

NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000

THIRD PARTY CONSENT FOR VOLUNTARY PARTICIPATION IN THE EMERGENCY USE
OF AN INVESTIGATIONAL AGENT (DRUG, BIOLOGIC OR DEVICE)

1. You, _____, parent/legal guardian (circle one) of _____, daughter/son/parent/other dependent (circle one; specify relationship of other dependent: _____) have been asked to voluntarily allow the participation of your dependent, named above, in the emergency use of the investigational agent _____ at Naval Medical Center, San Diego, CA, by the Department of _____.

2. WHY IS THIS INVESTIGATIONAL AGENT BEING OFFERED TO MY DEPENDENT?

The purposes of this emergency use of an investigational agent are

_____.

3. HOW LONG WILL MY DEPENDENT BE PARTICIPATING?

Your dependent will participate in this emergency use of an investigational agent for _____ days/months/years.

4. WHAT IS INVOLVED?

The procedures for this emergency use of an investigational agent are _____

_____.

5. WHAT IS THE EXPERIMENTAL PART OF THIS?

The experimental part of this emergency use of an investigational agent is _____

_____.

6. WHAT ARE THE RISKS TO MY DEPENDENT OF PARTICIPATING?

The possible risks to your dependent if your dependent participates in this emergency use of an investigational agent include _____

_____.

7. ARE THERE ANY UNFORESEEABLE RISKS?

In addition, this emergency use of an investigational agent may involve risks to your dependent which are currently unforeseeable and which may not become known until many months or years later.

Also, if your dependent becomes pregnant during this emergency use of an investigational agent, there may be unforeseeable risks to the embryo or fetus. You should promptly advise the investigator if your dependent becomes pregnant or contemplates breast feeding.

8. WHAT ARE THE BENEFITS TO MY DEPENDENT OF PARTICIPATING?

The potential benefits to your dependent of this emergency use of an investigational agent are _____

_____.

9. WHAT OTHER OPTIONS DOES MY DEPENDENT HAVE IF MY DEPENDENT DOES NOT PARTICIPATE?

The alternate treatments, should you decline enrollment of your dependent into this emergency use of an investigational agent are _____

_____.

10. WILL I OR MY DEPENDENT BE PAID TO PARTICIPATE?

No. Neither you nor your dependent will be financially compensated for participation.

12. WHAT IF MY DEPENDENT IS INJURED AS A RESULT OF PARTICIPATING?

If your dependent suffers any injury directly related to your dependent's participation in this emergency use of an investigational agent, immediate medical attention is available at the Naval Medical Center, San Diego, or at another closer medical treatment facility, if applicable. Any injury resulting from your dependent's participation will be evaluated and treated in keeping with the benefits or care to which your dependent is entitled under applicable Navy, other Department of Defense and other state or Federal regulations.

13. WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding this emergency use of an investigational agent, you may contact Dr. _____ at _____ . If you have any questions about your dependent's rights as an individual while participating in this emergency use of an investigational agent at the Naval Medical Center, San Diego, you may contact the Chairman, Institutional Review Board at (619) 532-8125, or Head, Clinical Investigation Department at (619) 532-8238. If you believe that your dependent has been injured as a result of your dependent's participation in this emergency use of an investigational agent, you may contact the Naval Medical Center, San Diego, Legal Department, at (619) 532-6475.

14. WHAT ARE MY DEPENDENT'S RIGHTS AS A PARTICIPANT?

Your dependent's participation in this emergency use of an investigational agent is voluntary, and if you refuse enrollment of your dependent, no loss of benefits or care to which your dependent is entitled will occur. If you should decide to withdraw your dependent from this emergency use of an investigational agent, you will notify Dr. _____ to ensure an orderly termination process. Your withdrawal of your dependent will involve no prejudice to your dependent's future health care or any loss of rights or benefits to which your dependent is otherwise entitled. Any new significant finding developed during this emergency use of this investigational agent which might affect your willingness to continue your dependent's participation will be communicated to you.

14. CAN MY DEPENDENT BE TERMINATED FROM THE STUDY?

The investigator may terminate your dependent's participation in this emergency use of an investigational agent if _____

_____.

15. WHAT ABOUT CONFIDENTIALITY?

The data collected in this emergency use of an investigational agent may be published to further enhance medical knowledge. You specifically give your permission for publication of your dependent's data. In all publications and presentations your dependent's anonymity will be protected. Records regarding the emergency use of this investigational agent may be inspected by the Food and Drug Administration (FDA) as part of their responsibility to ensure that such use is conducted in a safe, consistent and humane manner.

16. SIGNATURE

You are making a decision whether or not to allow your dependent to participate in this emergency use of an investigational agent. Your signature indicates that you have had this information presented to you, have had the opportunity to ask questions about your dependent's participation, and agree to your dependent's participation. Further, your signature indicates that you have been provided with a copy of this consent document and a copy of a document entitled, "California Experimental Subject's Bill of Rights."

SIGNATURES AND DATES SIGNED PRINTED OR TYPED IDENTIFICATION

_____	_____ Patient's Name/Status/Sponsor's SSN
Parent or legal guardian	_____ Name/Status/Sponsor's SSN
_____	_____ Name/Grade or Rank
Witness	_____
_____	_____ Name/Grade or Rank
Investigator	_____

PRIVACY ACT STATEMENT

1. Authority. 5 USC 301.

2. Purpose. Medical research information will be collected to enhance basic medical knowledge or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury, or functional impairment.

3. Use. Medical research information will be used for statistical analysis and reports by the Department of the Navy, the Department of Defense, and other United States Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-Government agencies or individuals by the Chief, Bureau of Medicine and Surgery, in accordance with provisions of the Freedom of Information Act.

4. Disclosure. I understand that all information contained in this Consent Statement or derived from the medical research study described herein will be retained permanently at Naval Medical Center, San Diego, and salient portions thereof may be entered into my health record. I voluntarily agree to its disclosure to agencies or individuals identified in the preceding paragraph. I have been informed that failure to agree to such disclosure may negate the purposes for which the research study was conducted.

SIGNATURES AND DATES SIGNED:

PRINTED OR TYPED IDENTIFICATION:

Patient

Name/Status/Sponsor's SSN

Witness

Name/Grade or Rank

EXPERIMENTAL SUBJECTS BILL OF RIGHTS (CA)

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment;
2. Be given an explanation of the procedures to be followed in the medical experiment and any drug or device to be used.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of appropriate alternative procedures, drugs, or devices that might be advantageous to the subject and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if any complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that the consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of a signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not consent to medical experiment without intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.
11. Be assured that the subject's confidentiality will be preserved and his/her name will not be released without his/her permission.

Any questions regarding this research study should be directed to the principal investigator or associate investigators. Information is available from the Chairman, Institutional Review Board, established for the protection of volunteers in research projects at this facility by calling (619) 532-8125 or writing the Chairman, Institutional Review Board at Naval Medical Center, Clinical Investigation Department (KCA), San Diego, CA 92134-5000.