

Onsite Review Checklist (for QI staff use only)

QI staff: _____ Date of Review: _____ Reason: _____

General Information

Principal Investigator: _____ Institution/Division: _____

IRB Protocol Number: _____ Sponsor: _____

Type of study: Drug Device Tissue/Sample Repository
 Genetics Questionnaire Medical Records/Database
 Other: _____

Funding Sources (check all that apply): Industry Sponsor Department
 Government/NIH Foundation

Does the PI hold an IND or IDE? Yes No

Title:

Co-Investigator(s):

Study Staff:

Has PI or any study staff previously worked with the QI Program (substantial contact)? Yes No

Was the PI available during the onsite review? Yes No

Name of person(s) QI staff met with: _____

QI Staff Initials: _____

1. REGULATORY DOCUMENTATION

Corrective action required/government Corrective action required/Partners

- 1.1 Is the most recent approved protocol on file? Yes No
- 1.2 Are there previous versions of the protocol? Yes No
- 1.2.1 If yes, are all previous versions of the protocol on file? Yes No
- 1.3 Is this an FDA regulated study? (If yes, answer the following; if no, go to 1.4) Yes No
- 1.3.1 Is there a signed FDA 1572 on file? Yes No
- 1.3.2 Is the Clinical Investigator Financial Disclosure form on file for each individual listed on the 1572? Yes No
- 1.3.2.1 If no, describe: _____
- 1.3.3 Is there a signed FDA 1571 on file (when PI is IND sponsor)? Yes No
- (if yes, answer the following; if no, go to 1.4)
- 1.3.3.1 Are there 1571s on file for the following:
- | | | |
|--------------------------|------------------------------|-----------------------------|
| 1.3.3.1.a Original | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 1.3.3.1.b All amendments | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 1.3.3.1.c Annual Reports | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
- 1.3.3.2 Who is listed as the monitor in section 14 of the 1571? _____
- 1.4 CVs of PI/Co-PI and all study staff on file? Yes No
- 1.5 For all CVs on file, are they updated within the past two years? Yes No
- 1.6 For all CVs on file, are they signed and dated? Yes No
- 1.7 Is there a subject enrollment log? Yes No
- 1.7.1 If yes, is the subject enrollment log complete? Yes No
- 1.8 Is/will the site (be) monitored? (If yes, answer the following; if no, go to 1.9) Yes No
- 1.8.1 How often? _____
- 1.8.2 Is there a monitoring log? Yes No
- 1.8.2.1 If yes, is the monitoring log complete? Yes No
- 1.8.3 Is there a monitoring plan in the approved protocol? Yes No
- 1.9 Is there a staff signature log? Yes No
- 1.9.1 If yes, is staff signature log complete? Yes No
- 1.10 Has PI delegated responsibilities? Yes No

QI Staff Initials: _____

1.10.1 If yes, is there documentation of delegation of responsibility? Yes No

1.11 Is there an investigational drug or device? Yes No

1.11.1 If yes, is investigational product information on file? Yes No

(e.g. IB, Device manual, package insert, dose administration guidelines, etc.)

1.12 Are lab tests required? (If yes, answer the following with regard to all labs used; if no, go to 1.13) Yes No

1.12.1 Is lab **internal** or **external/commercial**? (Circle all that apply)

1.12.2 Are normal lab values on file? Yes No

1.12.3 Is lab certification on file? (e.g. CLIA) Yes No

1.12.4 Is the Lab Director's CV on file? Yes No

1.13 Is this an industry or FDA regulated study? Yes No

1.13.1 If yes, is correspondence to and from sponsor and/or FDA on file? Yes No

1.14 Is this a NIH funded study? Yes No

1.14.1 If yes, is NIH grant and progress reports to date on file? Yes No

1.15 Is there a DSMB for this study? Yes No

1.15.1 If yes, is a DSMB report or indication of DSMB review and/or recommendations on file? Yes No

1.15.1.1 If no, explain: _____

2. IRB DOCUMENTATION

Corrective action required/government Corrective action required/Partners

2.1 Does study staff listed on documents match those listed in Rex, initial application, amendments, etc.? Yes No

2.2 Is all correspondence (e.g. amendments, AE reporting forms and responses, submissions and notifications) to and from the IRB on file? Yes No

2.2.1 If no, what types of correspondence are missing? _____

2.3 Is initial IRB approval letter on file? Yes No

2.4 Date of Initial IRB Approval: _____

2.5 Have there been any continuing reviews of this study? Yes No

2.5.1 If yes, how many continuing reviews? _____

QI Staff Initials: _____

Date of CR submission	Approval date	Copy of submission on file? (Yes or No)	Copy of original approval letter on file? (Yes or No)

2.5.2 Was each CR submitted on time (45 days prior to expiration date)? Yes No

2.5.3 Any lapsed period(s) between approval date and expiration date? Yes No

(If yes, answer the following; if no, go to 2.6)

