

Full Board Review by the Institutional Review Board
Human Subjects Research
Naval Medical Center Portsmouth, VA
Contact Clinical Investigation Department at (757) 953-5939

STUDY TITLE

PRINCIPAL INVESTIGATOR	
Name (Rank Name Degree):	PRD (MM/YY): 00/00
Command:	Department: CITI (MM/DD/YY): 00/00/00
Phone/Pager:	CV (MM/DD/YY): 00/00/00
Email:	RIT (MM/DD/YY): 00/00/00
<input type="checkbox"/> AD <input type="checkbox"/> Staff <input type="checkbox"/> Intern <input type="checkbox"/> Resident <input type="checkbox"/> Other: _____ <input type="checkbox"/> CIV	

RESEARCH TEAM MEMBERS	
Name (Rank Name Degree):	PRD (MM/YY): 00/00
Command:	Department: CITI (MM/DD/YY): 00/00/00
Phone/Pager:	CV (MM/DD/YY): 00/00/00
Email:	RIT (MM/DD/YY): 00/00/00
<input type="checkbox"/> AD <input type="checkbox"/> Staff <input type="checkbox"/> Intern <input type="checkbox"/> Resident <input type="checkbox"/> Other: _____ <input type="checkbox"/> CIV <input type="checkbox"/> CTR: Company _____	

RESEARCH MONITOR	
Name (Rank Name Degree):	PRD (MM/YY): 00/00
Command:	Department: CITI (MM/DD/YY): 00/00/00
Phone/Pager:	CV (MM/DD/YY): 00/00/00
Email:	RIT (MM/DD/YY): 00/00/00
<input type="checkbox"/> AD <input type="checkbox"/> Staff <input type="checkbox"/> Intern <input type="checkbox"/> Resident <input type="checkbox"/> Other: _____ <input type="checkbox"/> CIV <input type="checkbox"/> CTR: Company _____	

* Add more rows as needed.

If available, a proposed Delegation of Duties Log should be included to explain the duties, responsibilities, and role for each member of the Research Team. The PI may, for example, identify some AIs as able to perform consent, but assign different responsibilities, be they clinical, regulatory, or administrative, to others.

BASIC STUDY INFORMATION

Proposed Start Date:

Anticipated Protocol Duration in Years:

Command Where Research Will Take Place:

DISCLOSURES

Funding:

Yes

No

- a. Does this study receive funding for resources, personnel, materials, or equipment, etc.) by:
- An internal source such as BUMED-DSG, BUMED-WII, or the Commander's Fund?
 - An external source such as NIH, NSF, RDT&E P6, academia, or industry?

- b. Is there a Cooperative Research and Development Agreement (CRADA), Memorandum of Understanding (MOU), Interagency Agreement (IAA), Educational Partnership Agreement (EPA) or ANY other collaborative agreement associated with this study?

If yes, provide the identifier for this agreement:

Please list collaborating institutions: *Indicate what activities are occurring at each location:*
(For example, EVMS is collaborating, and Data Collection occurs at that location)

<input type="checkbox"/> Subject Recruitment	<input type="checkbox"/> Subject Consenting
<input type="checkbox"/> Data Collection	<input type="checkbox"/> Data Analysis
<input type="checkbox"/> Other: _____	

<input type="checkbox"/> Subject Recruitment	<input type="checkbox"/> Subject Consenting
<input type="checkbox"/> Data Collection	<input type="checkbox"/> Data Analysis
<input type="checkbox"/> Other: _____	

Conflict of Interest:

Do you or any other person responsible for the design, conduct or reporting of this research have an economic interest in or act as an officer or director of any outside entity whose financial interests would reasonably appear to be affected by this research?

If "yes", provide a written justification for continued association with this study.

