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| **FORM 1** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **UNIVERSITY OF HAWAII COOPERATIVE IRB**  **NEW RESEARCH PROJECT APPLICATION** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. | | PROJECT TITLE: | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 2. | | PRINCIPAL INVESTIGATOR’S NAME | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | Address: | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | E-mail: | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |  | | Specialty: | | | | |  | | | | | | | | | | | |  | |
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|  | | Title: | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |  | | Phone: | | | | |  | | | | | | | | | | | |  | |
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| 3. | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. | | AFFILIATED OR OTHER PARTICIPATING INSTITUTIONS: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Name: | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 5. | | A. SUB-INVESTIGATOR(S): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | B. OTHER RESEARCH PERSONNEL (who will assist with conducting the study and have medical record access) | | | | | | | | | | | | | | | | |
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| 6. | | SPONSORING AGENCY/ORGANIZATION: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Name: | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Address: | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 7. | | TYPE OF STUDY | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | |
|  | | Retrospective: | | | | | | | | | | | | | | | | | | | | | | | |  | Prospective: | | | | | | | | | | | | | | | | | | |  | | | | | | |
|  | | | | | |  | | | Medical Records (documents) | | | | | | | | | | | | | | | | |  | | | | |  | | | | Investigational New Drug (IND) | | | | | | | | | | | | | |  | Non-IND | | |
|  | |  | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | |  | | | Tissue/Blood/Specimens | | | | | | | | | | | | | | | | |  | | | | |  | | | | Investigational Device (IDE) | | | | | | | | | | | | | |  | Non-IDE | | |
|  | |  | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | |  | | | Other, please specify: | | | | | | | | | | | | | | | | |  | | | | |  | | | | Investigational Procedure | | | | | | | | | | | | | | | | | |
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| 8. | | INSTITUTIONS WHERE RESEARCH WILL BE CONDUCTED: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | |  | | | | | QMC | | | | | | | | |  | HPH | | | | | | |  | | | | Castle Medical Center | | | | | | | | | | | | |  | | | University of Hawaii | | | | | | | |
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|  | | Other: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 10. | | PROJECT SUMMARY: (This is only a summary. A separate, complete proposal must accompany the application forms.) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 11. | | | | PROJECT FUNDING: | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | |  | | | | | | | | | |  | | | | | |
|  | | | |  | | | | No | | | |  | | Pending | | | | | |  | Yes | | Amt.$ | | | | | | |  | | | | | | | | Source: | | | |  | | | | | | | | | |
|  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 12. | | | CLINICALTRAILS.GOV | | | | | | | | | | | | | | | |
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| APP 16 - UH Cooperative IRB New Research Project App, version 5/03 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | End of Form 1 | | | | | | | | | | | | | | | | | | |

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| **FORM 2** | | | | | | | | | | |
| **UNIVERSITY OF HAWAII COOPERATIVE IRB**  **STATEMENT OF GENERAL AGREEMENT** | | | | | | | | | | |
|  | | | | | | | | | | |
| 1. | PROJECT TITLE: | | | | |  | | | | |
|  |  | | | | | | | | | |
| 2. | PRINCIPAL INVESTIGATOR: | | | | | |  | | | |
|  |  | | | | | | | | | |
| The Principal Investigator must agree: | | | | | | | | | | |
|  |  | | | | | | |  | | |
|  | | a. | to attend a meeting with the Institutional Review Committee/Board upon request; | | | | | | | |
|  | | b. | to obtain approved and legally effective consent complying with the latest federal regulations from all research subjects prior to commencing research study; | | | | | | | |
|  | | c. | upon receipt of approval from institution, to inform the hospital through its appropriate representative and other involved parties, as to when the project will start and end; | | | | | | | |
|  | | d. | to abide by professional ethics and hospital policies regarding the conduct of research, physician/patient relationship and the confidentiality of patient information and records (except when proper patient authorization is obtained); | | | | | | | |
|  | | e. | to accept primary responsibility and liability for the conduct of this study; | | | | | | | |
|  | | f. | to submit a copy of revisions and/or addendums pertaining to human subjects for review and approval; | | | | | | | |
|  | | g. | to submit a progress report at least once a year for multi-year projects or mid-way during the course of the project for those lasting no more than one year, or as otherwise required by the hospital reviewing authority; | | | | | | | |
|  | | h. | to submit a request for renewal if project extends beyond one year or if protocols are closed but patients are still being followed; | | | | | | | |
|  | | i. | to inform the hospital’s research administrative authority immediately if research-related unexpected adverse reaction or death occurs; | | | | | | | |
|  | | j. | to submit a copy of the study’s final report after its completion and any paper derived from the study prior to its submission for publication; | | | | | | | |
