This document provides guidance for completing the the *Research Protocol Template (Non-Exempt Projects)* for research involving human participants. Please ensure your research protocol adequately addresses the applicable key considerations and best practices outlined within each section below.

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

1. BACKGROUND, AIMS, & SIGNIFICANCE

Key Considerations	Best Practices / Notes
▪ Briefly describe the goals of your research project. Summarize the background, prior literature, nature, rationale, and significance of the proposed project. ▪ In outline form, clearly state the objectives of the research, major hypothesis, and research design.	▪ The IRB is composed of individuals from many disciplines and thus the description of your research should be written in terms readily comprehensible by non-experts. ▪ Avoid the use of jargon and/or technical language. ▪ Be sure to spell out any acronyms at the time of first use

2. DESCRIPTION OF STUDY PROCEDURES

Key Considerations	Best Practices / Notes
General Considerations ▪ Provide a description of the procedures to be followed. ▪ Indicate the anticipated duration of the research from the participant's perspective, including the frequency, length, and total number of sessions (as applicable). ▪ 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. ***Use of Biomedical or Clinical Procedures*** ▪ Detail the nature of each procedure (e.g., blood draw, vital signs, saliva sample). ▪ Specify the location and the personnel involved (e.g., licensed clinician, lab technician). ***Use of 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	▪ Use plain language to describe procedures—IRB reviewers may not be experts in your field. ▪ Pilot-test your instruments or procedures when feasible, especially for new tools. ▪ Clearly differentiate between what's done for research vs. what's done for clinical care or education. ▪ For complex procedures, provide diagrams, flowcharts, or labeled images of the study activities in both the research protocol and consent materials. Visuals help reviewers understand unfamiliar procedures and support informed consent for participants with varying levels of health literacy. ▪ 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 protocol. ▪ 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 respondent cannot be ascertained. To ensure the

2. DESCRIPTION OF STUDY PROCEDURES

Key Considerations	Best Practices / Notes
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). ***Use of 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. The IRB recommends using secure, institutionally supported platforms such as REDCap or Qualtrics for online survey administration to ensure privacy and compliance with research data protection standards. ▪ 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 survey platform. ***Use of Experimental or Behavioral Tasks*** ▪ Describe each task participants will complete (e.g., memory test, reaction time task, VR simulation). ▪ Include timing, structure (e.g., randomized, counterbalanced), and expected outcomes. ▪ State whether deception is used and how/when participants will be debriefed. ▪ Mention any stimuli presented (e.g., images, videos, audio files). ▪ Clarify how performance will be recorded and analyzed. ***Use of Educational or Medical Records*** ▪ Describe what records are accessed (e.g., academic transcripts, educational records, EMRs). ▪ Justify why these records are necessary. ▪ Specify who will access them, under what authority, and how privacy will be protected.	survey is truly anonymous, confirm in the protocol that the survey platform does not collect IP addresses or other identifying information from respondents in the background, as these are considered identifiers. ▪ 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. ▪ Procedures involving the physical manipulation of human biospecimens require review and approval by the Institutional Biosafety Committee. IBC approval is required ***before*** submission to the IRB. Please reach out to the IBC via ibc@une.edu for questions. ▪ Procedures involving the use of radiation require an ancillary review by the Radiation Safety Office. The IRB will facilitate this review on the investigator's behalf. Please be aware that this process may result in extended review times. ▪ When FERPA applies, an ancillary review by the Registrar's Office is required and will be facilitated by the IRB on the investigator's behalf. Please be aware that this process may result in extended review times. ▪ If your research involves conducting studies on tribal lands, includes tribal members as participants, or addressed tribal culture, historical, or natural resources, you must: 1. Consult with the appropriate tribal nation or indigenous community to determine whether tribal approval or review is required. 2. Obtain any necessary approvals from the tribal review board or governing body ***before*** submitting your protocol to the UNE IRB. 3. Ensure your research complies with tribal laws, policies, and ethical standards, in addition to institutional and federal requirements.

2. DESCRIPTION OF STUDY PROCEDURES

Key Considerations	Best Practices / Notes

▪ If records are protected under **FERPA** or **HIPAA**, include any required letters of support from the record-holding entity (for non-UNE sites only).
 	
