

Use this form to terminate a project that is complete.

# **Research Title:**

# **IRB #:**

# **Personnel**

1. Principal Investigator (PI)

|  |  |
| --- | --- |
| Name (Last, First) | Degree(s) |
| Department | [ ] Student/Fellow/Resident[ ]  Physician Staff[ ]  Nursing Staff  |
| Mailing Address (if other than 800 W. Central Road) |
| Phone Number | E-mail Address |

# Termination Criteria

1. Pleasecheck the following boxes to confirm this project meets the criteria for termination.

[ ]  No patients were enrolled

[ ]  There are no active patients on the study

[ ]  No additional data will be collected on the patients

[ ]  If applicable, the close-out visit has been conducted (attach close-out letter from sponsor) or

[ ]  This is not an industry sponsored study/close out visit not required

# Enrollment

1. Initial approval was given for Click here to enter text. Subjects
2. Over the term this study was open to accrual, Click here to enter text. subjects were enrolled (include all patients who signed a consent form regardless of final eligibility)
3. This research is being terminated because:

[ ]  there has been no accrual, and accrual has been determined to be not feasible at our site

[ ]  all subjects have completed the study, and data collection/analysis has been completed

[ ]  of safety reasons (there has been unexpected serious harm to patients)

[ ]  there was a detrimental change to risk/benefit ratio

[ ]  the research intervention has been found to be not effective

[ ]  there was a loss of funding/support there was serious non-compliance

[ ]  Other (please describe):

1. Have any subjects withdrawn from the study since the last annual renewal?

[ ]  No

[ ]  Yes\* (If yes, please attach a summary of reasons for withdrawal.)

1. Have there been any subject complaints since the last annual renewal?

[ ]  No

[ ]  Yes\* (If yes, please attach a summary of these complaints).

1. Have there been any breaches of subject confidentiality since the last annual renewal?

[ ]  No

[ ]  Yes\* (If yes, please attach a summary of breaches of subject confidentiality).

1. Have there been any SERIOUS adverse reactions associated with the conduct of this research protocol at this site or, if applicable, at other sites that were not previously reported?

[ ]  No

[ ]  Yes\* (If yes, please attach a summary of these reactions).

1. Have there been any UNEXPECTED (i.e., to include reactions of a different nature or greater than expected severity or frequency) adverse reactions associated with the conduct of this research protocol at this site, or, if applicable, at other sites that were not previously reported?

[ ]  No

[ ]  Yes\*(If yes, please attach a summary of these reactions).

# Principal Investigator or designee

# I certify that the above information is correct, and that no patients are active on the study and all data collection has been completed:

Principal Investigator (Typed) Principal Investigator (Signature) Date

# IRB Reviewer

# Recommendation (check one):

[ ]  Approve as submitted

[ ]  Deferred for substantive changes (all changes must be listed in as much detail as possible, including document type and page number.

[ ]  Deferred for non-substantive changes

# Changes, Modifications, and Clarifications

Please list any changes, modifications, or clarifications required to the research protocol, informed consent form, or IRB application. If the research is to be deferred or disapproved, please also provide a brief explanation.

**Reviewers Name: Reviewers Signature: Date:**