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| **PI NAME** |  |
| **STUDY TITLE** |  |

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| --- | --- |
| Is this research funded by a federal agency (e.g., NIH, NSF, DoD, etc.)  **If yes,** identify the funding agency**:** | Yes No |
| Current Protocol Version/Date: | |

**Status of Research (choose one)**

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| --- | --- | --- | --- |
| **1.** |  | I have not initiated the research and no one has been enrolled. Explain: | |
|  | I will continue to consent and enroll subjects | |
|  | I will NOT continue to consent and enroll subjects **AND** (choose one) | |
|  | I am continuing to do research-related interventions with subjects or continuing to obtain/gather data about subjects;  **OR** |
|  | I am following subjects for long-term follow-up**\*** only. Please describe:  **OR** |
|  | I am only performing data analysis (all subject information has been collected)  If data are identifiable, you may be eligible to submit F-19 Annual Status Report instead of this form.  If all data have been permanently de-identified, you may be eligible to close the research but still continue analysis – please review F-12, Research Closure Form. |
|  | All research (including data analysis) is complete and the research should be closed. **DO NOT SUBMIT THIS FORM.** Please fill out and submit the Research Closure Form (F-12). | |
| \*Long-term follow-up includes:   * Research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); * Collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol.   Long-term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk. | | | |

**Enrollment**

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| --- | --- |
| **2.** | **Anticipated, IRB-approved enrollment number**: |

**Instructions:** Complete #3 **or** #4 – not both. For #3, please fill out each box – put “0” instead of leaving blank.

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| **Total Numbers enrolled since the beginning of the study** | | | |
| **3.** | a. | Adult participants (or LARs) who gave consent (do not include parents/guardians of minor participants) |  |
| b. | Minor participants (under 18) who gave assent (if applicable) |  |
| c. | Screen failures after consent/assent (Consented but did not meet inclusion/exclusion criteria) |  |
| d. | Passed screening and continued in the research |  |
| e. | Withdrew or were withdrawn by PI |  |
| f. | Completed the research |  |
| g. | Currently active (enrolled but has not completed all research procedures) |  |
| (A+B)-C=D & D-E-F=G  **If E+F+G is more than IRB approved enrollment number**, please explain: | | | |
|  | | | |
| **4.** | **If your research was granted a waiver of consent,** enter the number of individuals whose data, samples, etc. was collected. | |  |

**Staff**

|  |  |  |  |
| --- | --- | --- | --- |
| **5.** | **If there have there been any changes to research staff that have not already been reported to the IRB, please list those here.** | | |
| **Name** | **Add** | **Remove** |
|  |  |  |
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| If additional space is needed, attach a separate page. | | |
| **\*\*\*All added research staff must have active CITI IRB training.** Re-approval may be delayed due to expired training or new staff who have not completed the required training. **NOTE**: As the Principal Investigator, you are responsible for ensuring that all research staff have completed any other University or facility required training, such as training required by EHS. | | |

**Consent/Assent**

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| **6.** | **List the current version date of the following (if applicable)** | |
| Consent Form |  |
| Assent Form |  |
| Parental Permission Form |  |
| If the research has an approved Waiver of Documentation of Consent, list the current version date of the information sheet and/or consenting script: | |
| Check here if a Waiver of Consent was approved for this research. | |

**Study Problems/Issues**

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| **7**. | a. | In this approval period, were there any unanticipated problems involving risk to subjects or others?  **If yes**, provide a narrative summary of all unanticipated problems:    **If yes,** were these previously reported to the IRB during the approval period?  **If not previously reported**, explain: | Yes  No  Yes  No |
| b. | In this approval period, were there any adverse events or protocol deviations?  **If yes**, please provide a narrative summary: | Yes  No |
| c. | In this approval period, have you received any subject complaints?  **If yes**, summarize the complaint and provide the resolution, if applicable: | Yes  No |
| d. | In this approval period were there any subjects who withdrew or were withdrawn by the PI due to an adverse event, unanticipated problem, other reasons, or lost to follow-up (i.e., unable to contact any longer)?  **If yes**, please provide a reason for each withdrawal: | Yes  No |

**Study Assessment**

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| **8.** | a. | Describe the study progress so far, including any new information (published or unpublished) or interim findings, if any: | |
| b. | Has the risk level of the research changed?  **If yes**, explain: | Yes  No |
| c. | Have there been any unanticipated benefits to participants?  **If yes**, explain: | Yes  No |
| d. | Does your currently approved protocol require any modifications?  **If yes**, provide a revised protocol with the Change to Research (F-11) form in a separate package. | Yes  No |
| e. | Does the currently approved consent form require any modifications?  **If yes**, provide a tracked and clean version of the consent form with the Change to Research (F-11) form in a separate package. | Yes  No |
| f. | Does this study have an independent data and/or safety monitor (such as a DMC, DSMB, etc.)?  **If yes**, attach all reports that have not already been submitted to the IRB. | Yes  No |

**Publication**

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| **9.** | If the research results have been accepted for publication, poster presentation, conference presentation, etc., provide a citation and/or a copy of the article/presentation. |

**FDA Regulated Research**

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| **10.** | If your study involves an FDA regulated product, has there been any revision to the product information or investigator’s brochure?  **If yes**, attach those that have not already been submitted to the IRB. | Yes  No |

**International Research**

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| **11.** | Does this research have an international site(s)? | Yes  No |
| **If yes**, have there been any changes in the local context (cultural, political, religious, etc.) that has affected the conduct of the research?  **If yes**, explain. | Yes  No |

**Principal Investigator Attestation**

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| By submitting this form electronically through the IRBNet, you (the Principal Investigator or designee) are certifying the following:   * The information contained in this report is true, complete, and accurate to the best of your knowledge; * The research will be conducted in accordance with applicable laws, regulations, and Baylor University policies and procedures; * You are aware, as the Principal Investigator, you are ultimately responsible for the conduct of this research and the individuals to whom you delegate research responsibilities. |