**Protocol Status Form: *Continuing* Review of KABU-ERC Protocols**

Please see continuing review form for more information about this form and the Continuing Review process.

* **Please email one copy of this form to email Include in your email your current consent form(s) document(s) without the IRB stamp. Send a copy of the Protocol Status form with all appropriate signatures to the KABU-ERC office. Mail, P.O Private Bag 20157 or email (scanned document to email can submit signed materials.**
* **Please make sure that the KABU-ERC contact information on the consent form(s) is updated:**
* **If the study is closed to new enrollment, do not include the consent forms with your submission.**
* **If you have made modifications to the study, submit a *MODIFICATION FORM*.**
* **Do not resubmit your original protocol. You should, however, refer to the original protocol and any subsequent modifications approved by the KABU-ERC as you complete this form.**
* **If this study is completed or discontinued, DO NOT SUBMIT THIS FORM. Instead, complete and submit the *STUDY CLOSURE FORM*.**
* **In order to maximize your approval period, this form will be reviewed in the full board meeting prior to the expiration of the protocol even if you submit the form for an earlier meeting.**

**Current Protocol Information**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| KABU-ERC Protocol Number: | |  | | | | | |
| Protocol Title: | |  | | | | | |
|  | |  | | | | | |
| Principal Investigator: | |  | | | | | |
| Current mailing address: | |  | | | | | |
| Current e-mail address: | |  | | | | | |
| Current phone number: | |  | | | | | |
| Primary Contact (If other than PI; include name, KABU ID, email address, and phone) | |  | | | | | |
|  | |  | | | | | |
| (if applicable; please use full name and KABU ID): | |  | | | | | |
| Faculty supervisor KABU ID email | |  | | | | | |
| Current researchers (if applicable; please use full names and KABU ID): | |  | | | | | |
|  | |  | | | | | |
| Current funding source(s): | |  | | | | | |
| Grant title: (if different from protocol title): | |  | | | | | |
| Anticipated end date for this study (mm/yy): | |  | | | | | |
|  | | | | | | | |
| **Protocol Status (mark the appropriate box with an “x” and provide a “response” as directed)** | | | | | | | |
| 1. **Has there been a change in researchers since your last submission?** | | | YES | |  | NO |  |
| **If YES,** please make sure the researchers listed above reflect current personnel on the protocol, and briefly explain why the changes occurred. | | | | | | | |
| **Response 1 (respond below this header):** | | | | | | | |
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| 1. **Was this project undertaken?** | | | **YES** | |  | **NO** |  |
| **If YES**, please describe what you did during the past year. | | | | | | | |
| **If NO,** please briefly explain why this project was not undertaken. | | | | | | | |
| **Response 2 (respond below this header):** | | | | | | | |
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| 1. **Current Status (mark only one box with an “x”):** | | | | | | | |
|  | Open to enrollment of new participants | |  |  | | | |
|  | Closed to enrollment, but current participants still active in study | |  |  | | | |
|  | Performing data analysis (no active participants) | |  |  | | | |

1. **Subject Statistics: If you are conducting an archival data study only, please complete “a” below. All other studies complete “b” (even if your study includes archival data).**
2. **Archival Data Collection: Please provide an approximate number in all spaces to describe the data in your study.**

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| --- | --- |
| Approximate number of individual participant records in the data set(s) since last IRB review: |  |
| Approximate number of individual participant records in the data set(s) since original SBS approval date: |  |
| Approximate number of individual participant records in the data set(s) expected to include in the study in the upcoming year: |  |

1. **Prospective Data Collection: Please provide an approximate number in all spaces to describe the enrollment of participants in the study.**

|  |  |
| --- | --- |
| Approximate number of participants enrolled in study since last IRB review: |  |
| Approximate number of participants enrolled in study since original SBS approval date: |  |
| Approximate number of participants expected to enroll in the upcoming year: |  |

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| 1. Have there been any problems involving participants in this study since the last IRB review of this project? (Please include, but don’t limit to, unanticipated side effects resulting from participating in the research, complaints from participants about their experience in the research, a high rate of participant withdrawal from the research, and/or injuries to participants.) | | | | | | |
|  | | **YES** | |  | **NO** |  |
|  | **If YES,** describe any problem(s) and its (their) resolution(s). | |  | | | |
| **Response 5 (respond below this header):** | | | | | | |
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| 1. Are there any additional risks not described in the original protocol? | | | | | | |
|  | | **YES** | |  | **NO** |  |
|  | **If YES,** describe any problem(s) and its (their) resolution(s). | |  | | | |
| **Response 6 (respond below this header):** | | | | | | |
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| 1. Is there any published information about risks associated with this type of research? | | | | | | |
|  | | **YES** | |  | **NO** |  |
|  | **If YES,** please cite and summarize below. | |  | | | |
| **Response 7 (respond below this header):** | | | | | | |
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| **Signature of Principal Investigator** |  | **Date** |
|  |  |  |
|  |  |  |
| **Signature of Faculty supervisor (if applicable)** |  | **Date** |