Use of Digital Tools, Platforms, and AI
▪ List any third-party platforms used for:
  ○ Recruitment (e.g., social media)
  ○ Data collection (e.g., mobile apps, transcription tools)
  ○ Analysis (e.g., Copilot, ChatGPT, NVivo, SPSS)
▪ Specify whether these platforms are **UNE-approved**. If not, note that an ITS security review may be required.
▪ If using **generative AI** tools:
  ○ Provide a description of the tool, including its name and version number (e.g., ChatGPT-4.0), its intended purpose in the project, and how it will be used in interactions with participants.
  ○ Disclose if identifiable information is entered into AI systems.
  ○ Explain any risks (e.g., bias, misinformation, data leakage) and mitigation plans.
  ○ Clarify how AI-generated content will be disclosed to participants, if applicable.
	▪ For any third-party tools or applications not institutionally approved for use in research, and that collect, store, transmit, or process research data—including personally identifiable information (PII), protected health information (PHI), or other sensitive data—a security review by Information Technology Services (ITS) may be required. Documentation of this ancillary review may be requested as part of the IRB review process.
	▪ If using AI tools, please refer to the Guidance for the Use of Artificial Intelligence (AI) in Research (PDF).

3. USE OF MEDICAL DEVICES

Key Considerations	Best Practices / Notes
General Considerations ▪ Provide a detailed description of each medical device used in the study, including its intended purpose, how it operates, and how participants will be exposed to or interact with it (e.g., wearing, handling, observation). ▪ Specify whether the device is investigational or being used exactly as indicated in the FDA-cleared/approved labeling. ▪ Include the risks associated with the use of the device and how those risks will be minimized in **Section 12: Risks to Participants** of the protocol.	▪ For the purposes of IRB review, a **medical device** is defined in accordance with the U.S. Food and Drug Administration (FDA) as: "An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: 1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; or

3. USE OF MEDICAL DEVICES

Key Considerations	Best Practices / Notes
▪ Describe how adverse events will be monitored, reported, and managed. ▪ If the device collects or transmits data, describe what identifiers will be stored or transmitted by the device (e.g., IP address, biometric data). Explain how participant data will be protected in **Section 11: Confidentiality & Privacy Protections** of the protocol. ***Devices Used According to Approved Labeling*** ▪ If your research involves a medical device that has been cleared or approved by the FDA, you must submit documentation that shows what the FDA approved—specifically, the official labeling or a summary of the device. ▪ ***Note***: *The IRB may request a device manual or other supporting documentation at its discretion, particularly if the use of the device in the study is associated with elevated or unclear risk to participants.* ***Use of an Investigational Device*** ▪ Include a copy of the completed Investigational Device Information Form for each investigational device used in the project for IRB review.	2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or 3. Intended to affect the structure or any function of the body of humans or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body and is not dependent upon being metabolized for the achievement of its primary intended purposes." ▪ An **investigational device** is a medical device that is the subject of a clinical study and is being evaluated for safety, effectiveness, or performance. It includes: 1. Devices not yet approved or cleared by the FDA for marketing in the United States; or 2. Devices that are approved or cleared in the United States but are being studied for a new indication, different population, or altered use (e.g., modified design or delivery method) not previously reviewed by the FDA. ▪ When your project involves participant interaction with a medical device, provide clear, participant-friendly materials. This includes: ○ Diagrams or images of the device. ○ Simple, lay-language descriptions of how it works. ○ Instructions that are pretested with individuals similar to your study population to ensure they are understandable.

4. PARTICIPANT POPULATION

Key Considerations	Best Practices / Notes
▪ Describe the involvement of the research participants in the project. Clearly state the following:	▪ Inclusion/exclusion criteria should be scientifically or ethically justified. Avoid arbitrary exclusions unless necessary for the study design.

4. PARTICIPANT POPULATION

Key Considerations	Best Practices / Notes
○ Source of participants (e.g., patients from a specific clinic, students from a university course, individuals responding to public advertisements, or participants from an existing registry). ○ Inclusion and exclusion criteria, with a brief rationale for each. ○ Participant characteristics (e.g., age range, sex, health status, diagnosis, demographics). ○ Expected number of participants to be enrolled (for the group as a whole and within any subgroup if applicable). ○ What is the relationship (if any) between the researcher and the participants (e.g., instructor-student, clinician-patient, supervisor-subordinate)?	▪ Consider whether the participant population reflects appropriate diversity (e.g., age, sex, race/ethnicity, socioeconomic status) for the research aims. Justify any intentional exclusions of subpopulations. ▪ Provide a reasonable estimate of how many participants you expect to enroll, and be prepared to explain how this number aligns with your research design (e.g., statistical power, thematic saturation in qualitative work). ▪ If your research involves students as research participants, please refer to the Guidance for Recruiting Students as Research Participants (PDF). ▪ Research conducted in a foreign country that involves interaction or intervention with participants (whether in-person or online) requires completion of the **Supplemental Form: Transnational Research** found on the UNE IRB website.

