**SCDMH INSTITUTIONAL REVIEW BOARD**

**Project Applic****ation for Research Involving Human Subjects**

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| **Title of Research Project:** |  |
| **Principal Investigator:** |  |
| **Job Title:**  |  |
| **Business Address:**  |  |
| **Telephone Number:**  |  |
| **Email Address:**  |  |
| **Co-Investigator(s):** |  |
| **Research Intention** |
| **1. What is the purpose of this study (What research question are you addressing)?** |
| **2. What is the significance of this project (What will it accomplish)?** |
| **3. Briefly, outline what you believe to be the clear current and/or potential value to patients and staff of the Department of mental Health and how your research meets the agency's mission.** |
| **4. Briefly, outline your research design and include a copy of your study protocol.** |
| **5. Will you be requesting data from the Department of Mental Health (e.g. medical records) and/or the Office of Research Statistics? No** **[ ]  Yes** **[ ]** **If the answer is “yes,” specify the type(s) of data you will be requesting.**  |
| **Research Subjects: Includes all human subject contact and/or chart review** |
| **6. Who are your subjects (e.g., children, students, patients, volunteers, etc.)?** |
| **7. How many subjects will be involved?       What is the anticipated starting date of project?       Anticipated date of last contact with research subjects.       How will they be selected?       How will they be recruited?** |
| **8. What is the anticipated completion date of the research study?** |
| **9. What is the age of subjects involved ?****List any special psychological and physical characteristics with rationale for using any special groups whose ability to give voluntary informed consent      may be in question.****Check if there is no concern with consent.** **[ ]**  |
| **10. In non-technical terms what will happen to, and what will be expected of, the research subjects(s)?** |
| **Confidentiality/Privacy** |
| **11. In your estimation, do the procedures involve any potential risk for the subject – (physical, psychological, social, or legal) - or invasion of privacy?** **If yes, what is your assessment of likelihood and seriousness of such risks?** |
| **12. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used).** **Check here if not applicable.** **[ ]**  |
| **13. What, if any, are the potential benefits to subjects who participate in this research?** |
| **14. Does consenting to be a subject lead to additional costs in tests, medical care, etc.** **for the subject? If so, who is responsible for the costs?** |
| **Subject's Rights Describe your procedures for safeguarding the subject's rights with respect to the following:** |
| **15. Describe your procedures for safeguarding the subject's rights with respect to the following:** |
| **16. Security of person (all risks described in No. 13 above)**  |
| **17. Privacy and confidentiality (including protection, storage and retention of data)** |
| **18. Embarrassment, discomfort and harassment (i.e., would there be any stigma or repercussions from having participated?** |
| **19. Is there any deception involved in your research? Yes [ ]  No [ ] If so, how is it handled?** |
| **Consent** |
| **20. Attach a copy of the Informed Consent Form which will be used and describe what your procedures are for obtaining informed consent (include how and where informed consent will be obtained).** |
| **Research Team** |
| **21. How will interviewers or data collectors be trained, if applicable?** |
| **Attachments** |
| **22. Attach a copy of all test instruments to be used in the study. (Nationally known, common instruments that are likely to be known by the IRB may be listed and not included in the submission.)** |
| **23. If this project is being conducted to fulfill a college/university degree requirement attach a letter of project approval from your overseeing body, Dissertation Committee, (etc.).** |
| **24. List all other institutions (hospitals, schools, health care centers, etc.) other than the SCDMH, which will serve as sites for this research project. If these institutions have reviewed and approved this project, attach a copy of their approval form.** |
| **25. Attach CVs of principal investigator(s).** |
| **26. If the research requires the use of data/information from patient records attach a letter of project approval from the center or facility director.**  |
| **27. If the research requires the use of data/information from SCDMH Medical Director’s Office-Education, Training and Research Division attach a letter of project approval from the center or facility director.** |
| **28. Please provide any other information relevant to the study for a full, fair and impartial review by the IRB.** |
| **29. If the answer to any of the following questions is “yes,” attach a detailed explanation.*** + **Is there any financial relationship between a commercial sponsor of this project and you or co-investigators? No** **[ ]  Yes** **[ ]**
	+ **Is there any compensation that is affected by the study outcome? No** **[ ]  Yes** **[ ]**
	+ **Do you or your co-investigator(s) have any proprietary interests in any products used in this research, including patents, trademarks, copyrights, and licensing agreements? No** **[ ]  Yes** **[ ]**
* **Do you or any co-investigators have any equity interest in any company sponsoring this research or any company’s products used or being investigated in this research project? No** **[ ]  Yes** **[ ]**
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| **30. 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 and has completed a current. 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:**
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| **31.** **All investigators and key personnel submitting IRB applications are required by SCDMH IRB to complete training in human subject protection and submit proof of training.  “Key personnel” include all individuals responsible for the design and conduct of the study.**  |

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

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| **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. For a project to be considered by the IRB, all relevant materials must be submitted by the first Wednesday of the month. It is preferable that materials are submitted electronically to** IRB@scdmh.org**; hard copies can be sent to Lynelle Reavis, Ph.D. Director of Quality Management and Compliance, IRB Administrator at 2414 Bull Street Suite 302, Columbia, SC, 29201.**

**If you need assistance in the completion of this application, please contact Lynelle Reavis, Ph.D. 803 898-8619 or by e-mail at** IRB@scdmh.org **.**