BRIEF ABSTRACT (Use lay terminology and limit to one page)

PROTOCOL APPROVAL SIGNATURE PAGE

Investigator: I have read and understand NAVMEDCENTPTSINST 6500.2G. For information on the ethical conduct of research in vulnerable populations, please see the CID RSPD SOPs for the NMCP IRB reviewer checklists related to the review of research in vulnerable populations; the Office for Human Research Protections (OHRP) website; and to the Collaborative Institutional Training Initiative (CITI) website.

Printed Name	Signature	Date

Department Head: The principal investigator, who will be directly responsible for the study, is a member of my department, has current privileges at this facility, and is qualified to perform the proposed research. I have informed my Director that this research will be conducted within my Department. In the event of his/her detachment from this facility I will ensure that the principal investigator designates an appropriately qualified individual who will provide continuity for the study including all reports and obligations to the IRB and to the research subjects.

Printed Name	Signature	Date

Scientific Review

Printed Name	Signature	Date

IRB Chair/Vice Chair

 Minimal Risk

 Greater than Minimal Risk

 Recommend Approval

 Disapproved

Printed Name	Signature	Date

COMMAND APPROVAL

No research may begin unless approved by the Commanding Officer, NMCP.

Approved Disapproved

C. M. Culp, CAPT, MC, USN
Commanding Officer

Date

NMCP Assurance DOD N40003; IRBs: DON IRB#00017 or DON IRB#00018

NMCP Federal Wide Assurance #00006001; OHRP IRB #00003882 or OHRP IRB #00003883

COMMAND APPROVAL

No research may begin unless approved by the Commanding Officer, NMCP.

Approved Disapproved

M. Case, CAPT, MSC, USN
Commanding Officer
Acting

Date

NMCP Assurance DOD N40003; IRBs: DON IRB#00017 or DON IRB#00018

NMCP Federal Wide Assurance #00006001; OHRP IRB #00003882 or OHRP IRB #00003883

HUMAN USE ASSURANCE, INFORMED CONSENT, AND PRIVACY ACT STATEMENTS

All Principal and Associate Investigators are required to read the following instructions and agree to abide by them in order to participate in this research.

We, the Principal Investigator and Associate Investigators, on the above noted research project, have read and understand the provisions of DOD Instruction 3216.2 (Protection of Human Subjects in DOD Supported Research), SECNAVINST 3900.39D (Protection of Human Subjects), 32 CFR Part 219 (Protection of Human Subjects), NAVMEDCENPTSVA INST 6710.10E (Use of Investigational Agents in Human Beings), and the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects of Research". The DOD Assurance Numbers for this facility are DOD 40003, DON IRB#0017 and DON IRB#0018. The Federal Wide Assurance Number for this facility is FWA 00006001. We agree to abide by all applicable laws and regulations, and agree that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed during the conduct of this research project. In the event that we have a question regarding our obligations during the conduct of this Navy sponsored project, we have ready access to each of these regulations, as either a personal copy or available on file from the Chairperson, Institutional Review Board. We understand that the immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of that committee. We understand that failure to comply with reporting and/or review requirements may require suspension or termination of the project.

Informed Consent Document and Privacy Act Statement Procedures:

Proper consenting of subjects is an essential part of ethical research. One of the three principles contained in the Belmont Report guiding the conduct of ethical research is "respect for persons." Informed consent is an exchange between the investigator and the subject that ensures that the subject is respected as an autonomous individual capable of making a decision regarding participation in research once he/she has the necessary information to make such a decision. Improper consenting of subjects disregards the concept of "ethical research" and the principle of respect for persons. Improper consent of subjects may negate the use of their data for the purpose of analysis and may result in the suspension or termination of a study.

Procedures for consenting:

The investigator (PI, AI) will present the research project to the prospective subject. The explanation of the research project must include the purpose and nature of the study, the potential risks and benefits, an explanation of procedures and what is expected of the subject and for how long, and alternatives to the research. The explanation must also convey that refusal to participate in the study will not affect his/her medical care.

