|  |
| --- |
| Continuing Review of IRB-Approved Clinical Research Application Instructions |

#### How to complete your application

1. This form must not be handwritten
2. Fill out all of the questions on this form completely
3. Attach supporting documentation: consent form(s), assent form(s), protocol, survey instruments, interview schedules, solicitation letters, advertisements, etc

|  |  |
| --- | --- |
| Continuing Review of IRB-Approved Clinical Research Application FormVersion 2.2Updated December 16, 2005.This application form is based on the University of Minnesota IRB's *Continuing Review of IRB-Approved Medical Research* and has been adapted with their permission. | IRB Use Only |
| Date received: \_\_\_\_\_\_\_\_\_\_\_Project Number: \_\_\_\_\_\_\_\_\_IRB Review Date: \_\_\_\_\_\_\_\_[ ] Approved as submitted[ ] Approved with minor suggestions for changes[ ] Approved with stipulations[ ] Deferred[ ] Not approved |

|  |  |  |  |
| --- | --- | --- | --- |
| Study #  |  | Expiration Date: |  |
| Study Title: |       |
| PI: |  |

**1. What is the status of this study?**

[ ]  Data Analysis Only.

[ ]  Study on Hold.

[ ]  Study Not Begun.

[ ]  Following Subjects.

[ ]  Recruiting Subjects. *Include a copy of the currently approved consent form(s) used in this study (even if unchanged from previous submission). Application forms received without consent form(s) will be returned.*

[ ]  Completed/Discontinued. Should the IRB inactivate this study? [ ] Yes. [ ] No.

**2. Total number of subjects *approved* for the study:**

**3. If this is a multi-center study and available, what is the total national accrual to date?**

**4. Complete the chart below with the numbers of subjects *enrolled since* *last IRB review (continuing or initial):***

If this study is supported by NIH funds, the demographic information is required. If not, complete “Totals” column only.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Ethnic Categories | Racial Categories |  |
|  | Hispanic or Latino | Not Hispanic or Latino | **Ethnic Category Total** | American Indian or Alaskan Native | Asian | Black, not of Hispanic Origin | Native Hawaiian or Pacific Islander | White, not of Hispanic Origin | More than one race | Other or Unknown | Racial Category Total | Totals |
| **F****emale** |       |       |       |       |       |       |       |       |       |       |       |  |
| **Male** |       |       |       |       |       |       |       |       |       |       |       |  |
| **Unknown** |       |       |       |       |       |       |       |       |       |       |       |  |
| Total |       |       |       |       |       |       |       |       |       |       |       |  |

**5. Complete the chart below with the numbers of subjects *enrolled in the study to date*:**

If this study is supported by NIH funds, the demographic information below is required. If not, complete “Totals” column only.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Ethnic Categories | Racial Categories |  |
|  | Hispanic or Latino | Not Hispanic or Latino | **Ethnic Category Total** | American Indian or Alaskan Native | Asian | Black, not of Hispanic Origin | Native Hawaiian or Pacific Islander | White, not of Hispanic Origin | More than one race | Other or Unknown | Racial Category Total | Totals |
| **Female** |       |       |       |       |       |       |       |       |       |       |       |  |
| **Male** |       |       |       |       |       |       |       |       |       |       |       |  |
| **Unknown** |       |       |       |       |       |       |       |       |       |       |       |  |
| Total |       |       |       |       |       |       |       |       |       |       |       |  |

**6. Is this project funded?**

[ ] Yes. [ ] No. **If yes**, provide current funding agency name(s) and grant number(s):

|  |
| --- |
|       |

**7. Has your relationship with the study sponsor changed since IRB review in any way that might require conflict of interest disclosure under the Northwestern Health Sciences University policy on Conflict of Interest? (e.g. stock purchases, royalty payments, patents, Board position, etc.)**

 [ ] Yes. [ ] No. **If yes**, explain:

|  |
| --- |
|       |

**8. Is this research a clinical investigation of a new drug or medical device?**

 [ ] Yes. [ ] No. **If yes**, provide IND/IDE #:

9. Have translated consent short forms been used in conjunction with an interpreter to obtain subject consent for this study?

[ ] Yes. [ ] No. If yes, explain which translations were used and in what context:

|  |
| --- |
|       |

**10. Have there been any changes in Principal Investigator, Co-Investigators, or research personnel who have responsibility for the consent process, direct data collection from subjects, or follow-up. ?**

 [ ] Yes. [ ] No. **If yes**, explain. (Note: Describe the training and education completed in the protection of human subjects for any new individual involved with human subjects in the study.)

|  |
| --- |
|       |

**11. Summarize preliminary information about any results and/or trends:**

|  |
| --- |
|       |

**12. Describe any unanticipated problems, subject withdrawals, or complaints about the research in the conduct of the study:** *Attach an adverse and unexpected events overview report and an adverse and unexpected events description and resolution report.*

|  |
| --- |
|       |

**13. Have any serious and unexpected adverse events been reported to the IRB?**

 [ ] Yes. [ ] No. **If yes**, list events and dates and indicate if adverse event trends suggest that changes are needed in the consent form or in the study?

|  |
| --- |
|       |

**14. Is the side-effect profile for subjects different from the initial expectation?**

 [ ] Yes. [ ] No. **If yes**, describe what has changed from the initial expectations:

|  |
| --- |
|       |

**15. Is there anything in the relevant recent literature that the IRB should know about concerning the continuation of this research?**

 [ ] Yes. [ ] No. **If yes**, describe the literature and why it is of concern:

|  |
| --- |
|       |

**16. List changes in protocol and dates approved by the IRB:** *(if none, put “none”)*

|  |
| --- |
|       |

**17. If you would like this application to be considered by the IRB for expedited review, complete 17a. If not, continue to section 18.**

Continuing review of research previously approved by the convened IRB qualifies for expedited review as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified since the last review; or

(c) where the remaining research activities since the last review are limited to data analysis.

Continuing review of research previously approved for expedited review qualifies for expedited review as follows:

 (d) where the research activities present no more than minimal risk and involve only procedures in one or more of the expedited review categories 1-7 as previously approved.

**17a. Which expedited review category (a-d) apply to this research (include all that apply)?**

18. Submit the following materials along with this form for IRB continuing review:

1. All current consent/assent forms *(IRB-approved HIPAA Authorization forms* ***do not*** *need to be included)*

2. Any interim analysis that has been completed by a Data Safety Monitoring Board or other group since last IRB review.

**If this is a multi-center study,** submit any information from other sites.

***19. The Principal Investigator’s original signature is required.***

By signing below, the Principal Investigator assures the information contained on this form is true and accurate.

|  |  |
| --- | --- |
|  |  |
| **Original Signature of Principal Investigator** | **Date** |
| Name:       | Title:       |  |