5. PARTICIPANT RECRUITMENT

Key Considerations	Best Practices / Notes
▪ Describe the source of participants (e.g., patients from a specific clinic, students from a university course, individuals responding to public advertisements, participants from an existing registry). ▪ Describe the methods that will be used to identify potential participants. ▪ Specify when, where, and how participants will be recruited (e.g. advertisements, announcements in class, e-mail, internet, etc.). ▪ Describe the materials that will be used to recruit participants. ▪ Recruitment materials must, at a minimum, explain what participation involves, what the study is investigating, state that it's research, and clarify that participation is voluntary.	▪ Recruitment methods should ensure fair access to participation and avoid practices that could systematically exclude certain groups unless justified. ▪ Be aware of privacy provisions when designing recruitment activities, especially when targeting vulnerable populations and/or researching sensitive topics. ▪ If you plan to recruit participants from a vulnerable population, additional protections will need to be outlined in **Section 15: Additional Protections for Vulnerable Populations** of the protocol. ▪ 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 to obtain a partial waiver of HIPAA authorization.

5. PARTICIPANT RECRUITMENT

Key Considerations	Best Practices / Notes
▪ ***Note***: *The text of any advertisement, letter, flyer, oral script, or brochure used to solicit prospective participants must be provided for IRB review.*	▪ If you wish to incorporate a branded UNE logo within your recruitment material, please contact the UNE Office of Communications for more information. **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

6. RESEARCH SETTING

Key Considerations	Best Practices / Notes
▪ Describe the setting (e.g., a classroom) and the location (e.g., name of school) where the interaction or intervention with participants will occur. ▪ Specify if the results of the project will be shared with site leadership or stakeholders.	▪ Ensure the setting allows for privacy, especially if sensitive topics are discussed. For example, a quiet, private room is preferable to a public or shared space. ▪ Conducting research at a site where you are employed or hold another role (e.g., as a teacher, coach, or administrator) may raise ethical concerns. Explain how you will minimize coercion and manage potential conflicts. ▪ ***Note:*** When research is conducted at (or facilitated by) an outside institution or non-UNE site, a letter of support (from an appropriate signatory official) acknowledging and supporting the research project from the outside institution or non-UNE site is required.

7. MULTI-SITE RESEARCH

Key Considerations	Best Practices / Notes
▪ If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:	▪ U.S. federal law restricts the transfer of certain technologies, data, software, and biological materials to foreign persons—even if the transfer happens

7. MULTI-SITE RESEARCH

Key Considerations	Best Practices / Notes
○ All sites have the most current version of the protocol, consent document, and HIPAA authorization (if applicable). ○ All required approvals have been (or will be) obtained at each site (including approval by the site's IRB of record). ○ All modifications will be communicated to sites and approved (including approval by the site's IRB of record) before the modification is implemented. ○ All engaged participating sites will safeguard data as required by local information security policies. ○ All local site investigators conduct the study appropriately. ○ All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.	**within the U.S.** If your project includes **foreign collaborators, students, or research sites**, you must address export control concerns, even if the study is not externally funded. For questions about export control, please contact the Office of Research & Innovation at ori@une.edu.

8. COMPENSATION & COSTS

Key Considerations	Best Practices / Notes
▪ Describe any compensation or reimbursement. ▪ Explain the type (e.g. course credit, opportunity drawing for gift cards, cash payment, parking, etc.), the amount, and timing of the compensation or incentive. ▪ Describe any anticipated costs to participants. ▪ If conducting research in a classroom environment, state what alternative activities will be offered to students not participating, and describe how peer pressure or stigma for non-participants will be minimized.	▪ Compensation plans should be incremental (not contingent upon study completion) to avoid coercion or undue influence. ▪ Information about any anticipated costs to participants must be disclosed in the consent form. ▪ If your project offers compensation for completing an online survey, include verification checks to help ensure that only legitimate participants receive incentives. ▪ Any withholding of compensation until verification checks are completed must be disclosed in the consent form, as well as any conditions needing to be met for participants to be compensated.