|  | | k. | to withhold the identity of a hospital as the research site, unless prior approval or waiver has been received from the appropriate authority; | | | | | | | |
|  | | l. | to allow the Research & Institutional Review Committee or its designee access to all research-related records for monitoring and auditing; | | | | | | | |
|  | | m. | that papers prepared for publication shall include the following statement, “The findings, conclusions, (etc.), of this study do not necessarily represent the views of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ”; | | | | | | | |
|  | |  |  | | *(name of institution)* | | | | |  |
| I will comply with the above requirements. I also attest that all information provided in this application and all attachments are true and complete. I understand that non-compliance may result in termination of the study. | | | | | | | | | | |
|  | | | | | | | | | | |
| Signature of Principal Investigator: | | | |  | | | | | | |
|  | | | | | | | | | | |
| Date: | | | |  | | | | | | |
|  | | | | | | | | | | |
| UH Cooperative IRB, version 10-29-14 | | | | | | | | | End of Form 2 | |

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| **FORM 3** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **UNIVERSITY OF HAWAII COOPERATIVE IRB**  **USE OF HOSPITAL RESOURCES AND PROJECT BUDGET** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. | | PROJECT TITLE: | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. | | PRINCIPAL INVESTIGATOR: | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. | | PERIOD OF INVESTIGATION: | | | | | | | | | | | From: | | | | | |  | | | | | | | | | | | To: | |  | | | | | |
|  | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. | | USE OF HOSPITAL RESOURCES: (Be as specific as possible) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | A. | | Areas of Activity in Hospital: | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | B. | | Square Footage of Space Required: | | | | | | | | | | | | | |  | | | | | | | | | | | | |  | | | | | | |
|  | |  | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | C. | | Type and No. Of Hospital Equipment/Furniture Required: | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | D. | | Other use of hospital services or departments (laboratory, pharmacy, etc.) | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  |  | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | E. | | Have arrangements for reimbursement of hospital resources been made? Explain. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 5. | | PROJECT BUDGET: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | A. | | Funding organization: | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | B. | | Institution managing the account: | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
|  | |  | |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | C. | | Total grant: | |  | | | | | | | | | | | | | | | or per patient allocation: | | | | | |  | | | | | | | | |  | |
|  | |  | |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | D. | | Funding period: | | | | From: | | |  | | | | | | | | | | | | | To: | | |  | | | | | | | | |  | |
|  | |  | |  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | E. | | Number of hospital personnel hours or services\* including: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | (i) | Staff hours for patient interviews or data collection: Number of hours: | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | @ $ |  | | /hr |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | (ii) | Technical hours for procedures: | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | (iii) | Medical records request (as determined by the hospital): | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | (iv) | Pharmacy costs: | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | (v) | Central supplies or devices: | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | (vi) | Laboratory or diagnostic studies specific to project: | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | (vii) | Medications specific to project: | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6. | | I certify that the information provided above is correct and complete. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |  | | | | |
|  | | Signature of Principal Investigator | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | Date | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
| UH Cooperative IRB, version 10-29-14 | | | | | | | | | | | | | | | | | | | | | | | End of Form 3 | | | | | | | | | | | | | | |

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| **FORM 4**  **UNIVERSITY OF HAWAII COOPERATIVE IRB**  **STATEMENT OF CONFIDENTIALITY**  **Review of Sources of Information for Research Purposes** | | | | | | |
| This statement covers the review of medical records, databases, listings or other sources of information for research activities. | | | | | | |
|  | | | | | | |
| 1. | PROJECT TITLE: | |  | | | |
| 2. | IN ORDER TO MAINTAIN CONFIDENTIALITY OF MEDICAL RECORDS OR RESEARCH RELATED INFORMATION THE FOLLOWING CONDITIONS REQUIRE STRICT COMPLIANCE: | | | | | |
|  | A. | Access to information will be limited to persons involved in carrying out the research.  **Signing this form is assurance that protected health information will not be reused or disclosed to any other person or entity except as required by law; for authorized oversight; or for other research as would be permitted by federal privacy standards.** | | | | |
|  | B. | Patient’s identity will be concealed in any results obtained and/or published unless formal patient authorization for the release of medical information has been obtained. Personal identity information includes: name, social security number, address, phone number, relative’s name, relative’s phone number and address, and other information which can reveal patient’s identity. | | | | |
