**Actions to Take Before Completing a**

**Request for Continuation Form**

**Before you begin to complete the request for continuation form, the following actions should be taken.** After you have completed the actions below, complete the request for continuation form. Further guidance is available in the IRIS User manual titled:  **“*The Basic of Study Management – pages 7-23*”.**

**Training Requirement:**

If your Request for Continuing Review includes adding new study personnel to the study, make sure the new personnel listed in the Modification (e.g. new Co-investigator, new Study Coordinator, new Data Manager, new Consenter) are up-to-date with CITI Training***.*** Training must have been completed within the past 3 years to be valid. Training status may be checked on the master training list available at <https://ovpr.uchc.edu/services/rics/hspp/citi-instructions/>

**Financial Disclosures:**

Download from the IRB web site (<https://ovpr.uchc.edu/services/rics/hspp/irb/irb-instructions-forms-and-samples/>) the [***Significant Financial Interest form***](http://research.uchc.edu/wp-content/uploads/sites/1137/2015/08/HSPO-Form-SFI-Disclosure-Review.docx) and complete the process for obtaining disclosures and sign-off according to the instructions. If applicable, the signed/ completed SFI form will be attached to the request for continuation form.

**Submission Checklist**

As applicable to the type of review being requested (i.e. full board or expedited), download from the IRB web site (<https://ovpr.uchc.edu/services/rics/hspp/irb/irb-instructions-forms-and-samples/> ) either the [***Checklist for Initial and Continuing Review Full Board***](http://research.uchc.edu/wp-content/uploads/sites/1137/2015/08/HSPO-Form-ApplicationCheckListFullBoard.docx) or the [***Checklist for Initial and Continuing Review Expedited***](http://research.uchc.edu/wp-content/uploads/sites/1137/2015/08/HSPO-Form-ApplicationCheckListExemptExpedited.doc) ). Complete the checklist to ensure you have all relevant documents ready for submission. Documents that may be applicable to a request for continuation are notated with a **C**. The checklist and the relevant documents will be attached to the request for continuation form.

Use the comment box to provide clarifying comments to the IRB. For example, if the study is closed to enrollment, you could indicate that since enrollment is closed the consent form is no longer being submitted for approval.

**Enrollment Data:**

Ensure you have the enrollment information for the study available. If this is not the first request for continuation (e.g. study has been open form more than one year), the enrollment data should build off of the previously submitted request for continuation. You should use the enrollment data in the previously approved continuation form as a starting point.

For studies limited to retrospective chart reviews you will need to know the number of charts reviewed. Others studies will require enrollment data broken out as follows:

*Overall Numbers*: You will need to know the number of subjects who were enrolled at/by UConn Health during last year (i.e. subjects who were consented) and over the life of the study; the number of screen failures in the past year and over the life of the study, the number of withdrawals over during the last year and over the life of the study. For the first request for continuation, the numbers for the life of the study and over the past year will be the same. The table to be completed within the continuation form is provided here for reference.

|  |  |  |
| --- | --- | --- |
| **Local Enrollment Data** | **Since Start** | **Within Past Year** |
| **Number Enrolled** |  |  |
| **Number Screen Failures** |  |  |
| **Number Withdrawn** |  |  |

*Phase of Study Numbers*: Since the start of the study, provide the number of subjects in the active research phase, the number in long-term follow-up, and the number who have completed the study. The number in these three phases should equal the number enrolled since the start of the study, less screen failures and withdrawals.

The table to be completed within the continuation form is provided here for reference.

|  |  |
| --- | --- |
| **Local Enrollment Status:** | **Number**  |
| # Currently in Active Phase |  |
| # Currently in Long-term Follow-up |  |
| # Completed Entire Study |  |

*Racial/Ethnic Data by Gender:* Since the start of the study, for all subjects who provided consent, inclusive of subjects who were screen failures or withdrew, indicate by gender the number in each racial/ethnic group. The chart that will be required to be completed is provided below for reference. The total reported here should equal the total reported since the start of the study in the first table. The table to be completed within the continuation form is provided here for reference.

|  |  |  |
| --- | --- | --- |
| **Ethnic Category** | **Females** | **Males** |
| ***Hispanic or Latino*** |  |  |
| ***Not Hispanic or Latino*** |  |  |
| ***Unknown*** |  |  |
| **Racial Category** |  |  |
| ***American Indian/Alaska Native*** |  |  |
| ***Asian*** |  |  |
| ***Native Hawaiian or Other Pacific Islander*** |  |  |
| ***Black or African American*** |  |  |
| ***White*** |  |  |
| ***More Than One Race*** |  |  |
| ***Unknown or Not Reported*** |  |  |