2.5.3.1 Note the dates: _____

2.5.3.2 Was any subject enrolled during this lapsed period? Yes No

2.5.3.2.1 If yes, was a protocol violation submitted to IRB? Yes No

2.5.3.3 Were any study procedures done during the lapsed period? Yes No

2.5.3.3.1 If yes, were they approved by an IRB Chair? Yes No

2.5.3.3.2.1 If no, was a protocol V/D submitted to the IRB? Yes No

2.6 Have there been any changes to the study? Yes No

2.6.1 If yes, have all changes to the study been approved by the IRB before implementation? Yes No

Record amendment information:

Date of amendment submission	Approval date	Copy of submission on file? (Y/N)	Copy of original approval letter on file? (Y/N)	Describe what was amended:

QI Staff Initials: _____

3. SUBJECT RECRUITMENT PROCEDURES

Corrective action required/government Corrective action required/Partners

3.1 Potential subjects are identified by (check all that apply):

- Investigators (Medical Record Review; Database; Clinical Practice; Previous Study)
- Treating Physician or PCP
- Subject response to recruitment materials
- Other _____

3.2 Is initial contact made in compliance with institutional requirements/approved protocol? Yes No

3.2.1 If no, explain: _____

3.3 Are there recruitment materials for this study? (If yes, answer the following; if no, go to 3.4) Yes No

3.3.1 Are all recruitment materials (including pre-screen, intake form) IRB approved? Yes No

3.3.2 Are all currently approved recruitment materials on file? Yes No

3.3.3 Have there been changes to recruitment materials or methods? Yes No

3.3.3.1 If yes, was an amendment submitted to IRB to approve modified recruitment materials or methods? Yes No

3.4 Is a pre-screening telephone interview conducted? (If yes, answer the following; if no go to 4) Yes No

3.4.1 Is there a copy of the intake form used? Yes No

3.4.2 Is it approved by the IRB? Yes No

4. INFORMED CONSENT PROCESS

Section not applicable (consent waived)

Corrective action required/government Corrective action required/Partners

4.1 Is written consent required to be obtained by the IRB approved protocol? Yes No

4.1.1 If yes, how many versions of the consent form are there? _____

Valid date	Expiration date	Master copy of approved consent form on file? (Y/N)

QI Staff Initials: _____

4.2 Have any subjects been enrolled in this study? Yes No
(If no, skip the remaining questions in this section and go to section 5)

For the consent forms and documentation reviewed, complete the following questions:

4.3 How many subjects are/were enrolled to date? _____

4.4 How many subjects is/was the site approved to enroll? _____

4.5 How many subjects were chosen for review? _____ (use attached sheet for detailed observations)

4.6 Is the subject ID on all pages of the consent form? Yes No

4.7 Did each subject sign his/her own consent form? Yes No

4.8 Did each subject date his/her own consent form? Yes No

4.9 Did the study rep sign the consent? Yes No

4.10 Did the signing study rep date the consent? Yes No

4.11 Did anyone not approved by the IRB to consent subjects sign as study representative? Yes No

4.11.1 If yes, who? _____

4.12 Are there any unexplained date discrepancies? Yes No

4.12.1 If yes, describe: _____

4.13 Were invalid consent forms used? Yes No

4.14 Does the consent form include option sections? (If yes, answer the following; if no, go to 4.15) Yes No

4.14.1 Were all options completed? Yes No

4.14.2 If no, describe: _____

4.15 Did each subject receive a copy of the signed and dated consent form? Yes No

4.16 Is subject's receipt of a copy of the signed consent form documented? Yes No

4.17 Should a copy of the subject's signed consent form be submitted to Medical Records? Yes No

4.17.1 If yes, was a copy submitted? Yes No

QI Staff Initials: _____

5. SUBJECT SELECTION

Section not applicable (no subjects enrolled)

Corrective action required/government Corrective action required/Partners

5.1 Is there documentation of subject eligibility (note format used)? Yes No

5.1.1 Does documentation of eligibility for each subject include the dated signature/initials of the person obtaining eligibility information? Yes No

5.2 Did all subjects meet eligibility criteria? Yes No

5.2.1 If no, were they excluded appropriately? Yes No

5.2.1.1 If no, was a protocol deviation submitted to the IRB? Yes No

6. ADVERSE EVENT REPORTING

Section not applicable (no subjects enrolled)

Corrective action required/government Corrective action required/Partners

6.1 Is there evidence/documentation that any AEs occurred in the study? Yes No

(If yes, answer the following; if no, skip to 6.4)

6.1.1 If yes, how many AEs? _____ How many SAEs? _____

6.2 Have all AEs been reported to the IRB in accordance with the institutional regulations? Yes No

6.3 How many AEs were reported at the last continuing review? _____

6.4 Are there AEs that the site plans to report at the next continuing review? Yes No

For all SAEs complete the following information:

Subject ID	Date of Event	Date of Submission	Date of IRB Notification	Notification on file? (Y/N)