|  | C. | Patient identity information will not be made available to any “third party” (persons not involved in the study). | | | | |
|  | D. | Raw data will be kept in a secure, locked place. | | | | |
|  | E. | Federal and State rules and regulations pertaining to the disclosure of information regarding alcohol and drug abuse cases, human immunodeficiency virus, acquired immune deficiency syndrome (AIDS) related complex or AIDS cases require strict compliance. | | | | |
| 3. | PRIVACY SAFEGUARDS | | | | | |
|  | A. | Describe your plan to protect identifiers from improper use and disclosure: | | | | |
|  |  |  | | | | |
|  | B. | Describe your plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. And if there is a health or research justification for retaining the identifiers or such retention is otherwise required by law, please explain. | | | | |
|  |  |  | | | | |
| I HEREBY ACKNOWLEDGE the restrictions imposed upon me with regard to the disclosure of information in connection with working with patient’s charts or information, and with my signature below do accept the responsibility for myself and my designees of treating information as completely confidential for myself and my designees. | | | | | | |
|  |  | | |  | | |
|  | Signature of Principal Investigator: | | | |  | |
|  | | | | | | |
|  | Date: | | | |  | |
| Co-investigators and other research personnel listed on Form 1 are authorized to request research information. | | | | | | |
|  | | | | | | |
| UH Cooperative IRB, version 10-29-14 | | | | | | End of Form 4 |

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| **FORM 4B**  **UNIVERSITY OF HAWAII COOPERATIVE IRB**  **Application For Approval Of Alteration Or Waiver Of Authorization For Use Or Disclosure**  **Of Protected Health Information (PHI) For Research (45 CFR 164.512(i)(2))** | | | | | | | | | | | | | | | | | | | | | | | |
| 1. | | Project Title: | | | | | | | | |  | | | | | | | | | | | |  |
|  | |  | | | | | | | | | | | | | | | | | | | | | |
| 2. | | Check the appropriate box you are requesting: | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | |  | | | Use/disclosure of existing data. (for example, record review, specimen) | | | | | | | | | | | | | | |
|  | |  | | | |  | | | For subject recruitment/prescreening | | | | | | | | | | | | | | |
| 3. | | Provide a brief description of the PHI which will be used or accessed for this project: | | | | | | | | | | | | | | | | | | | | | |
|  | Name | | | | | | | | | | | Web site URL addresses | | | Medical Record number | | | | License Plate numbers | | | | |
|  | Address | | | | | | | | | | | E-mail addresses | | | | Fingerprints or Voiceprints | | | Device Identifiers/Serial numbers | | | | |
|  | Telephone number | | | | | | | | | | | Social Security number | | | | Certificate/License number | | | Health Plan Beneficiary numbers | | | | |
|  | Account numbers | | | | | | | | | | | Fax Number | | | | Internet Protocol (IP) addresses | | |  | | | | |
|  | Dates, such as birth date, admission or discharge date, and date of death | | | | | | | | | | | | | | | | | Full face photographs or comparable images | | | | | |
|  | Other: | | | | | | | | |  | | | | | | | | | | | | |  |
|  | | | | | | | | | | | | | | | | | | | | | | | |
| 4. | | | The use or disclosure of protected health information must involve no more than a minimal risk to the privacy of participating individuals. Provide the following: | | | | | | | | | | | | | | | | | | | | |
|  | | | A. | | | | A plan to protect the patient identifiers from improper use and disclosure; | | | | | | | | | | | | | | | | |
|  | | | | | | |  | | | | | | | | | | | | | | | |  |
|  | | | B. | | | | A plan to destroy the patient identifiers at the earliest opportunity consistent with the conduct of the research described above. | | | | | | | | | | | | | | | | |
|  | | | | | | |  | | | | | | | | | | | | | | | |  |
|  | | |  | | | | Please indicate if there is a health or research justification for retaining the identifiers, or retention is otherwise required by law. | | | | | | | | | | | | | | | | |
|  | | | | | | |  | | | | | | | | | | | | | | | |  |
| 5. | | | | Can the research described above be practicably conducted without the alteration or waiver? Explain. | | | | | | | | | | | | | | | | | | | |
|  | | | | |  | | | | | | | | | | | | | | | | | |  |
| 6. | | | | Can the research described above be practicably conducted without access to and use of the PHI? Explain. | | | | | | | | | | | | | | | | | | | |
|  | | | | |  | | | | | | | | | | | | | | | | | |  |
| 7. | | | | Name(s) and Address(es) of Investigator(s): | | | | | | | | | | | | | | | | | | | |
| 1. | | | | | | | |  | | | | | | | | | | | | | | |  |
| 2. | | | | | | | |  | | | | | | | | | | | | | | |  |
|  | | | | | | | | | | | | | | | | | | | | | | | |
|  | I certify on behalf of myself and the research team that the Protected Health Information covered by this alteration or waiver of authorization for use or disclosure of such information for the above-referenced research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the above-referenced research, or for other research for which the use or disclosure of Protected Health Information would be permitted by Subpart E of 45 CFR 164. | | | | | | | | | | | | | | | | | | | | |  | |
|  | | | | Signature(s) of Investigator(s): | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | | | | | | | |  |  | | | | | |  |  | |  |
|  | | | | Name | | | | | | | | |  | Signature | | | | | |  | Date | |  |
|  | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | | | | | | | |  |  | | | | | |  |  | |  |
|  | | | | Name | | | | | | | | |  | Signature | | | | | |  | Date | |  |
|  | | | | | | | | | | | | | | | | | | | | | | | |
| UH Cooperative IRB, version 10-29-14 | | | | | | | | | | | | | | | | | End of Form 4B | | | | | | |

