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| **Date of Submission** |  | **Study Expiration Date:** |  |
| **Principal Investigator:** |  | **Protocol Number:** | **HR-** |
| **Study Title** |  | | |
| **Faculty Advisor:** |  | **Sponsor:** |  |

**Current study details:**

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| --- | --- | --- | --- |
| **General** | **Yes** | **No** | **If yes, please provide more information** |
| 1 .Does your study have federal funding or has it received funding since the last continuing review? (NIH, NSF, Dept. of Ed, etc…) |  |  | Please list your Marquette ORSP Institutional Proposal # (XXXXXXXX), which can be found in Kuali: |
| 2. Was your study approved to waive consent all together or to alter the consent form?  *[If yes, please complete Appendix A to request to continue this waiver under the new regulations]* |  |  |  |
| 3. Are you still recruiting subjects or collecting data from subjects? |  |  |  |
| 4. Are you only analyzing identifiable data at this point? |  |  |  |
| 5. Is your study testing the safety or efficacy of an FDA-regulated medical device or drug? |  |  |  |
| 6. Are there any protocol deviations or adverse events that have not previously been reported to the IRB? |  |  |  |
| 7. Has any information appeared in the literature or evolved from this or similar research that might affect the IRB’s evaluation of the risk/benefit ratio for human subjects involved in this research? |  |  |  |
|  | | | |
|  | | | |
| **Subjects** | | | |
| 8. Total number of subjects approved by the IRB: |  | | |
| 9. Total number of subjects consented **OR** total number of records/specimens used since the beginning of the study: |  | | |
| **\*If your total enrollment is approaching the total number of subjects approved by the IRB, consider requesting an increase using the amendment request on the following page. Make sure to submit any revised documents (protocol form, consent forms, etc…) if requesting this.** | | | |

**10. Summary**

Please provide a concise summary of the progress of the study to date. Include any subject withdrawal or removals and the reasons.

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**11. Amendment request:**

* If you are also requesting an amendment to the current approved protocol, please describe and provide justification for the requested changes below.
* Indicate all changes by modifying the Protocol Form and any other applicable study documents using track changes, or highlights to distinguish between previously approved information and current requested changes. *Documents submitted without distinguishing between “new” vs “old” content will be returned to the PI and/or instructed to do so*.

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**12. If this study is still enrolling subjects: Please check your current approved consent form(s) for one of the following statements and mark which one you have. IMPORTANT NOTE:** If your consent form does not contain a statement like one of the statements below, please add the applicable statement, highlight it and submit the revised consent form along with other documents for the continuing review.

**[ ]** The data or samples collected in this study may be de-identified and used for future research or given to another investigator for future research without consent.

**[ ]** The data or samples collected in this study will not be used or distributed for future research even if de-identified.

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| **Submission Instructions:** Email this completed form and any supporting documents as attachments to [orc@mu.edu](mailto:orc@mu.edu) with the following subject line:  **Continuing Review for [first and last name of PI], HR-[XXXX]**   * In the body of e-mail, include the title of the study and an itemized list of attachments (**MUST include protocol form and any consent/recruitment materials if subject contact is ongoing**) * The email address of the sender must be the Principal Investigator’s Marquette email. * If the PI is a **student**, the faculty advisor **must** be cc’d.   Once submitted, the IRB will e-mail back a response of receipt. If you do not receive an e-mail confirmation of submission within 2-3 days of submission, please contact the IRB by email ([orc@mu.edu](mailto:orc@mu.edu)) to verify receipt. |

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**Appendix A: WAIVER OR ALTERATION OF CONSENT**

Are you requesting:

[ ] Waiver of consent

[ ] Alteration or removal of required elements of consent- State what will be altered or removed**:**

Respond to the following questions:

|  |  |
| --- | --- |
| 1. Does the research pose more than minimal risk to the participants? |  |
| 2. Will the waiver adversely affect participants’ rights and welfare? |  |
| 3. Why would it be impracticable to carry out the research without the waiver or alteration? |  |
| 4. When appropriate, how will pertinent information be returned to or shared with participants? |  |
| 5. Explain why the study cannot be conducted using de-identified datasets (if appropriate). |  |
| 6. Is this study approved by governmental officials, designed to evaluate public service programs and is impracticable to be carried out without the waiver? |  |