This guidance document is primarily designed for exempt research projects that involve interviews and surveys (exempt category 2), but applicable sections of this guidance could be applied to exempt projects that qualify as educational research (exempt category 1) or benign behavioral interventions (exempt category 3).

For questions related to regulatory or ethical considerations of your proposed research, please contact the Office of Research Integrity at irb@une.edu for assistance.

Excerpts of this guidance document were obtained with permission from the Maine Medical Center Research Institute – specifically the Center for Outcomes Research & Evaluation (CORE) which includes Research Navigation.

A. Introduction

Key Considerations	Best Practices / Notes
▪ **Provide an overview of your proposed project in lay language that a non-scientist would understand.** ▪ Summarize the prior work done by others (and yourself if applicable) in your proposed area of study. ▪ Provide rationale for why the project is important. ▪ Identify the gaps in knowledge that your project will address. ▪ Detail how the study will contribute to your field of inquiry.	▪ Don't assume the IRB reviewer has a background in your proposed research. ▪ Avoid the use of jargon and/or technical language. ▪ Be sure to spell out any acronyms at the time of first use.

B. Specific Aims

Key Considerations	Best Practices / Notes
▪ Succinctly describe the specific objectives or questions to be answered.	▪ Limit your specific aim statements to no more than 3. ▪ Each specific aim statement may be followed by a brief summary of your strategy or approach to achieve that aim.

C. Methods of Data Collection & Analysis

Key Considerations	Best Practices / Notes
General Criteria ▪ Outline your plan to collect and analyze the data required to complete your project. ▪ Specify the anticipated length of time you will be collecting data to answer your research question(s). ▪ If you aim to collect sensitive information about participants, describe what information you wish to collect and why it is needed for your research project.	▪ If you plan to go back to speak with participants to validate and/or further understand your findings, the additional time for this activity should be accounted for and described in your research proposal. ▪ For interviews, participants should be given the option to review the transcribed interview for accuracy. ▪ Any data collection tools (e.g., interview script/guide, questionnaire/survey, etc.) you propose to use in

C. Methods of Data Collection & Analysis

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Focus Groups / Interviews ▪ If conducting a focus group, describe who will facilitate the group, where the sessions will be held, how long they will last, how many focus group sessions you will hold, and the anticipated number and type of participants at each. ▪ If conducting a semi-structured interview, describe who will conduct the interview, where they will be held, how many interviews will be required, and how long they will last. ▪ Describe how data will be recorded (e.g., written notes, audio and/or video recordings) and transformed (e.g. interview transcription process). ▪ Detail the method(s) you will use to analyze and interpret the data collected in your project (e.g., strategies to code, including how coding discrepancies will be addressed, and to identify themes). ▪ If you will employ the use of software to assist with transcription and/or coding/analysis of themes, provide those details. ***Surveys*** ▪ Describe the source of the survey (e.g., a published, validated survey vs. a survey developed in-house). ▪ Specify the anticipated length of time it will take the participant to complete the survey. ▪ Detail the logistics for survey distribution and management. Indicate if the survey will be completed on paper vs. an electronic data collection platform.	your project must be included with your application for IRB review. ▪ After the IRB has issued you an exemption determination letter, any subsequent changes you wish to make to data collection tools must be submitted to the IRB for review prior to use.

D. Description of Participant Population, Research Setting, & Recruitment Procedures

Key Considerations	Best Practices / Notes
▪ Describe the population who you propose to enroll in your project. Indicate if you plan to recruit participants from a vulnerable population. ▪ Provide the rationale for choosing this population and list the inclusion and exclusion criteria that you will apply in selecting study participants.	▪ The recruitment of children is NOT allowed for exempt projects involving interviews and surveys. If you wish to recruit children as part of your project, please consult with the Office of Research Integrity to determine next steps. ▪ The IRB considers UNE students and employees to be a vulnerable population.

