**Marywood University - Institutional Review Board and Exempt Review Committee**

Immaculata Hall, 2300 Adams Avenue, Scranton, PA 18509

Phone: (570) 348-6211, x.2418 or Email: irbhelp@marywood.edu

 **CLOSURE REPORT FORM**

 **INSTRUCTIONS: Complete this form and submit it at [www.irbnet.org](http://www.irbnet.org) if your study is closing.** Do not submit writing assignments, theses or dissertation documents. The PI must e-sign in IRBNet before submitting. You are required to retain your records for as long as you have proposed after the official date of closure.

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| **Today’s Date** | Click or tap here to enter date. | **Principal Investigator** | Click or tap here to enter name. |
| **Study Title** | *Click or tap here to enter study’s title.* |
| **IRBNet Number** | Click or tap here to enter project #. | While viewing a project at IRBNet, the number appears at the top of each page, in brackets, directly under the photo header and next to the title. Enter only the number before the dash, which is the project number (not package number after the dash). |

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| **REASON FOR CLOSURE** |
| **Important:** Check only **ONE** box below. Insert information requested in orange. Do not list future dates. |
| **1**  | **Complete**[ ]  | The study was conducted and no activities remain (no advertising, enrollment, data collection, follow-up with subjects, or data analysis remains). **Enter completion date:** Click or tap here to enter date. |
| **2** | **Only De-Identified AnalysisRemains**[ ]  | The only remaining activity is analysis, but the information or specimens do not contain any identifiers, whether direct or indirect (e.g. coded/linked), and identities may not be associated by the investigator with the information or specimens collected. If your activity was covered by HIPAA, note that there are [18 identifiers](https://cphs.berkeley.edu/hipaa/hipaa18.html), so if any remain with analysis, closure cannot take place at this time. 1. **Enter the DATE data collection ended:** Click or tap here to enter date.
2. **Explain HOW records were de-identified or if identifiers were never recorded.**Click or tap here to enter text.
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| **3** | **Separation with Active Study**[ ]  | The Principal Investigator is separating from Marywood University and intends to continue the research under the auspices of another institution. No MU subjects, MU co-investigators, or MU research assistants will continue involvement after the separation. **Enter the New Institution’s FWA #, from** <https://bit.ly/2Nx6cjc>**:**  Click or tap here to enter FWA number.  |
| **4** | **Never Conducted**[ ]  | The research was approved, but either never initiated or no one enrolled.**Skip the rest of the form.**  |
| **5** | **Withdraw Before Approval**[ ]  | An application was submitted to a board, but is being abandoned while under review (no approval reached). **Skip the rest of the form.****Explain the reason for withdrawing:** Click or tap here to enter text. |
| **6** | **Other** [ ]  | The research must be closed for some other reason not described above. **Explain the reason:** Click or tap here to enter text. |

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| **STUDY DETAILS** |
| 1. **At your study’s end, what was the number** of subjects who had participated via intervention, interaction, or observation (even if online), OR the number of individuals’ existing records or specimens (secondary research) that you have accessed?
 | Click or tap here to enter #. |
| 1. How many subjects withdrew over the course of the study?
 | Click or tap here to enter #. |
| 1. Do you have signed copies of subjects’, LARs’ or parents’ informed consent forms, or children’s assent forms on file?
 | [ ]  Yes[ ]  No – Study was exempt, so no signatures were required or collected[ ]  No – Waiver of documentation was granted, waiving signature requirement[ ]  No – Full waiver of consent was granted, waiving the entire consent process |
|  | **YES** | **NO** |
| 1. Only if you checked reason 1, 3, 4, 5, or 6 on the first page of this form, are your study records directly identifiable, or are you able to associate identities with the information indirectly? Note that there are [18 identifiers](https://cphs.berkeley.edu/hipaa/hipaa18.html) if HIPAA applies. **If yes, describe how and where you will store your data.**  Click or tap here to enter text.
 | [ ]  | [ ]  |
| 1. Were all study procedures followed exactly as last approved?**If no, explain:**  Click or tap here to enter text.
 | [ ]  | [ ]  |
| 1. Have there been any adverse events or unanticipated problems that you have not previously reported, or have there been any concerns or complaints expressed by subjects?

**If yes, explain:**  Click or tap here to enter text. | [ ]  | [ ]  |
| 1. Did the research result in any publications, or are any pending?**If yes, name them:**  Click or tap here to enter text.
 | [ ]  | [ ]  |
| 1. **Clinical Trial Requirement:** If you have conducted a Federally-funded clinical trial\* **or** research involving an FDA-covered drug, supplement, biologic or device, have you registered study information and/or posted an IRB-approved informed consent form at [clinicaltrials.gov](https://clinicaltrials.gov/)? See information at [45 CFR 46.116(h)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116), [NIH](https://grants.nih.gov/policy/clinical-trials/reporting/index.htm) or [FDA](https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrialsgov-information).

\* Clinical trial means research in which one or more human subjects are assigned to one or more interventions (incl. placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes. | [ ]  Not Applicable[ ]  Yes[ ]  No |

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| **STUDY RESULTS** |
| **Provide a summary of your study’s purpose and results.** Skip if you chose reason 4 or 5 on p. 1. Click or tap here to enter text. |