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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 <u>irb@une.edu</u> 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.

Key Considerations	Best Practices / Notes
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.	the reviewer has a background in your proposed research.



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

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	