9. CONSENT/ASSENT PROCESS

Key Considerations	Best Practices / Notes
▪ Describe in detail your procedures for obtaining and documenting consent from each participant. Include who will conduct the discussion, the setting in which it will take place, and how you will ensure participants have adequate time to review the information. ▪ Specify how participants will be encouraged to ask questions or share concerns. ▪ Describe your plan for assessing participant understanding as part of the consent process. The goal is to ensure that participants are not only receiving the information but also truly comprehending what their participation involves. ▪ If you plan to recruit individuals with limited English proficiency, describe your plan for communicating with participants and how you will assess their on-going comprehension throughout the study. ▪ If you are requesting an alteration or waiver of informed consent or assent, provide a justification statement confirming all requirements under 45 CFR 46.116 (d) have been met (see IRB application). ▪ If you are requesting a waiver of documentation of informed consent, please provide a justification statement confirming all requirements under 45 CFR 46.117 (c) have been met (see IRB application). ▪ As applicable, indicate in the consent form whether, and how, research information will become part of a participant's medical record. ▪ If your project involves minors or adults with diminished capacity to consent, describe: ○ The process for obtaining assent from participants, permission from parents/guardians, or consent from a legally authorized representative (LAR), as appropriate. ○ How capacity will be assessed, what information will be shared, and how understanding and voluntary participation will be ensured. ○ If adults with impaired decision-making capacity will be recruited, specify whether the impairment is permanent, intermittent, or temporary. The degree of impairment will	▪ Consent documents should be written in **plain language** at a level appropriate to the subject population, generally at an **8th grade reading level**. For more information, please refer to the Guidance for Drafting a Readable Participant Information Sheet or Consent Form (PDF), the Program for Readability In Science and Medicine (PRISM), and the PRISM Readability Toolkit (PDF). ▪ Informed consent, whether oral or written, must not contain language that requires or appears to require participants to waive any of their legal rights or to release the investigator, sponsor, institution, or its agents from liability or negligence. ▪ Obtaining assent from children is typically required for children 7 years and older. ▪ When it comes to **child assent**, a child can demonstrate willingness to participate in research in several ways. ○ The research should be discussed with the child at a developmentally appropriate level and the use of photographs, images or videos may assist with conveying information and enhancing comprehension. ○ Children should be directly asked if they understand and to repeat back, in a sentence or two, what they are being asked to do. ○ In addition to obtaining verbal assent, the child's behavior should be observed. Behavior may provide additional clues as to eagerness or reluctance to cooperate with study procedures. ▪ Enrolling **adults with diminished capacity to consent** may necessitate the involvement of a legally authorized representative (LAR). When a LAR is acting on behalf of the prospective participant, researchers should consider the most appropriate methods to present information to the LAR and the participant about the research and its risks and anticipated benefits.

9. CONSENT/ASSENT PROCESS

Key Considerations	Best Practices / Notes
impact the consent/assent process (e.g., capacity assessments at certain time points, reconsent once capacity is restored). ***Note**: Provide a copy of the verbal assent script or written assent form for IRB review.*	

10. USE OF PARTICIPANT HEALTH INFORMATION

Key Considerations	Best Practices / Notes
Access or Use of PHI from a HIPAA Covered Entity ▪ Describe the following: ○ The types of PHI that will be accessed or used (e.g., medical records, lab results, diagnostic codes) and who will have access. ○ The name(s) of the HIPAA-covered entity and/or any designated health care components involved. ○ How access to PHI will be obtained (e.g., through a data use agreement, EMR access). ○ Whether a HIPAA Authorization will be obtained from participants, or if you will be requesting a waiver of HIPAA authorization from the IRB. ○ A description of how PHI will be created, used, or disclosed, including a list of any direct or indirect identifiers that will be retained. ○ A justification that the PHI requested represents the minimum necessary information needed to achieve the research objectives. ▪ Attach copies of the HIPAA Authorization Template for Research Purposes, Request for a Waiver of HIPAA Authorization for Research Purposes, and Research Involving PHI of Deceased Individuals Attestation Form as applicable. ***Collection & Use of Research Health Information (RHI) (e.g., not from a HIPAA covered entity)*** ▪ Describe the following: ○ The types of RHI you will collect directly from participants (e.g., survey responses, biometric	▪ UNE has declared itself a hybrid covered entity and has designated the following units as its health care components under HIPAA: ○ Coleman Dental Hygiene Clinic ○ Student Health Care – Petts Health Center and Portland Health Center ○ MatureCare ○ Oral Health Center ▪ **Protected Health Information (PHI)** refer to individually identifiable health information that is created, received, maintained, or transmitted by a HIPAA-covered entity or its business partner, and that relates to: 1. The past, present, or future physical or mental health or condition of an individual; 2. The provision of health care to the individual; or 3. The past, present, or future payment for the provision of health care to the individual. PHI includes information that can identify the individual (e.g., name, address, birthdate) and is transmitted or maintained in any form (electronic, paper, or oral). ▪ In the context of research, access to PHI held by a HIPAA-covered entity is **strictly regulated** and permitted **only with appropriate authorizations or IRB approvals**. Researchers must obtain either:

