**SCDMH INSTITUTIONAL REVIEW BOARD**

**CONTINUING REVIE****W OF RESEARCH PROJECT**

|  |
| --- |
| **ORA Use Only** |
| **IRB PROJECT NO.:** |  |
| **Date Received:** |  |

|  |  |
| --- | --- |
| **PROJECT TITLE:**  |  |
| **PRINCIPAL INVESTIGATOR:** |  |

The purpose of the continuing review is to ensure that all subjects participating in research projects are protected from research risks as established in procedures approved by the SCDMH Institutional Review Board (IRB) during the initial review. Continuing Review of on-going projects by the IRB is required by federal regulations no less than once per year.

While the questions on this form should serve to organize your response, their primary function is to assist the Board, and you, in certifying that: (1) the project has not deviated in any significant way from the original approved proposal; and (2) no new data has come to light since the last review that would increase the known risks to subjects.

**Please answer the following questions:**

1. How many subjects have been initiated into the research project?
2. What is the minimum number of subjects required in the original proposal to complete this project?
3. Has your project methodology been altered since the original review or last review by the Board in any way that would increase the risks to the subject?
 Yes [ ]  No [ ]  (If yes, attach a statement of methodological changes.)
4. Have any research subjects withdrawn from the research project since your last review?
Yes [ ]  No [ ]  (If yes, please attach a statement explaining the circumstances of the withdrawal.)
5. Has any information been learned thus far in your project that would increase the "benefits to research subjects who participate" beyond any benefits outlined in your original proposal?
Yes [ ]  No [ ]  (If yes, attach a statement outlining these benefits.)
6. Have any research subjects experienced any adverse reactions as a result of participation in your study since your last review ?
Yes [ ]  No [ ]  (If yes, please attach a statement detailing the frequency, severity, nature of reaction, possible cause(s) you have considered, proposed or implemented correction and/or your recommendation regarding corrective action.)

7. Based upon the results of your study thus far, has there been, in your opinion, any increase in the risks to subjects beyond any risks specified in your original proposal or since your last review?

Yes [ ]  No [ ]  (If yes, please attach an explanation of the nature of the risks, any recommendation or plans to reduce these risks and an assessment of the risks/benefit relationship.)

8. Has any new information related to your project come to light since the last Board review which might influence any decision of the Board?
Yes [ ]  No [ ]  (If yes, please attach.)

9. Please write a brief statement outlining the current stage of your project.

10. Have any modifications to the Informed Consent been done since Board approval or your last review?
       Yes [ ]  No [ ]  (If yes, please attach the revised Informed Consent and highlight the areas where modifications were made.)

11. Please indicate when this project is expected to terminate:

        Date:

12. **If you are not a DMH employee, you must have a DMH employee, approved by the facility in which the project is being conducted, who has agreed to oversee the conduct of this project. If you are not a DMH employee, please list the following:**

* + - **Name of DMH employee/sponsor:**
		- **Employee’s job title:**

**Employee’s facility and phone number:**

I certify that the above and the attached information are, to the best of my knowledge, complete and accurate.

|  |  |
| --- | --- |
| Signature: |       |
| Title: |       |
| Date: |       |

Note: Electronic transmission of this document will be considered a valid signature, if originating from the Investigator’s email address. The SCDMH Institutional Review Board meets on the fourth Wednesday of each month at 11:30 a.m. If you need assistance, please contact Lynelle Reavis, Ph.D. at 803-898-8619 or by e-mail at IRB@scdmh.org