

OKLAHOMA STATE UNIVERSITY CENTER FOR HEALTH SCIENCES
OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD

APPENDIX J CONTINUING QUALITY IMPROVEMENT

<Date>

<Investigator's name/address>

Dear _____ ,

As you are aware, problems associated with research involving human participants have received a great deal of attention over the past several years. OSU Center for Health Sciences Institutional Review Board (IRB) in conjunction with the Office of Research have begun a Continuing Quality Improvement (CQI) Program. The goals of the program are to increase the availability and visibility of the Office of Research as a resource for investigators and research staff and to ensure compliance with federal and state regulations regarding the protection of human participants in research.

The CQI program will consist of site visits from the Institutional Review Board (IRB) Administrator and/or members of the IRB. Studies will be chosen after they are approved by the IRB.

The initial visit will be scheduled at the time the study is ready to begin enrollment. The purpose of this visit is to review the plans for study conduct with the investigator and the research staff.

The follow up visit will be scheduled to coincide with the enrollment of a participant. One of the purposes of this visit is to observe the informed consent discussion and ask permission from the participant to contact them later in the study for an assessment of their research experience. This visit will be scheduled once several participants are enrolled so review of study records and documentation can also be accomplished.

You and your research staff have been chosen to participate in the program through the study titled, _____.

Please call the IRB Administrator to schedule the initial site visit. The subsequent audits of your research may be scheduled or unscheduled.

Sincerely,

OSU CHS IRB Administrator

NAME OF INVESTIGATOR: _____

IRB # _____

NAME OF COORDINATOR(S): _____

Continuing Quality Improvement Program

Initial Visit Worksheet

Date: _____

For sponsored clinical trials:

- Did the Principal Investigator attend the start-up meeting? Yes No N/A

If not, does the PI's knowledge of the protocol seem adequate? Yes No

- Did the Coordinator attend the start-up meeting? Yes No N/A

If not, does the Coordinator's knowledge of the protocol seem adequate? Yes No

- Is the study drug/device stored in a limited access area inside a locked cabinet? Yes No

If No, comment: _____

- Are the drug/device accountability records adequate? Yes No

Comments: _____

For all studies:

- Who will obtain and return Medical Records? _____

- Record-keeping procedures (documentation in Medical Record, filing consent forms, initial IRB application, modifications to protocol, etc.) were reviewed. Yes No

- Recruitment methods reviewed with PI. Yes No

Comments: _____

- Recruitment materials reviewed with PI. Yes No

Comments: _____

NAME OF INVESTIGATOR: _____

IRB # _____

NAME OF COORDINATOR(S): _____

Continuing Quality Improvement Program

Initial Visit Worksheet continued

- The plan for obtaining informed consent (who, when, where) was reviewed. Yes No

Comments: _____

- A process is in place for ensuring that only currently approved informed consent form(s) will be used. Yes No

Describe: _____

- Continuing Review Process reviewed. Yes No

With: _____

- Adverse Event Reporting reviewed. Yes No

With: _____

- Procedures for reporting Serious Adverse Events and protocol violations were reviewed. Yes No

With: _____

- The requirement to forward monitoring reports from the sponsor or CRO to Office of Research was reviewed. Yes No

- Was the Study Coordinator prepared to initiate the study, including preparing adequate resource documents? Yes No

Signature(s) of person(s) conducting initial visit:

Signature _____

Date _____

Signature _____

Date _____

Signature _____

Date _____

NAME OF INVESTIGATOR: _____
NAME OF COORDINATOR(S): _____

IRB # _____

Continuing Quality Improvement Program

Second Visit Worksheet

Date: _____

Study Questionnaires:

- Type of data recorded: reviewer verified that data recorded included variables approved by the IRB e.g. names, addresses, phone numbers, income, SS#, etc. Yes No

Participant Characteristics and Eligibility Criteria:

- Number of participants enrolled: reviewer asked to see documentation of the number of enrolled participants. Yes No

Number of participants enrolled _____

- Inclusion/Exclusion criteria: reviewer looked at documentation verifying that enrolled participants met the study selection criteria. Yes No

Informed Consent Process and Procedures:

- Obtaining informed consent: reviewer obtained a description of how consent is obtained from the investigator. Yes No
- Clinical Coordinator witnessed the consent process with an actual participant. Yes No
- Reviewer looked at consents to verify that valid [IRB approved] consents are being used. Yes No
- Consent documentation: reviewer looked at consents to verify that they are signed and dated by the participant and a witness. Yes No
- Reviewer verified that participants are given a copy of the consent. Yes No

NAME OF INVESTIGATOR: _____
NAME OF COORDINATOR(S): _____

IRB # _____

Continuing Quality Improvement Program

Second Visit Worksheet continued

IRB Documentation:

- Reviewer verified that IRB approved protocol and consents are on file. Yes No
- Reviewer verified IRB correspondence is on file of initial approved letter, conditional approval letters and modification letters. Yes No

Data Management and Record Keeping:

- Data coding system: reviewer looked at and discussed system of coding information to protect confidentiality. Yes No
- General confidentiality procedures: reviewer assessed where data is stored and who has access to the data once recorded to ensure confidentiality procedures are being followed. Yes No

Signature(s) of person(s) conducting second visit:

Signature _____

Date _____

Signature _____

Date _____

Signature _____

Date _____

NAME OF INVESTIGATOR: _____

IRB # _____

NAME OF COORDINATOR(S): _____

Continuing Quality Improvement Program

Evaluation from Investigator

Was the process of IRB review satisfactory?

Yes No

If not, why not? _____

What could Office of Research do to improve the process? _____

General Comments: _____

NAME OF INVESTIGATOR: _____

IRB # _____

NAME OF COORDINATOR(S): _____

Continuing Quality Improvement Program

Participant Follow-up

Date: _____

Follow-Up Interview with Research Participant

Date: _____

Check method used for interview:

Telephone:

In person:

Written questionnaire:

Indicate the participant's responses to the following questions or attach completed questionnaire:

1. Were you given enough information about the study to make a good decision about whether or not to participate? Yes No

Comments: _____

2. Did you get most of your information from reading the consent form or speaking with the research staff? Consent form Staff

3. Was there anything about the study procedures that you wish you had known before you agreed to participate? Yes No

Comments: _____

4. Did you understand that the research study was voluntary and that you could quit at any time?

Yes No

Comments: _____

NAME OF INVESTIGATOR: _____

IRB # _____

NAME OF COORDINATOR(S): _____

Continuing Quality Improvement Program

Participant Follow-up continued

5. *Were you satisfied with the way you were treated in this research study?* Yes No

Comments: _____

6. *Would you consider participating in another research study here?* Yes No

If not, why not? _____

Signature of person conducting follow-up interview:

Signature _____

Date _____