MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES

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

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.

DHSS IRB PROJECT NUMBER

1. TITLE OF STUDY

2. DATE PROJECT INITIALLY APPROVED BY DHSS IRB

3. DATE PROJECT BEGAN

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 ☐ FEDERAL (Select Division Below) ☐ STATE ☐ PRIVATE

☐ ACF ☐ ACL ☐ AHRQ ☐ ATSDR ☐ CDC ☐ CMS

☐ FDA ☐ HRSA ☐ HIS ☐ NIH ☐ SAMHSA

15. DHSS DIVISION, OFFICE, BUREAU, OR PROGRAM INVOLVED WITH STUDY - DHSS PROGRAM AFFILIATION REQUIRED

16. HAS THE PROJECT BEEN COMPLETED?

☐ Yes ▸ If YES, enter date of completion _____ and skip to #25 ☐ No ▸ Attach current IRB training certificate (within 3 years)

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 HOW MANY SUBJECTS HAVE WITHDRAWN SINCE THE LAST IRB REVIEW?

19. HAVE YOU MODIFIED THE ORIGINAL RESEARCH PLAN IN ANY WAY SINCE IT WAS REVIEWED AND APPROVED BY THE IRB? STAFFING AND LOCATION CHANGES MUST BE REPORTED.

☐ 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.

☐ No

DHSS Co-Investigator approval _____ Date _____

20. DOES PROJECT REQUIRE INFORMED CONSENT? ☐ No ☐ Yes ▸ IF YES, ATTACH A COPY OF THE CURRENT INFORMED CONSENT DOCUMENT.

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. DOES PROJECT INVOLVE MULTI-CENTER TRIAL REPORTS? ☐ No ☐ Yes ▸ If *YES*, attach a copy of the relevant reports.

25. SIGNATURE OF PRINCIPAL INVESTIGATOR

NOTE: If #16 is YES, your signature below signifies that you have destroyed all data as stated in your project protocol upon project completion.

25. TYPED NAME OF PRINCIPAL INVESTIGATOR	26. DATE

Return completed and signed copy with attachments (e.g., training completion certificates, consent forms, literature, etc.) to:

EXTERNAL INVESTIGATORS:
Missouri Department of Health and Senior Services
Attn: Enter the Name/Unit of the DHSS Co-Investigator
P.O. Box 570
Jefferson City, MO 65102-0570

Note: All external researchers are required to collaborate with a DHSS Co-Investigator.

DHSS INTERNAL INVESTIGATOR/CO-INVESTIGATORS:
Missouri Department of Health and Senior Services
Attn: Human Subjects Protections Administrator
930 Wildwood Drive
Jefferson City, MO 65109