10. USE OF PARTICIPANT HEALTH INFORMATION

Key Considerations	Best Practices / Notes
data, wearable device outputs, biospecimens, behavioral assessments). ○ How the RHI will be collected (e.g., through interviews, surveys, mobile apps, devices, lab tests). ○ Whether the information will be individually identifiable, and if so, what identifiers will be retained (e.g., name, date of birth, coded ID). ○ Whether the RHI will be coded or de-identified. ○ Who will have access to the RHI. ○ A justification that the RHI requested represents the minimum necessary information needed to achieve the research objectives.	○ A valid HIPAA Authorization signed by the participant, or ○ An IRB-approved waiver of HIPAA authorization that meets federal criteria. It is important to understand that a clinician's routine access to medical records for treatment purposes **does not grant permission to use those records for research**. ▪ **Research Health Information (RHI)** refers to individually identifiable health information collected directly from research participants for the purpose of a research study, and not obtained from or maintained by a HIPAA-covered entity (such as a hospital or clinic). This information may include responses to health questionnaires, data from wearable devices, physical measurements, biological samples, or results from study procedures. While this type of information is **not subject to the HIPAA Privacy Rule** (unless obtained from or shared with a covered entity), it is still considered **sensitive and identifiable** in many cases. Therefore, researchers must: ○ Treat it with the same level of care as other confidential information. ○ Implement appropriate privacy and security protections. ○ Describe data handling procedures clearly in the research protocol. ○ Disclose any data collection, storage, or sharing practices in the consent form.

11. CONFIDENTIALITY & PRIVACY PROTECTIONS

Key Considerations	Best Practices / Notes
▪ Describe how participant privacy will be protected throughout the study, including during recruitment, informed consent, and data collection. Consider the	**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

11. CONFIDENTIALITY & PRIVACY PROTECTIONS

Key Considerations	Best Practices / Notes
physical or virtual setting (e.g., private rooms, closed doors, secure video platforms) to ensure privacy is maintained. ▪ Describe the context and setting in which participants will interact with research staff (e.g., in-person, by phone, or virtually), and how that setting supports confidentiality. ▪ Explain how the research team will access participant information, including the sources of identifiable data and whether access is necessary and appropriately authorized. Specify who will have access to participant information. ▪ List any personally identifiable information or identifiers that will be collected during the study (e.g., name, date of birth, medical record number, photos, or audio/visual recordings). ▪ If identifiers will be stored, specify the length of time they will be retained, how and where they will be securely stored, and when and how they will be destroyed or anonymized. ▪ If coded data are used, describe whether a master list or linking key will be maintained, how it will be securely stored separately from the data, and the specific time point and method for its destruction. ▪ If recordings (audio or video) are collected, indicate how long they will be retained, the conditions for their destruction, and the secure methods that will be used to delete them. ▪ If your research is federally funded and uses identifiable data or biospecimens, explain why the study cannot be conducted using only de-identified data or specimens. ▪ Describe how and where data or biospecimens will be stored, how long they will be retained, how access will be controlled, and who will have access. ▪ List what specific data elements will be associated with each specimen, if applicable. ▪ Describe any plans to release data or specimens to other researchers or entities. Include the request process, required approvals, who may obtain the materials, and what associated data will be shared.	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. Below are examples of strategies researchers may use to protect participant privacy, depending on the study design and setting: ▪ When research involves physical exams, wearable devices, biospecimen collection, or body imaging, ensure private settings, gender-appropriate staff (when needed), and respectful communication. ▪ Inform the participant that you will conduct 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. Examples of methods to protect participant data confidentiality include: ▪ **Physical Records**: Storage of paper records in a locked file cabinet within a locked office accessible only to the PI and/or study team. ▪ **Electronic Data**: Protect electronic data by using encrypted and password-protected files, password-protected computers, and secure storage platforms. For storing Protected Health Information (PHI) or Research Health Information (RHI), use institutionally approved platforms such as REDCap or Box, which are specifically designed to meet security and compliance standards. Alternatively, secure UNE network drives or the researcher's institutional Box or Microsoft 365 OneDrive account may be appropriate for other types of sensitive data, depending on institutional

