MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES

INFORMATION FOR CONTINUING REVIEW OF A PREVIOUSLY APPROVED PROJECT IRB FORM 2

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| All ongoing research activity that was not determined to be exempt from IRB review must be reviewed at least annually. The investigator must submit IRB Form 2 ‘Information for Continuing Review of a Previously Approved Project’ 45 days in advance of the annual or designated review date, along with the additional information stipulated on the form. See Information for Research Investigators’ Section IV D for additional information on continuing review. |
| PROJECT NUMBER      |
| 1. TITLE OF STUDY      |
| 2. DATE PROJECT INITIALLY APPROVED BY IRB      | 3. DATE PROJECT BEGUN      |
| 4. PRINCIPAL INVESTIGATOR      |
| 5. PRINCIPAL INVESTIGATOR’S POSITION      |
| 6. PRINCIPAL INVESTIGATOR’S INSTITUTION      |
| 7. FEDERALWIDE ASSURANCE NUMBER      |
| 8. BUSINESS ADDRESS 1      |
| 9. BUSINESS ADDRESS 2      |
| 10. CITY, STATE, ZIP      |
| 11. BUSINESS TELEPHONE NUMBER      | 12. BUSINESS FAX      |
| 13. PRINCIPAL INVESTIGATOR’S E-MAIL      |
| 14. FUNDING SOURCE      |
| 15. DHSS DIVISION, OFFICE, BUREAU, OR PROGRAM INVOLVED WITH STUDY      |
| 16. HAS THE PROJECT BEEN COMPLETED?[ ] Yes If “yes”, enter date of completion       and skip to #25 [ ] No Attach current IRB training certificate |
| 17. HOW MANY SUBJECTS HAVE BEEN ACCRUED THUS FAR?      | HOW MANY MORE WILL BE RECRUITED?      |
| 18. HOW MANY SUBJECTS HAVE WITHDRAWN SINCE THE LAST IRB REVIEW?      |

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| 19. HAVE YOU MODIFIED THE ORIGINAL RESEARCH PLAN IN ANY WAY SINCE IT WAS REVIEWED AND APPROVED BY THE IRB?[ ] Yes If “yes”, you must submit the changes to the IRB Chair for review after signed approval from DHSS co-investigator. Use any additional sheets as necessary.      [ ] NoDHSS co-investigator approval Date       |
| 20. ATTACH A COPY OF THE CURRENT INFORMED CONSENT DOCUMENT, IF APPLICABLE |
| 21. DESCRIBE IN DETAIL ANY ADVERSE EVENTS OR UNANTICIPATED PROBLEMS THAT HAVE BEEN ENCOUNTERED IN REGARD TO HUMAN SUBJECTS, ESPECIALLY THOSE RELATING TO SUBJECT RISK, INFORMED CONSENT, OR CONFIDENTIALITY OF DATA. (USE ADDITIONAL SHEETS AS NECESSARY.)      |
| 22. DESCRIBE ANY COMPLAINTS ABOUT THE RESEARCH SINCE THE LAST IRB REVIEW      |
| 23. DESCRIBE ANY RECENT LITERATURE RELATED TO THE PROJECT, ANY NEW INFORMATION ABOUT RISKS THAT MAY BE ASSOCIATED WITH THE RESEARCH AND YOUR FINDINGS THUS FAR.      |
| 24. ATTACH COPIES OF RELEVANT MULTI-CENTER TRIAL REPORTS, IF APPLICABLE. |
| 25. SIGNATURE OF PRINCIPAL INVESTIGATOR |
| NOTE: If #16 is yes, your signature signifies that you have destroyed all data as stated in your project protocol upon completing the project. |
| 25. TYPED NAME OF PRINCIPAL INVESTIGATOR      | 26. DATE      |
| **Return completed and signed copy to (see note below):**Dawn Parker, IRB Human Research Protections AdministratorMissouri Department of Health and Senior ServicesSection of Epidemiology for Public Health Practices920 Wildwood DriveP.O. Box 570Jefferson City, MO 65102-0570**Note:** For legitimate scientific research involving Vital Records (VR), Missouri Cancer Registry and/or Patient Abstract System (PAS) data, the IRB Form 2 should be submitted to the Section of Epidemiology for Public Health Practice along with your ‘Request for Review’ form. The Protocol Coordinator will forward the review packet to the IRB Chair after the initial review is complete. Submit completed packets to:Section of Epidemiology for Public Health Practice Attn: Protocol CoordinatorPO Box 570Jefferson City, MO 65102-0570 |