D. Description of Participant Population, Research Setting, & Recruitment Procedures

Key Considerations	Best Practices / Notes
▪ If you plan to recruit non-English speaking people, translation of the Information Sheet is necessary. Describe how information will be translated and by whom. ▪ Describe how participants will be identified, approached, and recruited to participate in your project. ▪ Indicate the anticipated number of participants that you will enroll in your project (for the group as a whole and within any subgroup if applicable). ▪ If the project design relies on saturation (e.g., when there is enough data to ensure the research questions can be answered) to determine recruitment/end of data collection, include criteria to determine saturation. If project design requires representative sampling (e.g., a small number of participants chosen to represent the larger population), describe how these participants are to be chosen. ▪ Recruitment materials must include basic information about what the participation entails (e.g., a 30-minute recorded interview conducted via Zoom); what topics are being investigated/explored; and identify that the project is research and participation is voluntary. For specific requirements for advertisements/flyers, see the column to the right. ▪ When research is conducted at an outside institution or site, a letter of support (from an appropriate signatory official) acknowledging and supporting the research project from the outside institution or site is required.	▪ If you plan to recruit participants from a vulnerable population, additional protections will need to be outlined within applicable sections of your research proposal (typically sections F & G) and the standalone 'Participant Information Sheet' document. ▪ If your screening/recruitment process requires access to protected health information (PHI) from a UNE covered entity (click here for details) to verify project inclusion/exclusion criteria, you will need to submit an **Application for Approval to Use Protected Health Information** (click here) to request a partial waiver of HIPAA authorization. ▪ Any recruitment materials (e.g., flyers, social media advertisements, sample e-mail solicitations, verbal scripts, etc.) you propose to use in your project must be included with your application for IRB review. ▪ If you wish to incorporate a branded UNE logo within your recruitment material, you must obtain approval from the UNE Office of Communications prior to submitting your application. ▪ After the IRB has issued you an exemption determination letter, any subsequent changes you wish to make to recruitment materials must be submitted to the IRB for review prior to use. ***What Content Should an Advertisement/Flyer Include?*** ▪ Name of the investigator and affiliation with UNE ▪ Statement that this is a research project and participation is voluntary ▪ Purpose of the research project ▪ Summary of inclusion/exclusion criteria ▪ Brief list of procedures involved ▪ Time or other commitments required of participants ▪ Compensation or incentives (if offered) ▪ Contact information for more information

E. Participant Information Sheet

Key Considerations	Best Practices / Notes
▪ How and when do you plan to disseminate the Participant Information Sheet?	▪ Research projects that qualify for exemption do NOT fall under the jurisdiction of the federal human

E. Participant Information Sheet

Key Considerations	Best Practices / Notes
▪ Describe the process for going over the content of the Information Sheet with the participant. Will participants be provided an opportunity to ask questions or express concerns during this process? ▪ How do you plan to solicit acknowledgment from the participant that they are ready to proceed with the interview/survey?	subjects protection regulations. As such, there is no requirement to obtain signed informed consent from participants. In lieu of a consent document, participants should be provided with a 'Participant Information Sheet' that summarizes the salient points of the proposed research project. ▪ A modifiable **Participant Information Sheet Template (Exempt Projects Only)** is located on the UNE IRB webpage (click here) for use. ***Focus Groups / Interviews*** ▪ The Information Sheet should be sent to participants prior to the scheduled interview (e.g., sent as an attachment to the out-going recruitment e-mail, etc.). At the beginning of the interview, you should go over the content of the Information Sheet with the participant and answer any questions or concerns. As a last step, ask the participant for verbal acknowledgment that they are ready to proceed with the interview. ***Surveys*** ▪ If the survey is distributed by physical mail, the Participant Information Sheet should be provided as an enclosure within the envelope. ▪ If the survey is to be completed via an electronic platform, the Participant Information Sheet should be embedded at the beginning of the survey for the participant to read over. The completion of the survey implies consent by the participant.

F. Provisions for Participant Privacy & Data Confidentiality

Key Considerations	Best Practices / Notes
▪ Outline the procedures that will be employed to protect the participant's privacy during the project. ▪ Describe where and how data (both paper and electronic – including any audio/visual recordings) will be stored/managed. How will data be kept secure/protected and who will have access to the data?	**Privacy** refers to the right to control access to ourselves and our personal information. Participants have the right to control the degree, timing, and conditions for sharing their bodies, thoughts, and experiences with others. Privacy must be protected before and during recruitment, the consent process, as well as during