11. CONFIDENTIALITY & PRIVACY PROTECTIONS

Key Considerations	Best Practices / Notes
▪ Specify the record retention requirements for study records and research data. Researchers must retain study records and research data for a minimum of 3 years after study completion, in accordance with federal regulations. If the study involves HIPAA-covered data, all HIPAA-related documentation (e.g., HIPAA waivers, HIPAA authorizations, disclosures) must be retained for at least 6 years after the study's completion, per HIPAA Privacy Rule requirements.	policy. Avoid the use of thumb drives, flash drives, or USB drives, as these can be easily lost or stolen. ▪ **Group Settings**: When applicable (e.g., focus groups), inform participants during the consent process that they should not share or repeat information disclosed by other participants. Encourage respectful behavior and the nondisclosure of any information shared during group discussions. ▪ **Email Communications**: To protect participant identity, avoid group emails that reveal addresses or other identifiers. Use blind copy (BCC) or send individual messages. Clearly state how participants' contact information was obtained. ▪ **Transcription Process**: During the transcription of interviews, remove all personally identifiable information. Use pseudonyms or participant IDs instead of real names. ▪ **Audio/Video Recordings**: Destroy recordings as early as feasible in the research process (e.g., after verifying transcript accuracy). ▪ **Master List/Linking Key**: When collecting personally identifiable information during screening or recruitment, maintaining a separate master list linking participant identities to study codes is considered best practice. Store the master list securely and separately from the study data. Destroy the master list as soon as it is no longer needed (e.g., after transcript verification or data analysis completion). For more information about master lists, please refer to the 'Guidance for Using a Master List in a Research Project'.

12. RISKS TO PARTICIPANTS

Key Considerations	Best Practices / Notes
▪ List any reasonably foreseeable risks, discomforts, hazards, or inconveniences associated with participation in the research. Describe the probability,	▪ Risk is defined as the probability and magnitude of harm that may result from participation in the research.

12. RISKS TO PARTICIPANTS

Key Considerations	Best Practices / Notes
magnitude, duration, and reversibility of each risk, as applicable. ▪ Identify any procedures that may involve currently unforeseeable risks, if applicable. ▪ Describe any risks to an embryo or fetus if participants could be or become pregnant during the study, if applicable. ▪ Describe any risks to individuals other than participants, such as study personnel (e.g., risks related to handling medical devices), if applicable. ▪ Explain how each identified risk will be minimized or mitigated, including safety monitoring procedures, use of qualified personnel, or other protective measures.	▪ Risk may include psychological, physical, legal, social/reputational, and economic/financial harms. ▪ Certain topics may carry greater risk than others (e.g., illegal activity, drug or alcohol use, sexual behavior, or other stigmatized behaviors). ▪ If your project will recruit UNE students, they must be informed that their decision to engage/not engage in the research 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 must be informed that their decision to engage/not engage in the research will have no effect on their employability or performance review. ▪ Investigators must clearly identify any situations in which they are mandated to disclose confidential information, which may pose legal risks to participants (e.g., reporting suspected child or elder abuse or neglect, or threats of harm to self or others). ▪ Researchers cannot guarantee confidentiality for highly sensitive information unless they obtain a Certificate of Confidentiality to protect against forced disclosures.

13. POTENTIAL BENEFIT TO PARTICIPANTS & SOCIETY

Key Considerations	Best Practices / Notes
▪ Describe any potential benefits to individual participants, including (if applicable) the probability, magnitude, and duration of those benefits. ▪ Discuss the potential value or importance of the knowledge expected to result from the research. ▪ Explain why the risks and burdens to participants are reasonable in relation to the potential benefits and the importance of the knowledge to be gained. ▪ If there are no direct benefits to participants, clearly state this is the protocol. In such cases, emphasize the potential societal or scientific value of the knowledge to be gained and why participation is still ethically justified.	▪ Do not include monetary reimbursement, free clinic visits, or other incentives in this section. These details should be provided within '**Section 8. Compensation & Costs**' of the research protocol.

14. PROVISIONS TO MONITOR DATA FOR PARTICIPANT SAFETY

Key Considerations	Best Practices / Notes
▪ When applicable, describe your plan to monitor data for participant safety. Consider including the following elements: ○ Plan for periodic evaluation of collected data to assess both potential harms and benefits, and to determine whether it remains safe for participants to continue in the study. ○ Types of data to be reviewed, including safety data, adverse events, and efficacy data (if relevant). ○ How safety information will be collected, such as through case report forms, study visits, telephone follow-ups, or other methods. ○ Timing and frequency of safety data collection, including when monitoring begins and how often it occurs. ○ Who is responsible for reviewing the safety data, such as the PI, safety monitor, or data monitoring committee. ○ Frequency of cumulative data review, and whether interim analyses will be performed. ○ Statistical methods used to evaluate safety data, if applicable, to detect patters of harm or benefit. ○ Predefined conditions or thresholds that would trigger a temporary or permanent suspension of the study to protect participants.	▪ A monitoring plan is required for research involving *greater* than minimal risk to participants. ▪ **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater—in and of themselves—than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. ▪ The plan may include the establishment of a data monitoring committee and procedures for reporting the committee's findings to the IRB and the study sponsor (if applicable).

