MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES **REQUEST FOR REVIEW OF RESEARCH PROTOCOL IRB FORM 1**

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| **A. REQUEST FOR** | | | | |
| **1. IRB Review** **2. Expedited Review** **3. Exemption from Review** | | | | |
| **B. INVESTIGATOR INFORMATION** | | | | |
| 1. TITLE OF STUDY | | | | |
| 1. EXPECTED BEGIN DATE | | | | 1. EXPECTED END DATE |
| 1. PRINCIPAL INVESTIGATOR | | | | |
| 1. PRINCIPAL INVESTIGATOR’S POSITION | | | | |
| 1. PRINCIPAL INVESTIGATOR’S INSTITUTION | | | | |
| 1. FEDERALWIDE ASSURANCE NUMBER | | | | |
| 1. BUSINESS ADDRESS 1 | | | | |
| 1. BUSINESS ADDRESS 2 | | | | |
| 1. CITY, STATE, ZIP | | | | |
| 1. BUSINESS TELEPHONE NUMBER | | | | 1. BUSINESS FAX |
| 1. PRINCIPAL INVESTIGATOR’S E-MAIL | | | | |
| 14. FUNDING SOURCE | State  Federal  Other | NIH | Other |  |
| 1. DHSS DIVISION, OFFICE, BUREAU, OR PROGRAM INVOLVED WITH STUDY | | | | |
| **Your signature below indicates that you accept responsibility for conducting this research in accordance with the guidelines set forth in the Belmont Report.** | | | | |
| **PRINCIPAL INVESTIGATOR** | | | | **DHSS CO-INVESTIGATOR** |
| SIGNATURE | | | | SIGNATURE |
| TYPED NAME | | | | TYPED NAME |
| DATE | | | | DATE |

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| **B. INVESTIGATOR INFORMATION (CONTINUED)** | | | | | |
| List the name, title and position of other investigators. Include all persons who will work on this study and/or who will have access to data. | | | | | |
| **Name** | **Title** | **Role in Study** | | **IRB Training Completed** | |
| 1. |  |  | | Yes | No |
| 2. |  |  | | Yes | No |
| 3. |  |  | | Yes | No |
| 4. |  |  | | Yes | No |
| 5. |  |  | | Yes | No |
| \*Attach Training Certificate | | | | | |
| **C. SITES OF INVESTIGATION** | | | | | |
| **List expected sites of investigation** | | **FWA Number** | | | |
| 1. | |  | | | |
| 2. | |  | | | |
| 3. | |  | | | |
| 4. | |  | | | |
| 5. | |  | | | |
| Attach copies of memorandums of agreement/understanding or other documentation that provides evidence that all collaboration institutions and investigators have agreed to collaborate on the project. | | | | | |
| **D. OTHER IRB INFORMATION** | | | | | |
| **1. HAS THIS PROPOSED STUDY BEEN REVIEWED BY AN INSTITUTIONAL REVIEW BOARD (IRB)?**  Yes In Process No, go to Section E | | | DATE REVIEW REQUESTED (MM//DD/YY) | | |
| If YES, or IN PROCESS, in the box below provide name, address and the federal Department of Health and Human Services, Office for Human Research Protection registration number of IRB(s) involved. List the lead IRB first, if more than one IRB is reviewing the study. | | | | | |
| **IRB Name and Institution** | | **IRB Registration Number** | | | |
| 1. | |  | | | |
| 2. | |  | | | |
| 3. | |  | | | |
| 4. | |  | | | |
| 5. | |  | | | |
| **2. WAS THE STUDY APPROVED BY THE ABOVE NAMED IRB**  Yes No, go to Section E | | | | | |
| If YES, attach a copy of the letter that includes the date of approval from the IRB(s), including any modifications, limitations or conditions required by the IRB(s). | | | | | |

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| **E. RESEARCH METHODS (CHECK ALL THAT APPLY)** |
| Arterial and/or venipuncture (blood drawing) Existing pathologic or diagnostic specimens Data banks, archives, medical records, birth or death certificates Normal educational practices  Direct observation Secondary data analysis  DNA sampling Survey or interview procedure  Educational tests Other, specify: |
| **F. SUBJECT INFORMATION (CHECK ALL THAT APPLY)** |
| Employees Students  Mentally or physically impaired persons Subjects less than 18 years old  Normal, healthy subjects Subjects whose main language is not English  Patients or clients Terminally ill persons  Pregnant women Other, specify:  Prisoners, parolees, incarcerated persons |
| **WILL RESEARCHER(S) HAVE CONTACT WITH STUDY PARTICIPANTS?**  Yes No, go to Section G |
| If YES, check all that apply:  Anonymity will be maintained (i.e., no identifiers)  Confidentiality will be maintained  Recruitment incentives are used  Subject payment offered |
| **G. DATA AND RECORD SECURITY** |
| Describe the measures that will be taken to secure data |