

CLINICAL INVESTIGATION DEPARTMENT
Naval Medical Center San Diego, San Diego, CA 92134-5000

REQUEST FOR EXEMPT STUDY STATUS

Principal Investigator's Last Name: _____ First Name: _____ MI: _____
SS#: _____ Rank & Degree: _____ Department/Division: _____
PRD: _____ Phone: _____ E-Mail Address: _____
Protocol Title: _____

Associate Investigators:
Last Name, First Name, MI, SS# Rank/Degree/PRD Department/Division

TOTAL NUMBER OF HUMAN SUBJECTS TO BE STUDIED: _____ (estimate high since you cannot exceed this number)

Attach a Summary of Proposal (generally no more than one page) in the following format:

BACKGROUND: What led you to propose this study? Identify the gaps in existing knowledge your project is intended to fill.

SPECIFIC OBJECTIVES: State the specific question(s) the study will attempt to answer.

SUBJECT POPULATION: Identify the subject population and how they will be recruited or their data retrieved.

METHODS: Describe what data will be recorded.

STATISTICAL ANALYSIS: Describe how the data will be analyzed.

Initial each applicable item below, confirming that for this proposal:

- _____ questionnaires will be used and/or interviews conducted
- _____ existing records and/or specimens will be studied. Note: "existing" means on the shelf as of the date of this request. Records after this date cannot be used.
- _____ no subject identifiers will be recorded. Note: subject identifiers include name, initials, date of birth, SSN, etc. These cannot be recorded. The data set may not contain direct or indirect identifiers through which the identity of individual subjects could subsequently be ascertained (or re-identified) by anyone, including the investigators.
- _____ I will request approval from the IRB before making any changes to the protocol, questionnaire or data collection sheets.
- _____ I will file a progress report when requested by the IRB and a completion report when data collection is complete.

Attach a copy of all questionnaires and/or data collection sheets to be used.

Investigator signature: _____ Date: _____

APPROVAL - FOR CID USE ONLY:

This study meets the criteria for exemption per 32 CFR 219.101 (b) in the category checked below:

- (2) Research involving the use of...survey procedures, interview procedures ... unless ... Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects...
- (4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens ... if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

IRB Chair Signature: _____ Date: _____

Head, CID Signature: _____ Date: _____

BACKGROUND:

- 1) Definition and Scope of Problem
(Definition, context, and clinical relevance)
- 2) Literature Review
(Summary and evaluation of major studies)
- 3) Novel Contributions of this Study
(What is unique about this study)?

SPECIFIC OBJECTIVES: Language addressing this subject must be included.

SUBJECT POPULATION: Language addressing this subject must be included.

METHODS: Language addressing this subject must be included.

STATISTICAL ANALYSIS: Language addressing this subject must be included.

DATA COLLECTION SHEET: Language addressing this subject must be included.

OTHER:

CONFIDENTIALITY STATEMENT: In all publications and presentations resulting from this research study, information about the subjects will be kept in the strictest confidence and will not be released in any form. Additionally, no patient identifiers will be used in the preparatory phase or during the research proper.

CIP #: _____

**** SAMPLE ****
DATA COLLECTION SHEET

Sequential subject # _____

Date enrolled _____

Height (cm) _____

Weight (kg) _____

Temperature (F) _____

BP (Blood Pressure) _____

Pulse (/ min) _____

Respiratory rate _____

Urine Pregnancy _____

Cocci Serology _____

1:500 Coccidio _____

1:100 Coccidio _____

1:25 Coccidio _____

1:100 Coccidio _____

vehicle _____

sensitized Y

unsensitized Y