15. ADDITIONAL PROTECTIONS FOR VULNERABLE POPULATIONS

Key Considerations	Best Practices / Notes
▪ Describe any vulnerable populations included in the research (e.g., children, prisoners, pregnant persons, individuals with impaired decision-making capacity, economically or educationally disadvantaged persons, individuals with limited English proficiency, UNE students or employees), and outline the additional safeguards in place to protect their rights and welfare. ▪ Explain how potential coercion or undue influence will be minimized. This may include procedures such	▪ The IRB considers UNE students and employees to be a potentially vulnerable population, due to possible concerns about coercion or undue influence. ▪ If your project will recruit UNE students, they must be informed that their decision to engage/not engage in the research 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 must be informed that their decision to engage/not

15. ADDITIONAL PROTECTIONS FOR VULNERABLE POPULATIONS

Key Considerations	Best Practices / Notes
as assessing decision-making capacity, obtaining permissions from a legally authorized representative (LAR), obtaining participant assent (when appropriate), or involving a witness during the consent process.	engage in the research will have no effect on their employability or performance review. ▪ Investigators must clearly outline any situations in which they are mandated to disclose confidential information, which may place participants at risk for legal consequences (e.g., mandatory reporting of suspected child or elder abuse or neglect).

16. SHARING RESULTS WITH PARTICIPANTS & OTHERS

Key Considerations	Best Practices / Notes
▪ Indicate whether study results or individual participant results (e.g., results from investigational diagnostic tests, genetic testing, or incidental findings) will be shared with participants or others (such as the participant's primary care provider). If results will be shared, describe what will be shared, with whom, and how. ▪ 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. ▪ If the research involves Protected Health Information (PHI), describe how data sharing will comply with HIPAA and any other applicable privacy regulations or institutional policies. ▪ Describe how findings or results will be shared (e.g., publications, presentations, community reports, site leadership or stakeholder reports) in a way that honors participant contributions and safeguards sensitive data.	▪ The ethical principles of Respect for Persons and Beneficence support returning valid and reliable individual results, even if they are not clinically actionable, as a way to honor participants' contributions and support autonomy. ▪ Clearly label returned results as "research" findings (not diagnostic or clinical), and advise participants not to use them for self-treatment decisions without consulting a qualified healthcare provider. ▪ A well-defined plan for returning individual results should be included in the protocol and consent form. If added later, the plan must be submitted as a protocol amendment for IRB review, and re-consent may be required. ▪ Carefully consider when to return results: ○ Baseline or end-of-study results are often safe to share promptly. ○ Interim or in-study results may need to be withheld until after participation ends to avoid introducing bias (e.g. unblinding or influencing participant behavior). ▪ Explain to participants what the results mean—and what they don't mean—to minimize misunderstandings, therapeutic misconception, and overinterpretation. ▪ For potentially sensitive or easily misinterpreted findings, consider involving a healthcare provider in the disclosure process or requiring follow-up with a medical professional.

16. SHARING RESULTS WITH PARTICIPANTS & OTHERS

Key Considerations	Best Practices / Notes
	▪ For each category of individual results, assess the potential impact on trial validity—especially in blinded or placebo-controlled studies—and determine whether returning results is appropriate.

17. WITHDRAWAL OF PARTICIPANTS

Key Considerations	Best Practices / Notes
▪ Describe any anticipated circumstances under which participants may be withdrawn from the research without their consent, such as safety concerns, noncompliance, or investigator discretion. Include whether and how participants will be notified and what, if any, follow-up will occur after withdrawal. ▪ Describe the procedures for handling participant withdrawal, including: o Complete withdrawal from all study procedures and data collection. o Partial withdrawal, where participants stop some study procedures but allow continued use or collection of their data. ▪ Clarify whether participant data can be deleted upon withdrawal, and under what conditions: o If the study uses anonymous data collection (e.g., anonymous surveys), it may be impossible to identify and delete individual responses. o If data are coded and the master list or linking key is still maintained, it may be possible to delete a participant's data upon request. o Once the master list or linking key is destroyed, it may no longer be possible to associate data with individual participants for deletion.	▪ Participants may withdraw consent at any time—in writing, verbally, or by choosing not to continue participation. o The PI should inform the participant of any recommended end-of-study safety procedures, and ask whether the participant is willing to complete those procedures and any other final study activities. o If a participant withdraws—verbally or in writing—all study-related data collection must stop immediately, including collection of any Protected Health Information (PHI) or Research Health Information (RHI). At the time of withdrawal, the PI should ask whether the participant is willing to allow continued access to their health data for purposes such as long-term follow-up or outcome analysis. If the participant does not explicitly agree, no further health data may be collected or accessed. ▪ The PI may also withdraw a participant from the study if it is in the participant's best interest or for other justifiable reasons.

