

**OKLAHOMA STATE UNIVERSITY  
CENTER FOR HEALTH SCIENCES  
COLLEGE OF OSTEOPATHIC MEDICINE**

**OFFICE OF RESEARCH AND SPONSORED PROGRAMS  
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. The OSU- Center for Health Sciences Institutional Review Board (IRB) in conjunction with The Office of Research and Sponsored Programs (ORSP) will begin a new Continuing Quality Improvement (CQI) Program in 2003. The goals of the program are to increase the availability and visibility of ORSP 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 Teri Bycroft at 699-8643 to schedule the initial site visit. The subsequent audits of your research may be scheduled or unscheduled.

Sincerely,

Teri Bycroft, Certified IRB Manager  
OSU-CHS IRB Administrator

Adapted from the Scripps Clinic and San Diego State University's CQI programs

NAME OF INVESTIGATOR: \_\_\_\_\_

IRB # \_\_\_\_\_

NAME OF COORDINATOR(S): \_\_\_\_\_

## Research and Sponsored Programs (ORSP) CQI 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

Adapted from the Scripps Clinic and San Diego State University's CQI programs  
NAME OF INVESTIGATOR: \_\_\_\_\_ IRB # \_\_\_\_\_  
NAME OF COORDINATOR(S): \_\_\_\_\_

## Research and Sponsored Programs (ORSP) CQI 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 \_\_\_\_\_

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NAME OF INVESTIGATOR: \_\_\_\_\_ IRB # \_\_\_\_\_  
NAME OF COORDINATOR(S): \_\_\_\_\_

## Research and Sponsored Programs (ORSP) CQI Program

### *Evaluation from Investigator*

Was the process of IRB review satisfactory?  Yes  No

If not, why not? \_\_\_\_\_

What could ORSP do to improve the process? \_\_\_\_\_

\_\_\_\_\_

General Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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NAME OF INVESTIGATOR: \_\_\_\_\_ IRB # \_\_\_\_\_  
NAME OF COORDINATOR(S): \_\_\_\_\_

## Research and Sponsored Programs (ORSP) CQI 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: \_\_\_\_\_

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NAME OF INVESTIGATOR: \_\_\_\_\_

IRB # \_\_\_\_\_

NAME OF COORDINATOR(S): \_\_\_\_\_

## Research and Sponsored Programs (ORSP) CQI 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 ORSP 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 \_\_\_\_\_

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NAME OF INVESTIGATOR: \_\_\_\_\_ IRB # \_\_\_\_\_  
NAME OF COORDINATOR(S): \_\_\_\_\_

## Research and Sponsored Programs (ORSP) CQI 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: \_\_\_\_\_

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NAME OF COORDINATOR(S): \_\_\_\_\_

### Research and Sponsored Programs (ORSP) CQI 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 \_\_\_\_\_

Adapted from the Scripps Clinic and San Diego State University's CQI programs.