If the prospective subject is interested in participating in the study, the investigator will give the subject a copy of the Informed Consent Form (ICF), which must be in language understandable to them, and allow them adequate time to read it. The ICF must be a copy of the latest IRB and CO-approved version and must contain the CID approval stamp and be dated and initialed by CID staff.

When the prospective subject has finished reading the ICF, the investigator will return to discuss the research project and the document. The investigator will ask the prospective subject if they have any questions about the research project or the documents. The investigator will answer all of the subject's questions.

Once all of the subject's questions have been answered and the subject agrees to participate, the investigator will ask the subject to print their name and sign and date the ICF. A witness is not required. The investigator will make sure all items are signed and dated accurately and then print his or her name on the ICF, sign and date it in the presence of the subject. The investigator's printed name must be legible. Each person signing the consent form must sign on the same date and in the presence of the other persons signing.

The PI or AI designated by the PI to perform consenting and named in the approved protocol, must conduct the person-to-person consenting procedure. It is not acceptable for a person not named in the protocol to perform the consenting process. It is not acceptable for the investigator to sign the consent form in the absence of the subject and/or on a different date than the subject.

If a mistake is made in signing, it should be corrected immediately by the person making the mistake. A single line should be drawn through the incorrect information and the corrected information written next to the incorrect information. The person making the mistake should then initial and date the correction.

A copy of the ICF will be given to the subject or their representative. The subject-signed ICF original must be maintained by the investigator in a secure, private location. A copy of the subject-signed ICF is submitted to the CID Compliance Advisor at the time of the protocol's next scheduled continuing review. Any exceptions to these policies should be discussed with CID.

We have read and understand the above instructions and agree to abide by them.

NAME, GRADE/RANK/DEGREE Phone#/Pager # Department	POSITION or ROLE: ORGANIZATION STATUS: (Staff, Trainee, etc.)	Signature:
Name: Phone: Department:	Role Status:	

You may insert additional rows in the table as needed using copy and paste.

CONFLICT OF INTEREST DECLARATION

In evaluating whether a researcher has a Conflict of Interest, the following items may be considered:

In the past year I (and/or spouse, and/or dependent child) have received salary, consulting fees, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts or other enrollments, “in kind” compensation, whether for consulting, lecturing, travel, service on an advisory board, or for other purposes not directly related to the costs of research or other medical center activity, that in the aggregate have exceeded \$10,000, or are expected to exceed that amount in the next twelve months.

If no, please indicate below that you do not have a conflict of interest.

If yes, please indicate below that you do have a conflict of interest. If you indicated that you have a conflict of interest, CID will contact you for additional information. You may be required to disclose the extent and basis of your monetary award or potential for gain. You may be required to develop a management plan for this conflict or you may be asked to withdraw from this research. A final decision will be made by the Commanding Officer.

Name	I do not have a conflict	I have a conflict

Please Initial

Enter name of each Research Team Member (*e.g.*, PI, AI).

Use the tab key in last cell to add rows to table.

SUPPORT STATEMENT

If the proposed project may impact other product or service lines within this facility, describe in detail the support needed from department. Send this to the department head for his/her approval. Include details in this proposal for the Committee's information.

Enter NA when appropriate. Attach continuing pages as needed.

LABORATORY:

PHARMACY:

RADIOLOGY:

NUCLEAR MEDICINE:

NURSING SERVICES:

PATIENT ADMINISTRATION:

BED OCCUPANCY/DURATION OF STAY:

CLINICAL INVESTIGATION:

MEDICAL RECORDS:

OTHER SPECIAL REQUIREMENTS:

IMPACT SIGNATURES: Specify any difficulties your service or product line may have in providing the support requested.

Signature: Name: Rank: Title: Comments	Signature: Name: Rank: Title: Comments

RESEARCH MONITOR

A research monitor must be identified for all protocols reviewed as “greater than minimal” risk, and at the discretion of the PI and the IRB for protocols which are “minimal risk”.

