**Research support and external relations |Institutional Review Board**

compliance@ki.se

### IRB RENEWAL FORM

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **SECTION A: General Information** | | | | | | | |
| 1. | EPM Dnr and date of approval: | |  | | | | |
| 2. | Project Title: |  | | | | | |
| 3. | Project Expiration Date: | |  | | | | |
| 4. | Principal Investigator(Prime): | | |  | | | |
| 5. | Principal Investigator(Subaward): | | |  | | | |
|  | | | | | | |
|  |
|  | Please provide name of funder and Grant number:    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |  |  | |

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| **SECTION B: Status of Study** | |
| 1. | What is the current status of your study? |
|  | Not Started. Study start planned within the next year. |
|  | New subject enrollment or data collection still in progress. |
|  | Enrollment closed but subjects are still involved in data collection procedures. |
|  | Subject involvement completed; analyzing data with identifiable information. |
|  | Subject involvement completed; analyzing data with no identifiable information (e.g., identifiers removed from data). |
|  | Other (explain): |

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| **SECTION C: General Study Information** | |
| 1. | Provide a brief summary (100-200 words) of the study progress to date. If the study as not begun explain reason for delay and likelihood that the study will start in the next year. |

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| 2. | Do you have any changes/amendments to your protocol application that need to be submitted for IRB review and approval? | |
|  |  | **I have modifications that need approval and provide the submitted and approved amendment to the Swedish EC (Etikprövningsmyndigheten) to this form** |
|  |  | **No modifications at this time.** |
| 3. | Attach a copy of the current consent form(s), only if you still have active subjects. This includes assent forms, parent/guardian consent forms, verbal consent scripts, etc. Not applicable for data analysis of identifiable information. | |
|  |  | **Documents attached:** |
|  |  | **Not Applicable** |

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| **SECTION D: Participants** | | | | |
|  | **Not Applicable** | | | |
| 1. | Indicate the **total number** of participants that have been enrolled **to date**. If you have multiple subject pools (e.g., parents and children) indicate how many total participants have been recruited for each SEPARATE group. | | | |
|  | | **PARTICIPANT GROUP** | **PLANNED ENROLLED/ ACTUAL ENROLLED** |  |
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|  | | **Comments:** | |  |

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| 3. | Provide a summary of any subject attrition since the last IRB review, and reasons for attrition, if known. |

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| **SECTION E:**  **unanticipated problems/adverse events** | |
| |  |  | | --- | --- | |  | **Not Applicable** | | |
| 1. | Provide a summary of both any unanticipated problems and available information regarding adverse events. |

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| 2. | Have you received any complaints about the research? | | | |
|  | | **YES** | **NO** |  |
| 3. | If YES, please describe the complaint and how it was handled: | | | |
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| **SECTION F: Investigator Comments** |
| Please provide any additional information that may be helpful for the IRB’s review of this renewal. |

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| **SECTION G: Signatures** | | | | | |
|  | | | | | |
| *By signing this form, the PI attests that the information submitted for IRB review is accurate.* | | | | | |
|  | |  |  |  |  |
| **Principal Investigator (Subaward)** | |  | **Signature** |  | **Date** |

*Submit completed form to* [*compliance@ki.se*](mailto:compliance@ki.se)*.*