



\* 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 human subjects and meet the Federal Requirements of exempt research. Only the information necessary to determine that exemption is required. Details about recruitment, informed consent processes and data gathering instruments is needed to ensure that human subjects are being protected. 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. If you have co-investigators; please list below along with their email address.

5. What is the first PI's role at SMU

Faculty

Staff

Student

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

7. Provide a short title for your investigation

8. Include your research questions (or PICOT question)

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

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10. Which of the following category 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 data.** Research involving the 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.
- 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; check which items apply. Commonly it is (i) and (ii) or (ii) and (iii).

- (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; check which items apply. Commonly it is (i) and (ii) or (ii) and (iii).

- (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. Indicate which **other Exemption Category** you are wanting to be considered.

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## Exemption Category 4: Existing Data

15. Indicate which data collection method will be used

- Gathering/extracting individual subject data from existing records **that will be anonymized and protected following extraction**
- Gathering/extracting **anonymous** individual subject data from an existing source
- Gathering/extracting **anonymous** individual subject data from publically available sources

16. Describe the existing records that will be targeted for data gathering including the process for accessing the records.

17. List the specific variables that will be extracted from the records and explain how these will be recorded and anonymized to protect individual subject identity.

18. Provide and briefly explain the **proposed activities and procedures** including estimated week/month of implementation and duration (in weeks) for each activity and procedure. **A reminder that data collection cannot commence before IRB approval.**

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## Procedures & Activities

Exemption Categories 1, 2 and 3

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

- Use of Survey to capture new data
- Interview process with subjects
- Observation of behaviors
- Review of artifacts such as discussion board or forum posts

20. **Provide and briefly explain the proposed activities and procedures** starting with the recruitment of subjects. Include the specific interventions involving the subjects, the data collection methods and the estimated time required by a subject to complete a survey or participate in an interview. Explain the plan for analysis of subject data and write-up of findings. Include the estimated week/month of implementation and duration (in weeks) for each activity and procedure. ***A reminder that subject recruitment and data collection cannot commence before IRB approval.***

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## Subject Population for Exemption Categories 1, 2 and 3

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.

21. Check all that apply regarding your human subjects

- Adults (over 18)
- There are no minors or other vulnerable population involved

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

23. Describe your processes for recruiting subjects for your project or study

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## Informed Consent: Exemption Categories 1, 2 and 3

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.

24. For studies **submitted under Exemption categories 1, 2 or 3; check all that is included** in your informed consent process. *Note: You will need to upload a copy of any documents that contain the Informed Consent information such as recruitment invitations and/or an information sheet at the end of this application.*

- 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

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

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### Benefits and Risks: Exemption Categories 1, 2 and 3

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

26. 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.

27. 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.**

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## Confidentiality Procedures

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

- Survey data captured anonymously (no personal identifying information including IP address)
- Redaction of any personal identifying information from captured/extracted data
- Use of pseudonyms to protect subject identity for interview, observation or other data gathering procedures
- Storing of any master list linking subject identity (identifiers) to de-identified data separate from data files
- Security of electronic data by password access and use of secure network to minimize risk of breach
- Hardcopy data secured safely to minimize risk of breach
- Confidentiality of participants and sites will be protected when results are disseminated

29. Provide any additional confidentiality measures planned

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## Additional Information

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

31. Upload the following supporting documents as individual files: **Recruitment Scripts for emails or fliers; Informed Consent forms; Permission/support from the research site; survey instrument/items; interview protocol including questions; observation tools.**

 Upload file

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

32. 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

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## Application Submission

Before submitting this application, check the box to receive a receipt of your application via email. Once you choose the **"submit"** button, you will see a notification indicating that your application has been submitted. Before you choose to "save your response"; in the upper right corner, click on the 3 dots and choose "print"; and then within print options, "save as a pdf" to have a downloadable copy of your application.


33. **Please confirm that you have discussed this application content with your faculty advisor. \***

Yes. My faculty advisor has approved

Not applicable; I am not a student

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