
- study closure report not submitted
- protocol deviations not reported to IRB

Protocol Non-Compliance:

- differences between protocol and study procedures
- inclusion/exclusion violations

Mismanagement of Subject Compensation:

- plan for subject compensation not included in IRB application or informed consent
- subject compensation withheld contingent on subject's completion of study
- actual subject compensation different than what is in approved informed consent
- incomplete or lack of documentation of subject compensation payments
- misuse or misplacement of subject compensation

Miscellaneous:

- potential for subject coercion
- funding not distributed to proper channel
- investigator unaware of consent requirement for all subjects and study closure responsibilities

Lack of Communication with FDA:

- personnel listed on Form 1572 form differs from IRB application
- missing information on Form 1572
- lack of annual progress report for investigator initiated studies