



Instructions for Completing the Continuing Review Principal Investigator Information Report Form

Federal regulations require continuing review of approved research at intervals that are appropriate to the degree of risk, but not less than once per year. Continuing review of ongoing research is necessary to examine risks, potential benefits, informed consent, safeguards and any new information that may affect the subjects' willingness to participate.

Section A: Main focus is to clarify the number of consented subjects participating in your study.

When determining the category of each subject, please remember that each subject must fit into ONLY 1 (one) category.

A. Indicate the total number of subjects that have signed a consent form and are currently active. Active subjects include those that are currently taking the study drug, using a device, participating in protocol procedures, and/or being followed but are NOT withdrawn.

Next: Separate the total number of subject listed in box A by identifying which group they belong in:

1. Those who are active but not withdrawn.
2. Those who have completed the procedural portion of the study and are now in follow-up.

B. Indicate the total number of subjects that have signed a consent form, completed the study, and are no longer being followed.

C. Indicate the total number of subjects that have signed a consent form, but were discontinued for reasons such as: serious adverse events (SAE), adverse events (AE), found ineligible to participate, or other.

Next: Separate the total number of subject listed in box C by identifying which group they belong in:

1. Those who were not eligible to participate in the study.
2. Those who were withdrawn due to an SAE or AE.
3. Those who withdrew for any other reason than those listed above.

D. Indicate the total number of subjects that have signed a consent form but are currently in the pre-screening process.

E. Indicate the total number of subjects that have signed a consent form.

1. No investigator may involve a subject without legally and effectively obtaining an informed consent from the subject or the subject's legally authorized representative. If this has taken place, you will need to complete the Ethical Review Committee's Deviations/Violations Report Form.

EXAMPLE FOR FORMULA:

| | |
|--|---|
| A. How many subjects at your site are currently active? | A: 8 |
| 1. Of those active subjects in answer A, how many are actively on study drug / in study procedures? 6 | |
| 2. Of those active subjects in answer A, how many have completed study drug / procedures but are still in follow-up? 2 | |
| B. How many subjects at your site (to date) have completed the entire study? | B: 15 |
| C. How many subjects at your site (to date) signed a CF and then discontinued prior to completion? | C: 10 |
| 1. Of those subjects in answer C, were any consented but discontinued before treatment and/or study procedures began? If yes, how many? 8 | <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes |
| 2. Of those subjects in answer C, were any discontinued due to an SAE or AE? If yes, you are required to identify the subject number and provide a description of the event for each: 1 Study participant #ABC123; Subject discontinued due to death | <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes |
| 3. Of those subjects in answer C, did any discontinue for any other reason(s) or were any lost to follow-up? If yes, you are required to identify the subject number and provide a description of the event for each: 1 Study participant #XYZ789; Subject moved out of state | <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes |

D. How many subjects at your site (to date) are in the screening stage? **D: 2**

E. How many **total** subjects at your site (to date) have signed an Informed Consent Form? **E: 35**

1. Was informed consent obtained from all enrolled subjects prior to performing any study procedures? No Yes

If no, an explanation is required: _____

The following formula must work-out or report will not be accepted.

| | | | | | | | | |
|---------------------------------|---|----------------------------------|---|----------------------------------|---|---------------------------------|---|----------------------------------|
| Answer to A: 8 | + | Answer to B: 15 | + | Answer to C: 10 | + | Answer to D: 2 | = | Answer to E: 35 |
|---------------------------------|---|----------------------------------|---|----------------------------------|---|---------------------------------|---|----------------------------------|

Section B: Main focus is to verify that the investigator is compliant with their role as the PI.

1. Provide a summary of any adverse events that have exceeded the expected frequency or severity and/or deviations.
2. Discuss any unanticipated problems involving risk to subjects or others not otherwise discussed in step 1.
3. Report any complaints that indicated an unanticipated study-related risk.
4. Discuss any new findings related to the study that you, as the PI, have discovered.
5. Discuss any new findings relating to study risks that you, as the PI, have discovered. Also, please indicate your assessment of whether any new findings related to questions 1-4 should be provided to study participants.
6. Discuss any new findings relating to study benefits that you, as the PI, have discovered.
7. List any changes to confidentiality procedures and/or safeguards that have changed within the last year.
8. List any publications, related to the study, which you have been involved with.
9. If the PI, member of the study team, and/or their immediate family members, acquired financial involvement with the study sponsor, this creates a potential conflict of interest, and must be disclosed.
10. Discuss any past (*within the last year*), current, or future suspensions you might/may have at your local hospital.
11. Discuss any past (*within the last year*), current, or future interruptions with your medical license.
12. Discuss any past (*within the last year*), current, or future claims with the licensing agency.
13. Discuss any past (*within the last year*), current, or future legal actions that have/will be filed.
14. Discuss if the Federal Drug Administration (FDA) has audited you.

Section C: Main focus is to verify that the sub investigator(s) are compliant.

1. Discuss any past (*within the last year*), current, or future interruptions with their medical license(s).
2. Discuss any past (*within the last year*), current, or future suspensions they might/may have at their local hospital.
3. Discuss any past (*within the last year*), current, or future claims with the licensing agency.
4. Discuss any past (*within the last year*), current, or future legal actions that have/will be filed.

Section D: Main focus is to obtain authorization of the application.

Only the Principal Investigator needs to complete the medical license portion of the application.

Please submit a copy of the current medical license for any and all Sub Investigators. ERC has already confirmed all PI's during the continuing review process.

Completion of the PI Checklist is not required. It is a tool for the PI and/or Coordinator.

PI must sign the application. Please do not use a stamp.