

(Sample Language for NON-EXEMPT Research)
(Use if you WILL CREATE a subject ID # or code; or collect PHI, with or without a Subject ID code)

REQUEST FOR WAIVER OR ALTERATION OF CONSENT AND HIPAA AUTHORIZATION Version 2011

Use this form if the procedure for this research will alter or will not include all of the required elements of consent [45CFR46.116(d)] and HIPAA authorization [45CFR164.512(i)(2)].

Please respond to each item in the allotted space below using protocol-specific language to provide justification.

Principal Investigator (PI) Name:	Your PI or Preceptor's name
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Protocol Title:	Your full Study Title
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1. Provide a brief explanation of why the research activity to be permitted by this waiver involves no more than minimal risk to the subjects.

This is a [retrospective] and/or [prospective] chart review. No Subject contact will be required. Recording of research data from the patient medical record [will or will not] include any identifiable protected health information (PHI); a Subject identification code [will or will not] be created. All data shall be destroyed as set forth below upon completion of study.

2. Describe the protected health information (PHI) to be collected and the source(s) of PHI.

List all data items to be collected, i.e. age, gender, length of stay, diagnosis, laboratory test results, reason for pain, methods of pain relief and the results, etc. The source(s) is(are) (Physician name &/or Hospital Name) medical records

3. Demonstrate that the research involves no more than minimal risk to the privacy of subjects by describing the plans requested below:

- A. Describe the plan to protect the identifiers from improper use and disclosure and indicate where the PHI will be stored and who will have access.

Coded [and/or] PHI will be recorded by Investigators. All patient identifiable information will remain in the medical record at (name of office or entity), which is subject to privacy and security regulations, policies and procedures. The researchers have been educated on HIPAA regulations and will be given password-protected access to medical records. No name will be used on any of the data worksheets or collection forms. Each Subject [will or will not] be identified in a coded manner. Only the Investigator and Student Researcher will have access to the Subject list or Subject identifier code. The identifier code will be stored in a separate secure location, not in the same location as the data worksheets or collection forms.

- B. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research (how and when identifiers will be destroyed). If there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, provide the reason to retain identifiers.

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Identifiers (Subject list and code) will be destroyed at the earliest opportunity consistent with the conduct of the research or at the end of the project after data collection and analysis have been completed.

C. Provide an explanation of written assurance that you will not re-use the PHI.

PHI will be coded, used solely for this research, not re-disclosed, and the Subject list and codes will be destroyed at the earliest opportunity consistent with the conduct of the research or upon completion of the project.

4. Explain why the research could not be practicably carried out without this waiver or alteration.

Due to the volume of potential Subjects in the study and the short data collection and analysis period, it would be impractical to contact each subject for consent, which could take months.

5. Explain why the research could not practicably be conducted without access to and use of the protected health information.

It would be impossible to investigate the hypothesis presented in the research without access to and use of the PHI due to the nature of the study.

6. Explain why this waiver or alteration will not adversely affect the rights and welfare of the subjects.

PHI will not be released or maintained. Strict confidentiality will be maintained.

7. Explain why the risks of the research are reasonable in relation to the anticipated benefits of the research.

The anticipated benefits of this research include (insert appropriate language, e.g. creating a better standard of care that can be utilized across several fields of medicine in order to prevent...) in patients, while presenting minimal risk to the Subjects being studied. The risk to the Subjects in the study is the potential release of PHI, or loss of confidentiality. Safeguards are in place to prevent this from occurring.

8. Whenever appropriate, explain how the subjects will be provided with additional pertinent information after study participation and what information will be provided.

The findings may assist the (insert appropriate language, e.g., physician in complying with practice standards or other pertinent language). Subjects will not be provided with any additional information.

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Principal Investigator's Assurance

I assure the PH IRB that the information that I provided in this application is accurate and complete; that the PHI that I request is the minimum amount of identifiable private information necessary for my research project; and that the PHI will not be re-used or disclosed to any other person or entity, except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of protected health information would be permitted by the HIPAA Privacy Rule.

My typed name below shall have the same force and effect as my hand written signature.

Type PI or Preceptor name here _____
Principal Investigator

and date here _____
Date

Type Your name here _____
Student Researcher

and date here _____
Date

(Please change font color to BLACK for your answers and delete all RED instructional language from final document.)