



Office for the Protection of Research Subjects
Continuous Quality Improvement
Assessment Tool

I. GENERAL INFORMATION

IRB # _____ Study Title _____

Principal Investigator _____ Level of IRB Review _____

Last IRB Review & Type _____

Study Expiration _____

Names of Assessment Staff _____

Date of Assessment _____ Location _____

I. INTERVIEW WITH PI/RESEARCH STAFF

1. Ask the PI/research staff to give an overview of the study and procedures.

Notes:

2. Did the investigator encounter any problems in recruitment, subject retention, or other areas? If so, what was the nature of the problem and how was it addressed.

3. Has the investigator encountered many adverse events? How were they handled?

4. Do the investigator and/or research coordinator(s) have any problems with the IRB, IRB staff or IRB reviews? If so, what are the problems and proposed solutions? How has the iStar submission process been (working or not working)?

5. How does PI maintain privacy and confidentiality as far as recruitment, consent, data storage and retrieval? Ask PI to describe.

6. Ask PI/research staff to describe the subject population and demographics. Are they vulnerable? If yes, what extra protections are being provided?

7. Ask PI to describe how they disseminate results back to the subject community.

Ila. Post-Interview CQI Staff Notes:

1. Briefly Evaluate the following: researcher attitudes, direction from PIs (or lack of), knowledge about study, procedures, regulations, commitment to Human Subjects protections.

Ilb. Inclusion / Exclusion Criteria

1. Do enrolled subjects meet the inclusion/exclusion criteria?(This information should be ascertainable in the subject file/binder).

III. RECORDS / DATA STORAGE

1. Where are the study records physically stored? (give Bldg & Room #)

A. Do file cabinets have locks? Yes_____ No_____

B. Are computers password protected? Yes_____ No_____

2. What storage location is listed in the iStar application?

3. Where are the consent documents stored?

A. Are they stored in an orderly fashion? Yes_____ No_____

If no, explain

IV. CONSENT INSPECTION

4. Are the consent documents complete (i.e. any missing pages)? Yes_____ No_____

5. Did subjects sign a valid consent document? Yes_____ No_____

(match signature date with expiration date stamped on the consent)

If no, explain:

6. Do the consents have all required signatures and dates? Yes_____ No_____

(subject, PI, witness, legally authorized rep, translator, etc.)

If no, explain:

7. Does the iStar application (item 22.1) indicate inclusion of minors?

Yes_____ No_____

If yes, was parental permission obtained? Waived?

Yes_____ No_____ Waived_____ NA_____

8. Did the minor subjects sign an assent form? Waived?
 Yes____ No____ Waived____ NA____

Miscellaneous

9. Did the PI provide documentation (e.g. CRF, consent) requested prior to the site visit for each subject identified by CQI staff?

Yes____ No____ NA____

If no, explain:

10. Were ALL requested documents made available to the assessment staff?

Yes____ No____

If no, explain:

Other Study Documents/Data (Questionnaires, Data Forms, etc.)

1. According to the iStar application (26.2), how will the data be recorded to protect privacy and is the research team following this method?

2. Does the PI have any documentation on adverse events, unanticipated problems, or protocol deviations? Was this reported in iStar?

IV. RECRUITMENT and CONSENT PROCESSES

<p>Is the process for subject identification and recruitment consistent with the IRB application and IRB policies? (Review Screening logs)</p>	
<p>Is the process for obtaining informed consent consistent with the IRB application and IRB policies? (skip if not observing consent)</p>	

V. CONTINUING REVIEW

Were any subjects enrolled during a lapse in IRB approval?	
Were any research procedures conducted during a lapse in IRB approval?	

Were continuing reviews submitted on time?	
Were any risks or required changes identified during continuing review? If yes, were they changes implemented?	

(Complete the sections below if the research follows a clinical protocol)

VI. DATA AND SAFETY MONITORING

Is a DSM Plan required? Why?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Details:
Did the PI specify a DSM plan in the iStar application?			
Is the study monitored by a DSMB?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Comments:
Does the PI have copies of DSMB reports and have they been submitted to the IRB?			
Is the PI is following the DSM plan?			

