

**NAVAL MEDICAL CENTER
SAN DIEGO, CA 92134-5000**

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

1. You, _____, have been asked to voluntarily give consent to participate 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 YOU?

The purposes of this emergency use of an investigational agent are _____.

3. HOW LONG WILL YOU BE PARTICIPATING?

You 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 YOU OF PARTICIPATING?

The possible risks to you if you participate in this emergency use of an investigational agent include _____.

Subject's Initials:

IRB Approval/Seal Required

7. ARE THERE ANY UNFORESEEABLE RISKS?

In addition, this emergency use of an investigational agent may involve risks to you which are currently unforeseeable and which may not become known until many months or years later. Also, if you become 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 you become pregnant or contemplate breast feeding.

8. WHAT ARE THE BENEFITS OF PARTICIPATING?

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

_____.

9. WHAT OTHER OPTIONS DO YOU HAVE IF YOU DON'T PARTICIPATE?

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

_____.

10. WILL YOU BE PAID TO PARTICIPATE?

No. You will not be financially compensated for your participation.

12. WHAT IF YOU ARE INJURED AS A RESULT OF PARTICIPATING?

If you suffer any injury directly related to your 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 participation will be evaluated and treated in keeping with the benefits or care to which you are entitled under applicable Navy, other Department of Defense and other state or Federal regulations.

13. WHO DO YOU CALL IF YOU 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 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 the Head, Clinical Investigation Department at (619) 532-8238**. If you believe that you have been injured as a result of your participation in this emergency use of an investigational agent, you may contact the **Naval Medical Center, San Diego, Legal Department, at (619) 532-6475**.

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14. WHAT ARE MY RIGHTS AS A PARTICIPANT?

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

15. CAN I BE TERMINATED FROM THE STUDY?

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

16. 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 data. In all publications and presentations your 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.

17. SIGNATURE

You are making a decision whether or not 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 participation, and agree to participate. 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."

SIGNATURE AND DATES SIGNED

PRINTED OR TYPED IDENTIFICATION

Patient

Name/Status/Sponsor's SSN

Witness

Name/Grade or Rank

Investigator

Name/Grade or Rank

Subject's Initials:

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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.

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