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| **FORM 5** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **UNIVERSITY OF HAWAII COOPERATIVE IRB**  **USE OF HUMAN SUBJECTS FORM** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. | | PROJECT TITLE: | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 2. | | PRINCIPAL INVESTIGATOR: | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 3. | | TYPES OF RESEARCH SUBJECTS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Please Provide an estimate of the total number of subjects that will be needed to conduct this study as well as an estimated number from the hospital to which this application is being submitted. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | |  | | |  | | | | | |  | |  | | | | | | | No. From This Hospital | | | | | | | | | | | | | | | | | | | No. From Others | | | | | | | | | | | | | Total Sample | | | | | | | | | | | | | | | | | | | |
|  | | A. | |  | | | Experimental Group Sample Size | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | |
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|  | |  | |  | | | Control Group Sample Size | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | |
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|  | | B | | Number of Participating Hospitals in Hawaii: | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | C | | Number of Participating Outpatient Clinics in Hawaii: | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | D | | Please describe other relevant characteristics of the sample required (e.g., ages, sex, disease category ...). | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 4. | | RISK FACTOR EVALUATION | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Any possibility of injury including physical, psychological or social to which a research subject is exposed should be checked under Section II.B of this form, Risk Involvement Inventory. Risk is defined as that possibility of injury greater than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | A. | | | Vulnerable Subjects: Will subjects be selected exclusively from any of the following? (Check all that apply) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | |  | | |  | | | | | Not Applicable | | | | | | | | |  | | Economically Disadvantaged | | | | | | | | | | | | | | | | | | | | |  | | | | Terminally Ill | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | | Minors (less than 18 years) | | | | | | | | |  | | Pregnant Women | | | | | | | | | | | | | | | | | | | | |  | | | | Prisoners | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | | Mentally Retarded | | | | | | | | |  | | Fetuses | | | | | | | | | | | | | | | | | | | | |  | | | | Elderly (65+ years) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | | Mentally Disabled | | | | | | | | |  | | Abortuses | | | | | | | | | | | | | | | | | | | | |  | | | | HIV/AIDS | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | Explain: | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | B. | | | Risk Involvement Inventory: Check all foreseeable risks to humans involved in your project. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | i. | | | | | NO RISKS | | | | | | | | | | | | | | |  | | | | |  | | | | | | |  | | | | | | | |  | |  | | | |  | |  | | | | | | | | | |  | | | | | | | | | | |
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|  | |  | | | ii. | | | | | PHYSICAL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | |  | | Death | | | | | | | |  | | | | |  | | | | |  | | | | | | |  | | Worsening of physical conditions | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | |
|  | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | |  | | Physical trauma or pain | | | | | | | |  | | | | |  | | | | |  | | | | | | |  | | Side effects of medication(s) | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | |
|  | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | |  | | Contraction of disease(s) | | | | | | | |  | | | | |  | | | | |  | | | | | | |  | | Experimental diagnostic procedure(s) | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | |
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|  | |  | | |  | | | | |  | | Experimental treatment procedure(s) | | | | | | | | | | | | |  | | | | |  | | | | | | |  | | Venipuncture | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | |
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|  | |  | | |  | | | | |  | | Intravenous catheters | | | | | | | | | | | | |  | | | | |  | | | | | | |  | | Other (e.g., financial, etc...) | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | |
|  | |  | | | Briefly explain items checked: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| UH Cooperative IRB, version 10-29-14 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. | | RISK FACTOR EVALUATION | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | |  | | | iii. | | | | | PSYCHOLOGICAL/SOCIAL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | |  | | Personal material (interviews, opinions, test scores) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  |  | | | Deception | | | | | | | | | | | | | | | |  | | | | |  |
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|  | |  | | |  | | | | |  | | Stress or emotional arousal (including but not limited | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  |  | | |  | | | | | | | | | | | | | | | |  | | | | |  |
|  | |  | | |  | | | | |  | | to embarrassment, disappointment or other disagreeable emotion) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  |  | | | Loss of privacy | | | | | | | | | | | | | | | |  | | | | |  |
|  | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | |  | | Alteration of self-concept (e.g., through knowledge of test scores) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  |  | | | Loss of legal rights | | | | | | | | | | | | | | | |  | | | | |  |
