This guidance document is designed for exempt research projects that involve retrospective chart review (exempt category 4).

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 your hypothesis, 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
▪ Outline your plan to collect and analyze the data required to complete your project. ▪ Describe where the data are currently housed. Will data be abstracted from the medical record? An existing database or registry? ▪ Indicate the health information and any identifiers to be collected for this project. ▪ Specify the time period the records to be retrospectively reviewed will be selected (e.g., review of medical records from January 2020 to January 2022).	▪ Any data collection tools (e.g., master list or key template, data abstraction form template) 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
▪ If you aim to collect sensitive information about subjects, describe what information you wish to collect and why it is needed for your research project. ▪ Describe how the data will be analyzed (e.g., provide details of the quantitative and/or statistical analysis to be employed).	

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

Key Considerations	Best Practices / Notes
▪ Describe the subject population for this research project. Does it include deceased individuals? ▪ Provide the rationale for choosing this population and list the inclusion and exclusion criteria that you will apply in selecting study subjects. ▪ Indicate the anticipated maximum number of records that you intend to review for this project. ▪ When protected health information (PHI) originates from a non-UNE covered entity and the project involves access to, use, or disclosure of PHI for research purposes, 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.	▪ Exemption Category 4 may be applied to research involving pregnant women and/or children, but NOT prisoners. However, the incidental inclusion of prisoners when the research is aimed at a broader audience (e.g., when prisoners are not the intended population of study) is allowed. ▪ Because retrospective chart review projects require access to PHI, you will need to submit a '**Request for a Waiver of HIPAA Authorization for Research Purposes**' form (click here) to obtain a full waiver of HIPAA authorization. ▪ When a distinct or significant part of the project requires access to PHI from deceased individuals, you will need to submit a '**Research Involving PHI of Deceased Individuals Attestation Form**' (click here) with your exempt application. ***Note**: A retrospective chart review project that only involves the incidental collection of PHI on deceased individuals would NOT be considered decedent research.* ▪ A letter of support from a non-UNE covered entity must attest that they are aware of the proposed project and support the access to, use, or disclosure of PHI to the study team for research.

E. Participant Information Sheet

Key Considerations	Best Practices / Notes
▪ Informed consent is not applicable. Therefore, no informed consent form or request to waive consent is required.	▪ Informed consent is not applicable. Therefore, no informed consent form or request to waive consent is required.

F. Provisions for Participant Privacy & Data Confidentiality

Key Considerations	Best Practices / Notes
▪ Outline the procedures that will be employed to protect the confidentiality of subject data during the project. ▪ Describe where and how data (both paper and electronic) will be stored/managed. Specify how data will be kept secure/protected and who will have access to the data. ▪ If a master list or key will be used to record personally identifiable information collected about participants during the data abstraction 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 regard to data retention requirements, please indicate the following: (1) the master list or key will be destroyed at the earliest opportunity, (2) 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, and (3) all other study data will be retained for a minimum of 3 years after completion of the project before being 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.	Methods to protect the confidentiality of subject data 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, storage of data in REDCap, a UNE secure network drive, or the researcher's UNE Box 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. ▪ **The use of a master list is deemed a best practice in research when personally identifiable information is collected during the data abstraction 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 data abstraction has been completed for all subjects). 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 the potential risk(s) that subjects are exposed to as a result of the retrospective chart review, and the precautions/safeguards you will employ to mitigate the risk(s) 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. ▪ For retrospective chart review projects, the biggest risk is typically associated with a breach or loss of confidentiality.

H. Statement of Potential Research Benefits to Participants

Key Considerations	Best Practices / Notes
▪ Indicate there is no direct benefit to the subjects. ▪ Describe the potential benefits of the knowledge gained from the research project.	▪ None