18. RESOURCES AVAILABLE

Key Considerations	Best Practices / Notes
▪ Describe the resources available to conduct the research. Include the following, as appropriate: o **Recruitment feasibility**: Justify your ability to recruit the required number of suitable	▪ The IRB expects a clear description of all internal approvals and institutional support mechanisms that enable and oversee the conduct of research.

18. RESOURCES AVAILABLE

Key Considerations	Best Practices / Notes
participants within the proposed recruitment period. For example, how many potential participants can you access? What percentage of them do you need to enroll? ○ **Time commitment**: Describe the amount of time that will be devoted to conducting and completing the research. ○ **Facilities**: Detail the facilities available to support the research activities. ○ **Support resources for participants**: Describe the availability of medical, psychological, or other support services that may be needed as a result of anticipated consequences of the research.	▪ The PI is responsible for detailing any internal permissions, oversight structures, or resource allocations necessary to carry out the study. ▪ **Examples of information to include**: ○ A description of institutional or departmental approvals required to conduct research at the site (e.g., clinic director approval, department head endorsement). ○ Confirmation of access to required equipment, facilities, space, or data systems. ○ If the PI is a student or lacks prior experience conducting non-exempt research, they must identify a faculty advisor or research mentor and describe the nature of that oversight relationship. ○ If applicable, the PI may upload a Letter of Support (LOS) as a supplemental document affirming institutional or mentor endorsement. ***Note**: The IRB reserves the right to request formal documentation (e.g., Letters of Support, Memoranda of Understanding) when the study's context, complexity, or investigator's experience warrants it.*

19. INTERPRETATION OF DATA

Key Considerations	Best Practices / Notes
▪ **Describe the method of data analysis**: Indicate whether the data will be analyzed using quantitative methods, qualitative methods, or a combination of both. Include the specific software or tools (e.g., SPSS, NVivo, R, Excel) that will be used for analysis, and briefly justify their appropriateness for the study. ▪ **Explain how the analysis will address the research question(s)**: Clearly articulate how your approach to interpreting the data will help answer or inform the research question(s) or hypotheses. ▪ **Describe how data will be reported**: Specify whether data will be reported in aggregate form, anonymously, using pseudonyms, or through another method that protects participant identity.	▪ Ensure data interpretation and presentation do not compromise participant confidentiality. Use aggregated data or pseudonyms, and avoid including identifiable details in qualitative excerpts or case descriptions. ▪ If interpreting data by subgroups (e.g., age, race, gender), explain how this will be done ethically and responsibly, avoiding stigmatization or overgeneralization. ▪ For quantitative studies, note how reliability and validity will be assessed. For qualitative studies, outline strategies such as triangulation, member checking, or audit trails.

19. INTERPRETATION OF DATA

Key Considerations	Best Practices / Notes
	▪ Especially in qualitative or subjective analysis, use more than one coder/interpreter to enhance reliability and reduce bias. Describe any consensus-building process. ▪ Consider how the interpretation of data could impact participants, communities, or policy. Avoid interpretations that could harm or misrepresent populations involved in the study.

20. STUDY TEAM EXPERIENCE & CONFLICT OF INTEREST

Key Considerations	Best Practices / Notes
▪ Describe the PI's experience conducting research of a similar nature or design. ▪ Describe the PI's experience working with the proposed subject population, especially if the population is considered vulnerable or requires specific expertise. ▪ Explain how all personnel involved in the study will be informed and trained on the protocol, study procedures, safety protocol, ethical considerations, and their specific roles and responsibilities. If training is required (e.g., students or inexperienced team members), describe how the PI will assess and verify their competency before allowing them to engage in research activities. ▪ Disclose any financial interests or relationships that may be related to the research (e.g., funding sources, equity holdings, IP or patents, consulting fees). ▪ Explain how any financial interests could potentially affect the rights and welfare of research participants. ▪ If financial relationships exist that could present actual or perceived conflicts of interest, describe how these will be managed or mitigated (e.g., disclosure, independent oversight, removal of the interest).	▪ If a student will interact with research participants, the PI or faculty advisor may be required (as determined by the IRB) to provide a letter attesting to the student's qualifications. This letter should confirm that the student's skills are appropriate for the responsibilities involved and specify the extent of supervision that PI or faculty advisor will provide. ▪ Any conflicts of interest must be disclosed in the consent form to promote transparency and allow participants to make an informed decision about their participation in the research.