A research monitor should have expertise commensurate with the nature of risk(s) identified within the research protocol, and they must be independent of the investigative team, although an individual may concurrently serve as the research monitor and an ombudsman, or a member of the data safety monitoring board. More than one research monitor may be named to a study, particularly if different skills or experiences are necessary to adequately monitor the protocol.

The duties of a research monitor are tied to specific risks or concerns identified by the PI or Board about a particular project. The IRB must approve a written summary of the monitors’ duties, authorities, and responsibilities.

The research monitor may serve as a medical monitor. In this role, a physician or dentist, military or civilian, shall be responsible for the medical or dental welfare, respectively, of all subjects. The research monitor must review all adverse events and document concurrence or non-concurrence with PI’s determination of status (*e.g.*, was the event serious and was it related to study participation). He or she will investigate as necessary and submit an independent review of any event.

The research monitor may also perform oversight functions, such as observing subject recruitment, enrollment and consenting; oversight of study interventions and interactions between investigators and subjects; examining monitoring plans and reports; and review of data matching, data collection, and data analysis procedures.

To satisfy these two areas of responsibility, the research monitor may discuss the research protocol with the investigators, interview study subjects, and consult with others outside of the project about the research. In the event a problem is identified, they have authority to stop a research protocol in progress, remove individual subjects from a study, and take whatever steps are necessary to protect the safety and well-being of subjects until the IRB can assess the monitor’s report.

Research monitors are required to promptly report their medical monitoring and oversight monitoring observations and findings to the IRB or other designated official.

The research monitor must include a current CV and documentation of DON “Investigators and Key Research Personnel-Biomedical” CITI training.

I agree to be the research monitor for the above named study.

RESEARCH MONITOR		
Name (Rank Name Degree):		PRD (MM/YY): 00/00
Command:	Department:	CITI (MM/DD/YY): 00/00/00
Phone/Pager:		CV (MM/DD/YY): 00/00/00
Email:		RIT (MM/DD/YY): 00/00/00
<input type="checkbox"/> AD <input type="checkbox"/> Staff <input type="checkbox"/> Intern <input type="checkbox"/> Resident <input type="checkbox"/> Other: _____ <input type="checkbox"/> CIV <input type="checkbox"/> CTR : Company _____		

Printed Name of Research Monitor	Signature	Date
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APPENDIX A: RESEARCH PLAN

Version: _____	STAMP
Date: _____	
CID: _____	

PI:	
Study Title:	

RESEARCH PLAN

1. OBJECTIVES/SPECIFIC AIMS

2. BACKGROUND AND SIGNIFICANCE

3. RESEARCH DESIGN/METHODS/SUBJECT JUSTIFICATION

a. General Approach

- (1) Research Objective
- (2) Detail How Many Groups or Arms are in the Study and what each Receives
- (3) Randomization Procedures

b. Methods and Materials

- (1) Experimental Procedure
- (2) If this project is collaborative, describe what research activities occur at each location (subject recruitment, subject consenting, data collection, data analysis, etc.)
- (3) Research Material To Be Collected
 - *If requesting a Waiver of Authorization for the Use of PHI provide justification and attach the appropriate form (see Appendix B)*
- (4) Data Collection Tools
- (4) Protection and Security of Data and Identifying Information
- (5) Disposition of Data and Identifying Information at End of Project

(6) Gender and Ethnicity

c. Subject Population

(1) Subject Inclusion and Selection Criteria

(2) Subject Exclusion

(3) Subject Recruiting Methods

- *It is strongly recommended that a visual representation of the timing for recruitment and screening procedures which lead to the consent process be included (such as a diagram, flow chart, or table)*

(4) Informed Consent Procedures

- *If requesting a Waiver of Consent or Waiver of Documentation of Consent provide a justification and attach the appropriate form (See Appendix C)*

(5) Justification for Use of this Subject Population

(6) Vulnerable Populations

(7) Number of Subjects and Justification

d. Risks

(1) List and Document Risks

(2) Justification of Risks

(3) Minimization of Risks

e. Benefits

f. Costs to Subjects

4. RESEARCH MONITOR
5. ADVERSE EVENT MANAGEMENT AND REPORTING
6. STATISTICAL ANALYSIS
7. SIGNIFICANCE TO NAVY MEDICINE
8. PATENT DISCLOSURES/INVENTIONS
9. POTENTIAL HAZARDS TO THE RESEARCH TEAM
10. ANTICIPATED ENROLLMENT TIMELINE

	Number of Subjects
Year 1:	
Year 2:	
Year 3:	

You may insert additional rows in the table as needed.