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|  | |  | | |  | | | | |  | | Loss of cognitive functioning | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  |  | | | Other (explain below) | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | Briefly explain items checked: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | C. | | | Risk Protection Procedures: Indicate procedures to protect subjects from risks: (Check all that apply) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | |  | | | i. | | | | | PHYSICAL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | |  | | M.D. or other appropriately trained individual(s) in attendance | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | | | | | | |
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|  | |  | | |  | | | | |  | | Sterile equipment | | | | | |  | |  | | | |  | | | |  | | | | | | | |  | | Other (explain below) | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | | | | | | |
|  | |  | | | Briefly explain items checked: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | |  | | | ii. | | | | | PSYCHOLOGICAL/SOCIAL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | | | |  | | Precaution in use of stressors or emotional material | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | | | |
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|  | |  | | |  | | | | |  | | When deception used, subjects fully informed as to nature of research at feasible time | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | | | |
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|  | |  | | |  | | | | |  | | Procedures to minimize changes in self-concept | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | | | |
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|  | |  | | |  | | | | |  | | Voluntary participation and withdrawal from study | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | | | |
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|  | |  | | |  | | | | |  | | Data from protected sources | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | | | |
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|  | |  | | |  | | | | |  | | Individual data confidentiality and anonymity will be maintained | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | | | |
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|  | |  | | |  | | | | |  | | No unauthorized use of data | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | | | |
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|  | |  | | |  | | | | |  | | All data and consent forms kept in a secure place | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | | | |
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|  | |  | | |  | | | | |  | | Debriefing on experimental purposes | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | | | |
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|  | |  | | |  | | | | |  | | Other (e.g., legal coverage, financial risks) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | | | |
|  | |  | | | Briefly explain items checked: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 4. | | RISK FACTOR EVALUATION ( Continued) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | D. | | | Procedures: List all procedures or tests to be done for this study which would not ordinarily be performed for the medical care of the patient (Check all that apply) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | i. | | | | | | New untested treatment, procedure, or device (Complete FORM 7 if applicable) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | |
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|  | |  | | | ii. | | | | | | Physical examination | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | |
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|  | |  | | | iii. | | | | | | Standard laboratory procedures (CBC, Chemistries, etc.) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | |
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|  | |  | | | iv. | | | | | | Administration of drug(s) (Complete FORM 6 as applicable) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | |
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|  | |  | | | v. | | | | | | Administration of blood components | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | |
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|  | |  | | | vi. | | | | | | Collection of specimens (blood, tissue, etc.) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | |
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|  | |  | | | vii. | | | | | | Interview or self-administered questionnaire | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | |
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|  | |  | | | viii. | | | | | | Other (explain below) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | | |  | | |
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| UH Cooperative IRB, version 10-29-14 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | | Briefly explain items checked: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | E. | | | Radioactive Materials: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | |  | | |  | | Will radioactive agents be administered? | | | | | | | | | | | | | | | | | | |  | | | | | Yes | | | |  | | | | |  | | | No | | | | | | |  | | | | |  | | | | | | | | | |  | | | | | | | | |
