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 MaineHealth Institute for Research – 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 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. **Note**: Include only the details you are asked to outline within **Section C**. Do NOT include details about the recruitment or consent process, or strategies you will employ to protect participant privacy and confidentiality of data. Those specific details should appear in the respective sections of the research proposal.	▪ 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. ▪ An anonymous survey means that no personally identifiable information is being collected about the participant in the survey, and the identity of the

C. Methods of Data Collection & Analysis

Key Considerations	Best Practices / Notes
▪ 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. ***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 when more than one person is responsible for coding, 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 (including the name of the software to be used). ***Surveys*** ▪ Describe the source of the survey (e.g., a published, validated survey vs. a survey developed in-house), and identify if the survey will be anonymous or confidential. ▪ If collection of data will occur via an electronic survey platform, specify the name of the platform to be used. ▪ Specify the anticipated length of time it will take the participant to complete the survey. ▪ Describe how the survey data will be analyzed (e.g., provide details of the qualitative/quantitative data analysis method or statistical analysis).	respondent cannot be ascertained. Additionally, for the survey to be anonymous please verify that the survey platform is not collecting IP addresses from respondent in the background as this would be considered an identifier. ▪ A confidential survey means that survey responses are connected to personally identifiable information and the identity of the respondent can be ascertained. ▪ Any data collection tools (e.g., interview script/guide, questionnaire/survey, etc.) you propose to use in your project must be included with your application for review. ▪ After the Office of Research Integrity has issued you an exemption determination letter, any subsequent changes you wish to make to data collection tools must be submitted for review prior to use via an '**Application for Amendment**' (click here).

C. Methods of Data Collection & Analysis

Key Considerations	Best Practices / Notes
▪ Detail the logistics for survey distribution and management. Indicate if the survey will be completed on paper vs. an electronic survey platform.	

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. ▪ 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 you plan to recruit individuals with limited English proficiency, describe your plan for communicating with the participant and how you will assess their on-going comprehension of the project. ▪ 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 (next page)**. ▪ When research is conducted at (or facilitated by) an outside institution or non-UNE site, a letter of support (from an appropriate signatory official)	▪ 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 Office of Research Integrity considers UNE students and employees to be a vulnerable population. ▪ If you plan to recruit participants from a vulnerable population, additional protections will need to be outlined within sections F & G of the research proposal. ▪ If your screening/recruitment process requires access to protected health information (PHI) to verify project inclusion/exclusion criteria, you will need to submit a '**Request for a Waiver of HIPAA Authorization for Research Purposes**' form (click here) to obtain 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 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 Office of Research Integrity has issued you an exemption determination letter, any subsequent changes you wish to make to recruitment materials must be submitted for review prior to use via an '**Application for Amendment**' (click here).

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

Key Considerations	Best Practices / Notes
acknowledging and supporting the research project from the outside institution or non-UNE site is required. ▪ Specify if the results of the project will be shared with site leadership. If yes, indicate if the data to be shared will be de-identified and presented in aggregate.	***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
▪ Describe how and when do you plan to disseminate the Participant Information Sheet. ▪ Describe the process for going over the content of the Information Sheet with the participant. Specify that participants will be provided an opportunity to ask questions or express concerns during this process. ▪ Describe how you plan to solicit acknowledgment from the participant that they are ready to proceed with the interview. ▪ For projects that involve surveys, state that completion of the survey implies consent on behalf of the participant.	▪ Research projects that qualify for exemption do NOT fall under the jurisdiction of the federal human 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 website (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 also be provided as an enclosure within the envelope.

E. Participant Information Sheet

Key Considerations	Best Practices / Notes
	▪ 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 prior to completing the survey. This can be accomplished by (1) pasting the content of the information sheet at the beginning of the survey, or (2) embed the information sheet file (or provide a hyperlink to the information sheet) at the beginning of the survey.

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 and survey data) will be stored/managed. Specify how data will be kept secure/protected and who will have access to the data. ▪ For interviews, specify the length of time any audio or video recordings will be retained. ▪ If a master list or key will be used to record personally identifiable information collected about participants during the screening/recruitment process, provide the following details: (1) describe how the master list or key will be stored separately and securely from the study data, (2) specify who will have access to the master list, and (3) indicate when the master list or key will be destroyed. ▪ With the exception of the master list/key and audio/video recordings (which should be deleted at the earliest opportunity), specify that all other study data will be retained for a minimum of 3 years after completion of the project before being destroyed. **Note**: If you are requesting a partial waiver of HIPAA authorization, you will also need to note that the final signed version of the '**Request for a Waiver of HIPAA Authorization for Research Purposes**' form will be kept for 6 years after receiving an exemption determination letter.	**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 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.

F. Provisions for Participant Privacy & Data Confidentiality

Key Considerations	Best Practices / Notes
▪ Should a participant request to withdraw from the project, describe the scenarios under which you will or will not be able to delete the participant's data. For example, if the project involves an anonymous survey you would likely have no way of identifying the participant's individual responses to delete them. Similarly, you could delete a participant's interview transcript when the master list or key is in existence, but may not be able to do so after the master list or key is destroyed. ▪ 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.	▪ Safeguarding electronic data through use of encryption, use of password-protected files, use of a password-protected computer, storage of data on a UNE secure network drive or the researcher's UNE Microsoft 365 OneDrive account, and restricting access to data to the study team only. 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 group discussions (including focus groups) to others. ▪ Stripping interviews of all personally identifiable information during the transcription process. Use of a pseudonym or participant ID 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). ▪ **The use of a master list is deemed a best practice in research when personally identifiable information is collected from participants during the screening/recruitment process**. 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.). For more information about master lists, please refer to the '**Guidance for Using a Master List in a Research Project**' available on the UNE IRB website.

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 or discomforts, and the likelihood that these harms or discomforts will occur.	▪ 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

G. Statement of Potential Research Risks to Participants

Key Considerations	Best Practices / Notes
▪ If your project only involves the completion of an anonymous survey, relay that the probability and magnitude of harm/discomfort anticipated as a result of participation in the project are not greater than those ordinarily encountered in daily life. ▪ 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, describe the precautions/safeguards you will employ to mitigate the risk of harm.	sources of potential harm are invasion of privacy, stigmatization, or breach/loss 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, class grade(s), or relationship with any instructor at UNE. ▪ 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.