Missouri Department of Health and Senior Services

REQUEST FOR REVIEW OF RESEARCH PROTOCOL

**ABSTRACT OF PROTOCOL**

1. Purpose

1. How will the research data be collected? (Questionnaires, interviews, collection of tissue or body fluids, review of existing records, data, etc.) Indicate if researchers will have contact with subjects.

1. Hypothesis and variables to be investigated

1. What are the potential risks to the subjects and benefits to subjects and/or society?

1. How will anonymity OR confidentiality be assured?

1. Will informed consent be sought from all subjects and documented in writing?

[ ]  YES ↓ [ ]  NO

If yes, a copy of the consent form must be included with application for review.

1. Is informed consent waiver or alteration requested? [ ]  YES ↓ [ ]  NO

If requesting a waiver or alteration of informed consent requirements, what are the reasons?

1. If requesting exemption, explain which category of exemption applies (see 45 CFR 46.104 (d)).