F. Provisions for Participant Privacy & Data Confidentiality

Key Considerations	Best Practices / Notes
▪ State whether you have plans to use the data collected for future research. If yes, the request will also need to be communicated within the Participant Information Sheet. ▪ For interviews, specify the length of time any audio or video recordings will be retained. ▪ Will you be collecting personally identifiable information as part of the recruitment process? If yes, what identifiers will you be maintaining? How will you protect these identifiers? Will you store these identifiers separately from the study data? When will the identifiers be destroyed? ▪ Will you be using a master list or key to temporarily link personally identifiable information collected about the participant to coded study data? If yes, will the master list or key be stored separately and securely from the study data? When will the master list or key be destroyed? ▪ Differentiate between the length of time study data will be retained vs. the length of time participant personally identifiable information (e.g., collected solely for recruitment purposes) will be retained. ▪ Describe what happens to the participant's data if they chose to withdraw from the project (e.g., any data collected will be deleted and not used in the study). ▪ Provide a plan for any data movement or sharing outside of UNE, if applicable. Specify what data will be provided, to whom, under what circumstances, and when.	participation in research activities. Methods to protect participant privacy include: ▪ Informing the participant that you will be conducting the interview in a private setting to ensure others cannot hear your conversation. ▪ For interviews conducted online, participants should be informed they have the option to not turn on their camera if they choose. ▪ Ensuring that private data are not collected without the participant's knowledge and consent. **Confidentiality** refers to agreements made between researchers and participants, through the consent process, about if and how researchers will protect information provided by the participants. Methods to protect participant data confidentiality include: ▪ Storage of paper records in a locked file cabinet in a locked office accessible only by the PI and/or study team. ▪ Safeguarding electronic data through use of encryption, use of a password-protected computer, and restricting access to data. The use of a thumb drive/flash drive/USB drive should be avoided because they can be easily lost/stolen. ▪ Where applicable, advise participants that they should not repeat anything they learn from interviews or group discussions (including focus groups) to others. ▪ Stripping interviews of all personally identifiable information during the transcription process. Use of a pseudonym instead of the participant's name. ▪ For interviews, destroying the audio/video recording at the earliest opportunity during the project (e.g., after all transcripts have been verified for accuracy). ▪ Destroying participant personally identifiable information (e.g., name, e-mail, physical address, etc.) obtained for recruitment purposes at the earliest opportunity during the project (e.g., after all transcripts have been verified for accuracy). At

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	minimum, the remaining study data must be retained for 3 years following the completion of the project. ▪ If a master list or key is used to retain identifiers linked to coded study data, the master list is stored securely, and separately from the study data. The master list or key is destroyed when it is no longer needed (e.g., after all transcripts have been verified for accuracy, immediately after data analysis is completed, etc.)

G. Statement of Potential Research Risks to Participants

Key Considerations	Best Practices / Notes
▪ Describe how participation in the project may affect the participant, including risks of participation in terms of the nature and severity of potential harms, and the likelihood that these harms will occur. ▪ If a potential harm is identified, describe the steps taken to reduce the probability of occurrence. ▪ Describe the available support services or procedures to be followed should harm occur (e.g., participant experiences emotional distress during or after the interview). ▪ If your study involves the inclusion of a vulnerable population, what precautions/safeguards will be instituted to mitigate the risk of harm?	▪ Risk is defined as the probability and magnitude of harm anticipated as a result of participation in the research. ▪ Risk may include psychological, physical, legal, social/reputational, and/or economic/financial harm to participants. In qualitative research, common sources of potential harm are invasion of privacy, stigmatization, or breach of confidentiality. ▪ Certain topics carry greater risk of harm than others (e.g., sensitive information relating to illegal conduct, drug use, sexual behavior, use of alcohol, etc.). ▪ If your project will recruit UNE students, they should be informed that their decision to engage/not engage in your project will have no effect on their academic status or class grade(s). ▪ If your project will recruit employees of UNE, they should be informed that their decision to engage/not engage in your project will have no effect on their employability or performance review. ▪ The investigator must clearly outline specific situations (where applicable) in which they are mandated to disclose confidential information, therefore putting participants at risk for legal action (e.g., reporting suspected child/elder abuse and/or neglect).

H. Statement of Potential Research Benefits to Participants

Key Considerations	Best Practices / Notes
▪ Describe the anticipated benefit for the individual, the community, your profession, or for society in general. ▪ If there is no direct benefit to the individual, describe the potential benefits of the knowledge gained from the research project.	▪ Compensation or incentives provided for participation is NOT considered a benefit to participants.