

Sample Language for EXEMPT Research – Use if you WILL NOT CREATE a Subject ID # or 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 chart review, involving data in existence at the time of IRB decision. No Subject contact will be required. Recording of research data from patient medical records will not include any patient identifiers, including coded identifiers. 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 tests / 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.

Only de-identified information 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 identifiable information will be used on any of the data worksheets. No codes will be created that could link a subject to the data collected and recorded. Any patient lists created will be destroyed at the earliest opportunity consistent with the conduct of the research. Only the investigator and student researcher will have access to the patient list and data.

- 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

Request for Waiver or Alteration of Consent and HIPAA Authorization

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.

Coded identifiers will not be created. Any patient lists created will be destroyed at the end of the project after data collection and analysis have been completed or at the earliest opportunity consistent with the conduct of the research.

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

PHI will be de-identified, used solely for this research, not re-disclosed, and any patient list will be destroyed as described above.

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.

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 be not be recorded, 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 (insert appropriate language, e.g. assist the physician in complying with practice standards). 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.)