Request for Determination of Exemption

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. What is your current role at SMU

- ○ Faculty
- ○ Staff
- ○ Student

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

Enter your answer

3. PI email address

Enter your answer

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

Enter your answer

5. What is the title of your investigation?

Enter your answer

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

Enter your answer

7. 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

8. 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). Three 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: Education 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 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: Analysis 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.b
- ( ) **Other Exemption Category** as listed at 45 CFR 46

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.

9. Check all that apply regarding your human subjects

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

10. Describe the subject population including inclusion criteria.

Enter your answer

11. Describe how the subjects will be recruited

Enter your answer

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 informed consent is needed.***

12. Check all that is included in your informed consent process

- [ ] Study involves only existing data previously collected without any personal identifying information
- [ ] 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 and 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

13. Describe where and how the informed consent will be communicated

Enter your answer

Confidentiality Procedures

Protecting subject identity and securing all investigation records, both electronic and physical is essential.

14. Check the procedures that will be used to maintain confidentiality

- [ ] Anonymity of survey data (no personal identifying information including IP address)
- [ ] Redacting any personal identifying information from captured data
- [ ] 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 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

15. Provide any additional confidentiality measures planned

Enter your answer

Additional Information

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

Enter your answer

17. 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. (Non-anonymous ⓘ) question

18. 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. *

4/17/2023