

**Institutional Review Board**

**IRB STUDY CLOSURE FORM**

**Instructions:** Complete this form when an approved human subject research is **CONCLUDED** or **CANCELLED**. Studies that involved long-term follow-up of subjects or studies involving data analysis must remain open, even if enrollment of new subjects has ended. *Whenever possible, please include a separate final summary of the study with this form or a sponsor letter (if funded) requesting closure of the study.*

**Part A – General Information:**

|  |  |
| --- | --- |
| IRB Number: |  |
| Principal Investigator: |  |
| Department, phone number, and email address: |  |
| Study Title: |  |
| Faculty Advisor/Mentor (if applicable): |  |
| Number of total subjects enrolled: |  |

**Part B – Closure Information:**

1. **Study Status:**

|  |  |
| --- | --- |
|  | Confirm the study status is closed to enrollment, and all research related activities, long-term follow-up, and data analyses have been completed. |

1. **This research project is being closed for the following reason(s):** (Check all that apply.)

|  |  |
| --- | --- |
|  | All research activities including data analysis and reporting are complete. |
|  | Human Subjects involvement is complete (e.g., there is no follow-up planned with subjects, data no longer contain identifiers, and there are no identifying codes to the de-identified data that can link the data to individuals). |
|  | The research is no longer funded. |
|  | The PI never initiated the study. |
|  | The research project has been open for a period of three or more years, and the PI has neither enrolled any subjects in the study, collected any data from records, nor collected or received specimens during this interval. |
|  | The PI is leaving the institution. (Study closure at D’Youville may be appropriate even if the PI intends to continue the research activities at another institution.) |
|  | The sponsor is requesting closure. (Provide reason below.):  Enter your response here |
|  | The study is being closed for another reason. Please describe reason for closure:  Enter your response here |

|  |  |
| --- | --- |
| 3. | Were there any interim findings associated with this study?  Yes  No  If yes, summarize any preliminary findings resulting from the research in sufficient detail.  Enter your response here |
| 4. | Have there been, or will there be any new publications resulting from this study?  Yes  No  If yes, list each publication and provide a copy in PDF format.  Enter your response here |
| 5 | Were there any unanticipated problems?  Yes  No  If yes, summarize details, clarify when submitted to the IRB, and overall outcome.  Enter your response here |

**Part C – Participant Information:**

|  |  |  |
| --- | --- | --- |
| 1. | Target Enrollment (Total # of participants IRB approved to enroll): |  |
| 2. | Number of Participants Enrolled to Date: |  |
| 3. | Number of Participants Enrolled since last approval: |  |
| 4. | How many participants remain on study? If greater than 0, submit continuing review. |  |
| 5. | How many participants are considered off study? Must equal the sum of all below. |  |
|  | a. How many have completed participation? |  |
|  | b. How many have withdrawn of their own initiative? If any, explain why.  Enter your response here |  |
|  | c. How many have been removed by the PI? (ex: failed screening, erroneously enrolled)  Enter your response here |  |
|  | d. How many have been lost to follow up? |  |
|  | e. How many have died while on-study?  If any, clarify if related to study participation.  Enter your response here |  |
| 6. | Have any participant complaints been received?  Yes No  If yes, clarify complaint and resolution.  Enter your response here |  |
| 7. | Have any participants experienced any harm as a part of enrollment?  Yes  No  If yes, clarify harm and resolution.  Enter your response here |  |

**Record Retention**

Study records must be retained even if a study is closed or canceled before it is completed. For federally funded, supported, conducted, or regulated research, there are specific requirements that must be followed. You should familiarize yourself with these requirements.

For FDA-regulated research involving:

* Drugs (21 CFR 312.57 and 312.62): Retain records for 2 years after a marketing application is approved, or, 2 years after FDA is notified that investigational use has stopped, or longer if required by the sponsor
* Devices (21 CFR 812.140): Similar

For DHHS funded, supported, or conducted research, records must be retained for **3 years** after the last expenditure report on the grant.

**Part D - Investigator Assurance:**

I attest the information provided is accurate and complete to the best of my knowledge.

|  |  |
| --- | --- |
|  |  |
| Signature of Principal Investigator | Date: Select a date. |