11. BIBLIOGRAPHY FOR BACKGROUND SECTION AND RESEARCH PLAN

APPENDIX B: REQUEST FOR WAIVER OF AUTHORIZATION FOR THE USE OF PHI

To be completed by PI if a Waiver of Authorization for the Use of PHI is being requested.

- I am requesting a Waiver of Authorization for the Use of PHI
 I am NOT requesting a Waiver of Authorization for the Use of PHI

APPENDIX C: REQUEST FOR WAIVER OR ALTERATION OF CONSENT / WAIVER OF DOCUMENTATION OF CONSENT

To be completed by PI if a Waiver of Consent is being requested.

- Request for Waiver of Consent
 Request for Waiver of Documentation of Consent
 Request for Alteration of Consent
 I am NOT requesting a Waiver of Consent – Subject consent will be obtained

APPENDIX D: DATA COLLECTION FORMS, QUESTIONNAIRES, INVESTIGATOR BROCHURES, DRUG PACKAGE INSERTS, LETTERS OF SUPPORT, ETC.

To be appended to application by PI

APPENDIX E: INFORMED CONSENT, RECRUITING MATERIALS

To be appended to application by PI

APPENDIX F: SCIENTIFIC REVIEWS

To be conducted by CID prior to IRB review

APPENDIX G: IRB REVIEWER CHECKLISTS

To be added by CID following IRB review

APPENDIX H: OUTSIDE AGREEMENTS.

Contact CID for assistance. Because outside agreements take a long time to process, action to draft such an agreement should be taken as soon as possible, even prior to submitting the protocol for committee review. If an outside agreement is required, then the agreement must be complete before the protocol may be sent to the CO for final approval.

APPENDIX I: CITI CERTIFICATES, CURRICULUM VITAE, RESEARCH INTEGRITY TRAINING

To be appended to application by PI

ELECTRONIC SUBMISSION CHECKLIST

Please confirm that all relevant documents are attached to your submission. Missing documents will cause your submission to be returned for revisions.	Yes	N/A
WORD Version of Application		
PDF of Signature Pages		
CITI / CV / RIT for Research Team		
Literature Search and Assessment of Impact on Current Project		
Consent Form(s) (if applicable)		
Waiver of Authorization for the Use of PHI (if applicable)		
Waiver of Consent/Waiver of Documentation of Consent (if applicable)		
Data Collection Tool(s)		
Instrument / Subject ID Key/ Questionnaire / Diary, etc.		
Recruitment Materials		
Agreement - CRADA, MOU, etc. (if applicable)		
Other:		

APPENDIX B

**Request for Waiver of Authorization for the Use of PHI
Human Subjects Research
Naval Medical Center Portsmouth, VA
Contact Clinical Investigation Department at 953-5939**

Principal Investigator	
Study Title	

To grant a waiver of the HIPAA Privacy Authorization requirement, the IRB must determine that your project involves no more than minimal risk to the privacy of individual participants and meets all of the criteria listed in the Privacy Rule and in accordance with DoD 6025.18-R, C7.9.

Submit this form if you will access identifiable records (*e.g.*, medical, research, billing records) without written authorization

- To abstract identifiable information for research,
- To create a limited data set, or
- To de-identify data for use in research (unless the data sources are limited to your own patients or research subjects). Data are identifiable unless fully de-identified according to the HIPAA standard (see page 3) and you can't re-identify the data subjects.

