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

2. EXPECTED BEGIN DATE	3. EXPECTED END DATE

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

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

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 copies of Human Subjects training completion certificates for all study personnel, must be completed within the last 3 years.

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). Any requirements for reliance on a sole source IRB must be noted in the IRB approval letter.

E. RESEARCH METHODS (CHECK ALL THAT APPLY)

- ☐ Arterial and/or venipuncture (blood drawing)
- ☐ Data banks, archives, medical records, birth or death certificates
- ☐ Direct observation
- ☐ DNA sampling
- ☐ Educational tests
- ☐ Existing pathologic or diagnostic specimens
- ☐ Existing pathologic or diagnostic specimens
- ☐ Normal educational practices
- ☐ Secondary data analysis
- ☐ Social media, platform: _____
- ☐ Survey or interview procedure
- ☐ Other, specify: _____

IF USING SOCIAL MEDIA, CHECK ALL THAT APPLY

- ☐ Communication
- ☐ Surveillance
- ☐ Data Source
- ☐ Recruitment
- ☐ Intervention

F. SUBJECT INFORMATION (CHECK ALL THAT APPLY)

- ☐ Employees
- ☐ Mentally or physically impaired persons
- ☐ Normal, healthy subjects
- ☐ Patients or clients
- ☐ Pregnant women
- ☐ Prisoners, parolees, incarcerated persons
- ☐ Students
- ☐ Subjects less than 18 years old
- ☐ Subjects whose main language is not English
- ☐ Terminally ill persons
- ☐ Other, specify: _____

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 collected including IP addresses)
- ☐ Confidentiality will be maintained
- ☐ Recruitment incentives are used
- ☐ Social media engagement
- ☐ Subject payment offered

G. DATA AND RECORD SECURITY

Describe the measures that will be taken to secure data.