6.5 Have any off-site SAE/AEs (safety reports) been received? Yes No

6.5.1 If yes, have they been correctly reported to the IRB? Yes No

QI Staff Initials: _____

7. PROTOCOL VIOLATIONS/DEVIATIONS

Section not applicable (no subjects enrolled)

Corrective action required/government Corrective action required/Partners

7.1 Have any protocol violations/deviations occurred that have not been reported to the IRB? Yes No
(If yes, answer the following; if no, go to 7.2)

7.1.1 How many? _____

7.1.2 Of these, how many occurred in the consent process? _____

7.2 For reported violations/deviations, complete the following information:

Date of V/D submission	Date of IRB Notification	Copy of signed and dated submission on file? (Y/N)	Copy of approval letter on file? (Y/N)

7.4 Were there any exceptions? Yes No

7.4.1 If yes, was IRB approval obtained prior to implementation? Yes No

7.5 Are there any sponsor-approved protocol violations/deviations? Yes No

7.5.1 If yes, have the sponsor-approved v/d been correctly reported to the IRB? Yes No

8. DRUG/DEVICE DISPENSING & ACCOUNTABILITY

Section not applicable (not a drug/device study)

Corrective action required/government Corrective action required/Partners

8.1 Is there documentation of drug/device use for each subject? Yes No

8.2 Who is responsible for shipping/receiving?

Study Site Research Pharmacy Other _____

8.2.1 If the site is responsible, are shipping receipts/packing slips on file? Yes No

QI Staff Initials: _____

8.3 Who is responsible for storage?

Study Site Research Pharmacy Other _____

8.3.1 If the site is responsible, are appropriate logs
(e.g. temperature) maintained?

Yes No

8.4 Who is responsible for drug dispensing to the subject?

Study Site Research Pharmacy Other _____

8.4.1 If the site is responsible, are appropriate logs
(e.g. accountability) maintained?

Yes No

8.5 Who is responsible for drug accountability with the subject?

Study Site Research Pharmacy Other _____

8.6 Is there appropriate documentation for the return and/or destruction of drug/device?

Yes No

8.7 Is there evidence of any drug/device related errors to date?

Yes No

8.7.1 If yes, have they been reported to the IRB appropriately?

Yes No

9. DATA COLLECTION & SOURCE DOCUMENTATION

Corrective action required/government Corrective action required/Partners

9.1 How is data captured? CRF eCRF Data collection sheets Other: _____

Remainder of section not applicable (e.g. no subjects enrolled)

9.2 Is data collection complete for each subject?

Yes No

9.3 Does CRF/data collection sheet include dated signature/initials
of the person obtaining the information?

Yes No

9.4 Are there adequate and complete source documents to corroborate
data entries for each subject?

Yes No

9.4.1 If no, describe: _____

9.5 Do source documents include dated signature/initials of the person obtaining the
information?

Yes No

9.6 Are changes/cross-outs (if any) routinely initialed and dated in subject file?

Yes No

QI Staff Initials: _____

10. RECORD KEEPING

Corrective action required/government Corrective action required/Partners

10.1 Is there a binder/folder for regulatory documents? Yes No

10.2 Is there a binder/folder for IRB correspondence/documents? Yes No

10.3 Is there a study file for each subject? Yes No

10.4 Is there documentation of any inappropriate disclosures of confidential information? Yes No

10.4.1 If yes, describe. (eg. Identifiable health info, status as a research participant, etc.)

11. ALLOCATION OF RESPONSIBILITIES

Corrective action required/government Corrective action required/Partners

11.1 Who prepares reports to the IRB? PI Co-I Study Staff Other _____

11.2 Are responsibilities allocated appropriately? Yes No

11.2.1 If no, describe (e.g. lacks appropriate training, etc.): _____

12. GENETIC RESEARCH

Section not applicable (study does not involve genetic samples)

Corrective action required/government Corrective action required/Partners

12.1 Is written consent required? Yes No

12.2 Are/Were subject identifiers collected? Yes No

12.2.1 Where are identifiers stored; how are they maintained? (e.g. separate, secure locked location – be as specific as possible):

12.3 Are samples coded? Yes No

12.4 Is there any secondary use of samples? Yes No

12.4.1 If yes, is there IRB approval for these uses? Yes No

QI Staff Initials: _____

- 12.5 Are immortal cell lines created? Yes No
- 12.6 Are there procedures in place to remove samples? Yes No
- 12.7 Are these procedures described in the consent form? Yes No
- 12.7.1 If no, explain: _____
- 12.8 Are samples being sent to 3rd parties? Yes No
- 12.8.1 If yes, are these samples anonymized? Yes No
- 12.8.1.1 If no, explain: _____
- 12.9 Where are samples stored? _____
- 12.10 Are there provisions in place for dealing with sample/storage failure? Yes No
- 12.11 Are "mailers" being used to collect samples? Yes No
- 12.11.1 If yes, provide details (e.g. when/how consented, timelines, etc.) _____
- 12.12 Is there any evidence of unintentional disclosures? Yes No
- 12.12.1 If yes, have they been reported as unanticipated problems to the IRB? Yes No