Request for Determination of Exemption

Initiated June, 2023. Updated September, 2023

PI Application form for Exempt Research

* Required

* This form will record your name, please fill your name.

Ethical Principles for Research Considered Exempt from IRB Review

SMU has a process for reviewing research considered to pose minimal risks to subjects and meet the Federal Requirements of exempt research. Only the information necessary to determine that exemption is required. Less detail about recruitment, informed consent processes or data gathering instruments is needed however, even when research is eligible for exemption, the researcher must adhere to the basic ethical standards that protect and respect research subjects. Research participation must be *informed*, *voluntary* and pose the *lowest level of risk possible*.

1. If you are completing this application and NOT the PI, please provide your name and role.

2. Enter the name of the principal investigator (PI) of the project. First PI only, if multiple investigators

3. PI Samuel Merritt University email address

4. What is the PI's role at SMU

- ◯ Faculty
- ◯ Staff
- ◯ Student

5. If you are a student, indicate Faculty advisor name and university email address

6. Please confirm your faculty advisor has reviewed this application's content and supports the proposed methods

- ◯ Yes. My faculty advisor has approved
- ◯ Not applicable

7. What is the title of your investigation?

8. Briefly describe the purpose and goal of your investigation in layman terms.

9. Which data collection methods are involved. Check all that apply

- [ ] Survey
- [ ] Interview
- [ ] Observation
- [ ] Review of existing de-identified data
- [ ] Review of artifacts such as discussion board or forum posts

10. Which one of the following categories of Exemption is applicable?
*To qualify as Exempt, the research must pose **no greater than minimal risk** and must fit within one or more of the Federal Guidelines exempt categories (45 CFR 46). Four of the most common categories are listed below. If your research satisfies exemption in one of the other 8 categories, choose other and explain in subsequent item.*

- ◯ **Category 1: Educational Research.** Research conducted in established or commonly accepted educational settings, involving normal educational practices.
- ◯ **Category 2: Surveys, interviews, educational tests, or public observations** if the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to the subjects OR if disclosure outside the research would not reasonably place the subjects at risk OR if information obtained is recorded and sufficient confidentiality safeguards are put in place.
- ◯ **Category 3: Benign behavioral interventions.** Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording if the subject prospectively agrees to the intervention and information is recorded in a manner that the identity of subject cannot readily be ascertained directly or through identifiers linked to the subjects OR if disclosure outside the research would not reasonably place the subjects at risk OR if information obtained is recorded and sufficient confidentiality safeguards are put in place.
- ◯ **Category 4: Secondary research of previously-collected, anonymous data**. Research involving the collection or study of existing data, documents, or records if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly, or through identifiers linked to the subjects.
- ◯ **Other Exemption Category** as listed at 45 CFR 46

11. Rationale for Category 1. Briefly describe the educational setting and how the investigation represents normal practices such as instructional strategies or effectiveness or comparison among instructional techniques, curricula or classroom management methods.

12. Which criteria of Category 2 Exemption will be met; you can select more than one

- [ ] (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
- [ ] (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation;
- [ ] (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, however appropriate confidentiality procedures have been added.

13. Which criteria of Category 3 Exemption will be met; you can select more than one

- [ ] (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
- [ ] (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation;
- [ ] (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, however appropriate confidentiality procedures have been added.

14. Rationale for Category 4. Briefly explain the source of existing data and how it was obtained.

15. Indicate which other Exemption Category you are wanting to be considered.

16. Provide and briefly explain the **sequence of activities** starting with the recruitment of subjects; specific interventions; data collection methods; analysis and write-up of findings. **Include an estimated timeline for each activity** (ie: month beginning and anticipated weeks for each; estimated time for subject to complete a survey or participate in an interview).

Subject Population

If you have minors or are involving a vulnerable population, your investigation may not qualify for Exemption. Seek consultation from the IRB Administrator or IRB Committee Chairperson.

17. Check all that apply regarding your human subjects

- [ ] Adults (over 18)
- [ ] There are no minors or other vulnerable population involved
- [ ] Using previously collected data

18. Describe the targeted population including inclusion criteria for your sample and any criteria for excluding a subject who meets inclusion criteria.

19. Describe how the subjects will be recruited

Informed Consent

Ethical research practices always includes a process for providing potential subjects with informed consent and procedures that ensure voluntary participation and protection of identity. While the use of a *formal informed consent form* containing all the elements of consent is NOT required for exempt research, it is expected that investigators provide sufficient information about the research to enable the potential participant to make an informed decision about participation. ***If study involves only de-identifed existing data or other artifacts without personal identifiers, no additional informed consent is needed.***

20. Are you submitting this study under Exemption Category 4: Secondary research of de-identified existing data?

- ◯ **Yes.** Study involves only existing data previously collected without any personal identifying information.
- ◯ **No.** New data is being collected.

21. For studies submitted under Exemption categories 1, 2 or 3; **check all that is included** in your informed consent process

- ☐ Explanation of the purposes of the research project
- ☐ A general description of study procedures and time commitment
- ☐ Indication that participation is voluntary and that participants may skip any questions and stop participation at any time
- ☐ Any potential discomfort or risk related to participation
- ☐ Description of how their privacy and confidentiality will be protected
- ☐ Description of how to contact the investigator if questions
- ☐ A general description of plan for data-sharing or any future research use of collected data
- ☐ Plans to audio or video record and how recordings will be used and retained

22. **Describe where and how** the informed consent will be communicated to your subjects.

Benefits and Risks

Consider the potential benefits of the investigation and the subjects perceived risks to participating

23. Explain any direct benefit to the subject for their participation **or** if there is no direct benefit to the subject, what is the overall benefit of this investigation.

24. Most all investigations pose some risk to individuals even if it is only a potential breach in confidentiality and/or a perceived risk by the potential subject. Describe the minimal risks to subjects for participating in this research and what procedures will be taken to minimize these risks.

Confidentiality Procedures

25. Check the procedures that will be used to maintain confidentiality **(check all that apply)**

- [ ] Anonymity of survey data (no personal identifying information including IP address)
- [ ] Redacting any personal identifying information from captured data either through anonymous survey or other data gathering procedures
- [ ] Use of pseudonyms to protect subject identity for interview or observation data
- [ ] Security of electronic data by password access and use of secure network to prevent breach of confidentiality
- [ ] Storing of any master list linking subject identity (identifiers) to de-identified data separate from data files
- [ ] Hardcopy data secured safely to prevent breach of confidentiality
- [ ] Confidentiality of participants will be protected when results are disseminated

26. Provide any additional confidentiality measures planned

Additional Information

27. Please provide any additional information supporting or explaining why you believe your research meets the criteria for exemption

28. You can upload any supporting documents that you feel provides more information about your procedures. These might include a full project proposal; copy of an Informed Consent form; Recruitment Script; Permission/support from the research site; copy of the survey instrument or interview protocol.

Upload file

File number limit: 10 Single file size limit: 100MB Allowed file types: Word, Excel, PPT, PDF, Image, Video, Audio

29. Evidence of research training is required of all study investigators. **Upload CITI Training Certificates for either Social Behavioral Research or Biomedical Research for each investigator. Certificate must be within 3 years of this application.**

Upload file

File number limit: 6 Single file size limit: 10MB Allowed file types: Word, Excel, PPT, PDF, Image, Video, Audio

30. Indicate the date of this submission. Before submitting this application, check the box to receive a copy of your application via email. Once you submit, you will see an option to print or obtain a pdf of your application. *