Do not submit this form if you will access or receive de-identified data only, and will have no ability to re-identify data subjects.

Do not submit this form if you are receiving or sending (but not creating) a limited data set

PLEASE NOTE: If the IRB approves this application, approval does not include permission to contact individuals whose records are reviewed. You may not use any information in the requested records to recruit subjects without separate IRB approval of the recruitment plan described in the IRB application.

Except as permitted in an IRB-approved recruitment plan, PHI may not be presented, published, or otherwise disclosed to third parties under an approved HIPAA waiver.

Request for Waiver of Authorization for the Use of PHI CHECKLIST

- A. 1. Describe the information that you would like to collect or access without a signed privacy authorization for this project. Include your data collection tool as part of the IRB application.

Be specific about the data points that you wish to obtain.

2. For studies involving the collection of retrospective data, “existing data” is defined by the regulations as data that exists before the study is proposed to an institutional official or to an IRB. Document the window for data to be collected:

Data collected is limited to data, documents, records, or pathological specimens,

Retrospective

- in existence prior to _____
DATE

OR

- existing between _____ and _____.
DATE DATE

Retrospective and Prospective

- existing between _____ and _____ (retrospective).
DATE DATE

AND

- existing between _____ and _____ (prospective).
DATE DATE

- B. Describe the source of the information (*e.g.*, EPR, records from previous study, pathology archive) that you want to study:

- C. Describe the plan that will adequately protect the identifiers from improper use and disclosure.

- D. Describe the plan to destroy the participant identifiers at the earliest opportunity consistent with the conduct of research, unless retention is required for reasons of health, research, or law. Please explain if the participant identifiers will be stored or retained and the length of time they will be stored or retained:

E. Explain why the research could not practicably be conducted without the waiver:

F. Explain why the research could not practicably be conducted without access to and use of the identifiers (PHI):

G. In applying for waiver of the HIPAA authorization requirement, you are assuring the IRB that the identifiers you request will not be used for any other purpose or disclosed to any other person or entity (apart from research team members listed in this application), except as required by law, for authorized oversight of the research study, or for use in future IRB-approved research.

Request for Waiver of Authorization for the Use of PHI AGREEMENT

By submitting this form, you agree that you and your research team will comply with NMCP HIPAA policies and the use and disclosure restrictions described above. *Specifically, you acknowledge and agree that you may share PHI obtained under a HIPAA waiver only with IRB-approved members of your study team, and you assume responsibility for all uses and disclosures of the PHI by members of your study team.*

This application form does not replace the requirement to submit an application for Human Subjects Research to the NMCP IRBs for an individual research project.

Investigator:

Printed Name

Signature

Date

After review of this request for waiver and relevant parts of the research protocol, as needed, the IRB has determined that your project involves no more than minimal risk to the privacy of individual participants and meets all of the criteria listed in the Privacy Rule and in accordance with DoD 6025.18-R, C7.9. The IRB therefore grants a waiver of the HIPAA Privacy Authorization requirement.

IRB Action:		
<input type="checkbox"/> Full Board Review	<input type="checkbox"/> Expedited Review	
Date Reviewed:	Review Cycle:	Risk Level: <input type="checkbox"/> Minimal Risk <input type="checkbox"/> Greater than Minimal Risk
<input type="checkbox"/> Approved <input type="checkbox"/> Disapproved		
Printed Name of IRB Chair/Vice Chair	Signature	Date

Request for Waiver of Authorization for the Use of PHI

DEFINITIONS OF HIPAA TERMS

De-identified Data: To “de-identify” data under the Privacy Rule safe harbor, you must ensure the following:

- (1) Each of the data elements listed below is removed from the data; **AND**
- (2) You do not know that any recipient of the data could re-identify a data subject, using the information alone or in combination with other publicly-available information.