VII. INVESTIGATOR/SPONSOR RESPONSIBILITIES

(skip if industry sponsored)

Is the original IND/IDE application on file?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Comments:
Were issues raised by the FDA resolved prior to the study's initiation?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Comments:

Are all participating investigators listed on the 1572?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Comments:
If there are other participating sites, are IRB approvals on file for each site? (coordinating center only)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Comments:
How is the investigator monitoring the conduct of the study?	Comments:		
Have all required IND safety reports or reports of unanticipated adverse device effects been reported to the FDA in accordance with FDA regulations?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Comments:
If there have been any new findings during the course of the study, have reports been submitted to the local IRBs? (coordinating center only)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Comments:
Have protocol amendments and reports of new findings been reported to the FDA?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Comments:
Have annual progress reports been submitted to the FDA?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Comments:

VIII. Regulatory Binder Inspection

VIIIa.

Regulatory Item	Check	Drug/Device Studies Comments (if any)
Current and all prior versions of the Investigator's Drug or Device Brochure		
Current and all prior versions of the Protocol		
Current approved and all previously approved versions of the consent form		
Any written material (other than consent form) that is distributed to subjects		
All applications and reports submitted to the IRB		
All correspondence between the PI and IRB		
All IRB approval notices		
Sample Case Report Forms		
Copies of all adverse events reported to the sponsor or FDA, and IRB		
Regulatory Item	Check	Investigator-initiated IND studies (comments)
Form FDA-1571 and FDA correspondence for investigator-initiated IND studies		
Regulatory Item	Check	IND studies (comments, if any)
Form FDA-1572 for IND studies?		
All correspondence between the PI and study sponsor		
Sponsor monitoring log and corresponding reports		
Investigators' CVs		
Lab certification for all labs involved in the conduct of the study		
Range of normal values for labs performing study analyses		
Participant screening and enrollment log		

Lab results		
Drug or device accountability records		Drug/Device studies

VIII b. Case Report Forms

.Regulatory Item	Check	Case Report Forms
Original signed informed consent and or assent form		
HIPAA form(s): signed HIPAA Authorization form, Waiver, etc. or equivalent letter		
Copy of all lab, radiology, physical exams including eligibility tests (i.e. lab results, CT scan reports, etc)		
All notes/observations taken		
Copy of Adverse Events (AE) Reports and Case Report Forms		
Completed Data collection sheet, questionnaires, etc.		

IX. Alternate Version of Section VIII.

1. Monitoring Reports from Industry Sponsors, Cooperative, Research Groups, Federal Agencies, etc.

Adequate	Inadequate	N/A
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2. Correspondence, if Any, With Federal Agencies

Present	Not Present	N/A
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3. CVs or Other Information regarding those obtaining consent

Present	Not Present	N/A
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4. Certificates of Education for Human Subjects and HIPAA training (if applicable)

Present	Not Present	N/A
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5. Indication of initial protocol review and approval by IRB

Present	Not Present	N/A
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6. Indication of review and approval of any and all continuing reviews

Present	Not Present	N/A
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7. Indication of IRB review and approval of any and all protocol amendments

Present	Not Present	N/A
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15. A list of all subjects accrued. The investigators will be requested to provide the list in advance to the CQI Staff, so that the staff can randomly select an appropriate number of subjects from the list, in general, 10-20% of subjects listed.

Present	Not Present	N/A
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16. The signed consent forms for the randomly selected subjects

Present	Not Present	N/A
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17. Other documentation of the informed consent process if applicable.

Present	Not Present	N/A
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18. Approvals from other agencies, and groups (on or off campus)

Present	Not Present	N/A
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19. Are the subjects paid?

Yes	No
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20. Is there a payment log?

Yes	No	N/A
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X. Observation of the Consent Process

1. Was the environment in which the consent process took place conducive to thoughtful decision-making on the part of the subject?
2. Was the length of time devoted to the consent process sufficient?
3. Was the subject given adequate opportunity to ask questions?
4. Was the subject given adequate explanation of the research using appropriate simplified language?
5. Did the subject demonstrate an acceptable understanding of the research before signing the consent form?
6. Who obtains consent?