

Naval Medical Center San Diego
Record/Chart Review and/or Computer Database Research Study

Protocol Title: _____

CIP#S - _____

Please return this form to the Clinical Investigation Department, Bldg. 1-G. Once signed, approval is good for one (1) year. Remember: if the research includes any form of patient contact, a full protocol application must be submitted for either "Expedited" or "full IRB" review. And, you may not commence work on this study until you have an approved version of this form in your possession.

Principal Investigator: _____ (name, rank, degree)

Department: _____ Division: _____

Telephone: _____ Pager: _____ E-Mail: _____

.....
What type of record/chart/database will be reviewed for research? Check those which apply:

- | | |
|--|--|
| <input type="checkbox"/> Medical Record/Chart Review | <input type="checkbox"/> Films/X-Rays |
| <input type="checkbox"/> Computer/Database | <input type="checkbox"/> Hospital Administrative Records |
| <input type="checkbox"/> Quality Improvement Records | <input type="checkbox"/> Other (specify): _____ |
| | _____ |

The source of funding for this study is:

- | | |
|------------------------------|---|
| <input type="checkbox"/> CID | <input type="checkbox"/> Other (specify): _____ |
| | _____ |

CID Amount: \$ _____

"Other" Amount: \$ _____

Name the individuals who will be responsible for accessing medical records/charts and or database for you. *This must be a Naval Medical Center San Diego staff member or employee.*

Name	Role in this Study	Telephone No.

List the names of all individuals who will be given access to the data, once it is collected:

Name	NMCS D Staff or Employee Yes or No	Role in this Study

What is the purpose of your study?

How many records will be reviewed (in terms of patient numbers)?

Will the data be sent outside of the Naval Medical Center San Diego? Yes No

If "No," subsequent release of this data outside of NMCS D require approval by the IRB.

If "Yes," tell us where the data will be sent:

Why is it necessary to send data outside of NMCS D?

How will data be sent? (Describe methods, coding and encryption plans)

Data will be collected from ___/___/___ to ___/___/___.
M D Y M D Y

If database(s) are to be accessed, specify which ones:

- | | |
|--|--|
| <input type="checkbox"/> Not using database(s) | <input type="checkbox"/> NMCS D-Data Warehouse |
| <input type="checkbox"/> ADS (Ambulatory Data Sys.) | <input type="checkbox"/> Departmental D-Base |
| <input type="checkbox"/> CHCS (Composite Health Care Sys.) | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> CEIS (Corporate Executive Information Sys.) | |
| <input type="checkbox"/> CDIS (Care Detail Information Sys.) | |
| <input type="checkbox"/> CMIS (Champus Medical Information Sys.) | |
| <input type="checkbox"/> CURES (Champus /TRICARE Util. Rept. & Eval. Sys.) | |
| <input type="checkbox"/> MEPRS (Medical Expense & Perform. Reptng. Sys.) | |
| <input type="checkbox"/> MCFAS (Managed Care Forecasting & Anal. Sys.) | |

- MEQS (MEPRS Exec. Query Sys. –Ver. III)
- MHS MART (M2) (Mgmt. Anal. & Reptng. Tool)

If records/charts are to be accessed, specify:

- | | |
|---|---|
| <input type="checkbox"/> Not using records/charts | <input type="checkbox"/> Departmental records |
| <input type="checkbox"/> Hospital/Clinic records | <input type="checkbox"/> Other: _____ |

The data that you collect will be used for:

- Publication
- Oral presentation
- Other: _____

Check all the categories of data that will be obtained during the record/database review?

- | | |
|---|---|
| <input type="checkbox"/> Demographics (age, sex, address) | <input type="checkbox"/> Drug/Device utilized |
| <input type="checkbox"/> Diagnosis | <input type="checkbox"/> LOS (length of stay) |
| <input type="checkbox"/> Lab values | <input type="checkbox"/> Location of Service (ED, OR, etc.) |
| <input type="checkbox"/> Radiology results | <input type="checkbox"/> Provider of record (who saw pt, signed d/c note, etc.) |
| <input type="checkbox"/> Procedures/Testing | <input type="checkbox"/> Other: _____ |
| <input type="checkbox"/> Billing/Charges | |

The following information is “identifiable” under the HIPAA Privacy Rule. Check all that will be obtained:

- | | |
|--|--|
| <input type="checkbox"/> Name | <input type="checkbox"/> Account numbers |
| <input type="checkbox"/> Geographic Information sm. than a state (town or city, state, zip code)** | <input type="checkbox"/> Certificate/License nos. |
| <input type="checkbox"/> Elements of dates incl. birth date, admission date, date of death, and all ages >89** (except year) | <input type="checkbox"/> Vehicle identifiers & ser. nos. incl. license plate |
| <input type="checkbox"/> Telephone numbers | <input type="checkbox"/> Device identifiers & serial nos. |
| <input type="checkbox"/> Fax numbers | <input type="checkbox"/> URLs |
| <input type="checkbox"/> E-mail address | <input type="checkbox"/> Internet Protocol (IP) address nos. |
| <input type="checkbox"/> Social Security Number | <input type="checkbox"/> Biometric identifiers, incl. finger & voice prints |
| <input type="checkbox"/> Medical Records numbers | <input type="checkbox"/> Full face photographic images & comparable images |
| <input type="checkbox"/> Health plan beneficiary numbers | <input type="checkbox"/> Any other unique identifying number, characteristic, hospital or medical record (in & out pt) |

**These items may be considered to be a “Limited Data Set.” Use of data under “Limited Data Set” provisions requires the signing of “Data Use Agreement” by the recipient, which includes researchers, or a request for a Waiver of Authorization or Authorization is required.

NOTE: Under HIPAA/Privacy Rule provisions, if any of the above are checked, the information cannot be considered “de-identified” and Authorization from the patient or a Waiver of Authorization granted by the IRB is required.

If you plan to use links to identifiers, describe the method developed for coding.

Investigators are required to obtain only the minimum necessary data in order to complete the research. Indicate below why the data you are obtaining is the minimum necessary.

Federal regulations require that Authorization to use protected health information (PHI) be obtained for all research involving human subjects, including medical record/chart/database studies. However, the NMCS D Institutional Review Board (IRB) can waive the requirement for Authorization for PHI, if the following conditions are met. If you intend to request a waiver of Authorization, provide the following information. Note: though IRB is unable to waive Informed Consent, some types of records/chart/database studies qualify as "Exempt," thereby by-passing the need for an Informed Consent.

1. The proposed use of this data presents no more than minimal risk to the privacy of the subjects because:

2. The research could not practicably be conducted without a Waiver of Authorization because:

3. The research could not practicably be conducted without access to and use of PHI because:

Describe the steps taken to insure the privacy and confidentiality of data and to protect the identifiers and their links from unauthorized use or disclosure.

You are required to destroy identifiers or links at the earliest possible time. Describe your plans to do so, specifying when this will occur. If you plan to retain identifiers, provide justification.

Principal Investigator's Statement:

I ensure that the information I obtain during the course of my investigation will not be used or disclosed to any other person or entity, with the exception of those listed on this form or as required by law or oversight of the research. If I want to use the information at any time in the future, I agree to make application to the NMCSD-IRB for approval in order to do so.

Principal Investigator – Print Name

Principal Investigator' Signature

Date