Data elements that must be removed:

- Names
- Geographic subdivisions smaller than a state (including street, city county, precinct), except first three digits of the zip code if, according to current Bureau of Census data:
 - (1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people, and
 - (2) The initial three digits of ZIP code for all such geographic units containing 20,000 or fewer people are changed to 000.
- All elements of dates (except year) for dates directly related to an individual, and all ages over 89 and elements of date (including year) indicative of such age, except that ages and elements may be aggregated into a single category of age 90 or older.
- Telephone numbers;
- Fax numbers;
- E-mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet protocol address numbers;
- Biometric identifiers, including voice and finger prints;
- Full face photographic images and any comparable images;
- Any other unique, identifying number characteristic, or code, except for a unique code that meets the following criteria:
 - (1) Is not derived from any other code (*e.g.*, MRN or SSN) and is not used for any other purpose; and
 - (2) Persons using the data for research have no access to the code key and the key is held by a source that is not part of the research team. An investigator (or her study team members) may not create the code for de-identified data that she will use in her own research.

APPENDIX C

**Request for
Waiver or Alteration of Consent / Waiver of Documentation of Consent
Human Subjects Research
Naval Medical Center Portsmouth, VA
Contact Clinical Investigation Department at 953-5939**

Principal Investigator	
Study Title	

Waiver of Consent is a means by which the IRB can release the investigator from the requirement that informed consent be obtained from subjects prior to their participation in research. Examples of studies for which a Waiver of Consent may be appropriate include, but are not limited to, retrospective chart reviews, or prospective research involving deception.

For Waiver of Documentation of Consent or Waiver of Consent to be granted, four criteria must be satisfied.

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waiver of Documentation Consent is a means by which the IRB can release investigators from the requirement to obtain a signed consent form for some or all subjects. Examples of studies for which a Waiver of Documentation of Consent may be appropriate include research in which unintended disclosure of participation or data may cause harm to subjects (including psychological pain and embarrassment, loss of social standing, economic injury, loss of employment, potential for legal action, loss of insurability, etc.) or studies that involve questionnaires or surveys in which completion of the instrument implies consent.

The IRB may waive documentation of consent if it finds:

- That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Even if a waiver of documentation of consent is granted, a consent process must still be in place. The consent process must include all the required elements and should generally take the form of an information sheet or verbal script, which must be submitted to the IRB in support of the Waiver request.

Request for Waiver or Alteration of Consent / Waiver of Documentation of Consent JUSTIFICATIONS

- Request for Waiver of Consent
- Request for Waiver of Documentation of Consent
- Request for Alteration of Consent

Please complete each item below in support of your request.

Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study

--

The research could not practicably be carried out without the waiver or alteration

--

The waiver will not adversely affect the rights and welfare of subjects

--

The research involves no more than minimal risk to the subjects

--

Request for WAIVER of DOCUMENTATION of CONSENT ONLY:

The signed consent would be the only record linking the subject to the research and the principal harm would result from breach of confidentiality

--

Request for Waiver or Alteration of Consent / Waiver of Documentation of Consent AGREEMENT

Investigator:

Printed Name

Signature

Date

IRB Action:		
<input type="checkbox"/> Full Board Review <input type="checkbox"/> Expedited Review		
Date Reviewed:	Review Cycle:	Risk Level: <input type="checkbox"/> Minimal Risk <input type="checkbox"/> Greater than Minimal Risk
<input type="checkbox"/> Approved <input type="checkbox"/> Disapproved		
Printed Name of IRB Chair/Vice Chair	Signature	Date

Request for Waiver or Alteration of Consent / Waiver of Documentation of Consent
BASIC ELEMENTS OF INFORMED CONSENT

- (a) Basic elements of informed consent.
- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
 - (2) A description of any reasonably foreseeable risks or discomforts to the subject;
 - (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
 - (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
 - (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
 - (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
 - (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- (b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
 - (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
 - (3) Any additional costs to the subject that may result from participation in the research;
 - (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
 - (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
 - (6) The approximate number of subjects involved in the study.