**Daemen University IRB – Human Subjects Research**

**Study Closure Form**

IRB STUDY NUMBER:

*Please type only in the gray boxes. To mark a box as checked, double-click the box, select “checked”, and click “OK”.*

## Section I: Investigator Information

**Principal Investigator:**

Name *(Last, First, Middle Initial)***:**

Department:      Phone:       E-Mail:

**Additional Study Contact**:

Name:       Phone:       E-Mail:

Project Title:

Sponsor/Funding Agency:       Sponsor Number:

## Section II: Current Study Status

[ ]  Study was not initiated:

 Explain and skip to Section IV:

[ ]  Study closed prior to completion

 Date closed:

 Explain:

[ ]  Study completed Date completed:

**NOTE: This study can only be closed under the following circumstances and conditions:**

1. No further interaction/intervention with subjects, including follow-up, or access to subjects’ personally identifiable information for the purpose of research data collection.

**AND**

1. ***Either*** of the following (*mark the appropriate box*)

[ ]  All data analysis involving the research site(s), as indicated in the approved protocol is complete.

**OR**

[ ]  Data has been de-identified, with no codes or keys that would allow for the potential of identifying individuals in the future.

If applicable, explain what will happen to data collected as part of the research study (for instance, how long will data be kept, where will it be stored, when will the data be destroyed):

## Section III: Subject Summary

[ ]  Check here if your study utilizes records (such as medical charts) or specimens versus human subjects. When the form asks for the number of subjects, document the number of subjects for which data/specimens have been collected.

[ ]  Check here if the IRB has approved a waiver of consent for your study. When the form asks for the number of subjects, document the number of records that have been reviewed.

1. **SUMMARY TABLE**

Date first participant was enrolled:

|  |  |
| --- | --- |
|  | **On-Site** |
| **Since last IRB review** | Total number of participants **CONSENTED** |  |
|  | Total number of participants who were **INELIGIBLE TO PARTICIPATE** (did not meet inclusion criteria) |  |
|  | Total number of participants who had **WITHDRAWN** from the study |  |
| **Since beginning of study** | Total number of participants **CONSENTED** |  |
|  | Total number of participants who were **INELIGIBLE TO PARTICIPATE** (did not meet inclusion criteria) |  |
|  | Total number of participants who had **WITHDRAWN** from the study |  |
| Number of participants who have **COMPLETED** the study |  |

If necessary, please provide further explanation regarding the participant summary:

1. **WITHDRAWAL**

Have any participants withdrawn from the study since the last IRB review?

[ ]  No

[ ]  Yes, state the reasons for withdrawal:

1. **Vulnerable Populations**. Are any of the participants who have consented or enrolled in the study members of a vulnerable population?

**[ ]** No

 [ ]  Yes

 [ ]  Did your approved study protocol include recruitment of these participants?

 [ ]  Yes.

[ ]  No. **You must submit an amendment to the IRB to request the inclusion of these subjects.** Subjects in the following vulnerable populations were enrolled without IRB approval:

[ ]  Children [ ]  Pregnant Women and Human Fetuses

[ ]  Prisoners [ ]  Economically/Educationally Disadvantaged

[ ]  Cognitively Impaired [ ]  Students

## Section IV: Protocol Event Summary

1. **Since the last IRB review**, did any unanticipated problems, including adverse events, protocol deviations, participant complaints, or noncompliance occur that required prompt reporting to the IRB?

[ ]  No.

 [ ]  Yes. Were these events reported previously to the IRB?

 [ ]  No. Please explain why these events were not previously reported:

 [ ]  Yes. Provide a **summary** of these events:

 [ ]  Check here if the **summary** is attached.

1. Is there a data safety monitoring plan for this study?

 [ ]  No. This study is minimal risk (exempt or expedited).

 [ ]  Yes. Summarize the findings of the data safety monitoring since the last IRB review, explain why findings are not available, or indicate that a summary has been attached:

1. Describe the progress of the research, including any observations and information about study results or trends:

## Section V: Investigator Statement of Compliance

This form must be signed (either by typing in your name or inserting an electronic signature) and appended to the appropriate application for review.

By signing this form, the Principal Investigator assures that all information provided is accurate and assures that no further research activities will occur, including enrollment of new participants, interaction with or intervention on study participants, and analysis of identifiable data.

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator: |  | Date: |  |
|  |  |  |  |