|  | |  | | | If yes, name these radioactive materials and complete the Drug Data Form (FORM 6): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | F. | | | Mechanism for Safety Monitoring: How will you detect if greater harm is accruing to your subjects than you anticipated? What will you do if such increased risk is detected? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 5. | | BENEFITS OR SIGNIFICANCE OF STUDY | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Briefly describe the benefits that will or may accrue to each human subject and/or to humanity in general, as a result of participation in this project: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 6. | | INFORMED CONSENT | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | Attach consent forms to be signed by each subject for committee review. Use the attached Guidelines for Preparation of an Informed Consent. (Refer to Appendix B for details of appropriate consent) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | A. | | | Indicate how you will obtain informed consent (check the appropriate box): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | |  | | | Subject (or parent/guardian) reads complete consent form and signs (“long” form) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |  | | | | | | | |  | |
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|  | | |  | | |  | | | Oral briefing by researcher or investigator with signing of simple consent form (“short form”) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |  | | | | | | | |  | |
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|  | | |  | | | 1. . | | | Other (explain) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |  | | | | | | | |  | |
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|  | | | Explain how subject recruitment will be conducted. (Remember that prior to approaching subject or conducting prescreening of charts, approval from the attending physician must be obtained.) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | Describe the process of obtaining informed consent. (i.e. Who will be responsible for what procedure. What steps will be taken.) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | If the study will require a pre-screening process at any of the study sites where protected health information will be used/disclosed before obtaining informed consent/HIPAA authorization, you must request a HIPAA waiver of authorization for the prescreening process. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | |  | | Will this be needed for this study? | | | | | | | | | | | | | | | | | | |  | | | | | | Yes, if yes, complete Form 4B. | | | | | | | | | | | | | | | | | | | | | | | |  | | | | No | | | | | | | | | | | | |
| 7. | | | OTHER. For further explanation, attach a page with the heading “7*. OTHER”* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| UH Cooperative IRB, version 10-29-14 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | End of Form 5 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| **FORM 6** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **UNIVERSITY OF HAWAII COOPERATIVE IRB**  **DRUG FORM FOR CLINICAL INVESTIGATIONS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name of Drug: | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | IND/ NDA # | | | | | | | | |  | | | | | | |
| Principal Investigator: | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Affiliated Institution, if any: | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name of Cooperative Study Group (e.g., SWOG, NSABP, etc.): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1. | DRUG STATUS | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | Investigational New Drug? | | | | | | | | | | | | | | | | | | |  | | Yes | | | | | |  | | | | | | | No | | | | | | | | | | | | | | | | | | | |
|  |  | | | If yes, have FDA certification requirements for IND been met? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | Yes | | | | |  | | | | No | | | | | | | |
|  |  | | | If drug is FDA-approved, is it to be administered in a new manner? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |  | | | | | | | |
|  |  | | | (e.g., unapproved route or unapproved indication) ? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | Yes | | | | |  | | | | No | | | | | | | |
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| 2. | BRAND OR TRADE NAME: | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 3. | GENERIC NAME: | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 4. | THERAPEUTIC CLARIFICATION: | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 5. | DRUG FORM: | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 6. | CHEMICAL NAME (if known): | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 7. | MANUFACTURER/SOURCE: | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 8. | STRENGTH: | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **STORAGE REQUIREMENTS** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | **DRUG ADMINISTRATION PROCEDURES** | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 9. | STABILITY/STORAGE REQUIREMENTS | | | | | | | | | | | | | | | | | | | | | | | | | | | | 10 | | | ADMINISTERED BY | | | | | | | | | | | | |  | | | MD | | | | |  | RN | |  | LPN |
|  | Prior to mixing: | | | | | | | | | | | | | | | | | | | | | | | | | | | | 11 | | | RECONSTITUTION DIRECTIONS: | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | Room temp. at | | | | | | | |  | | | | | | °C to | | | |  | | | | | | °C | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  |  | | Refrig. temp. at | | | | | | | |  | | | | | | °C to | | | |  | | | | | | °C | |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  |  | | Freezer temp. at | | | | | | | |  | | | | | | °C to | | | |  | | | | | | °C | | 12 | | | ROUTE OF ADMINISTRATION: | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  |  | | Protect from light | | | | | | | | | | | | | | | | | | | | | | | | | |  | | |  | | | | P.O. | | | |  | | | I.M. |  | | | I.T. | | | | | | |  | I.V. Bolus | | |
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|  |  | | Other (specify): | | | | | | |  | | | | | | | | | | | | | | | | | | |  | | |  | | | | I.V. Infusion (indicate rate): | | | | | | | | | | | | | | | |  | | | | | |
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|  |  | After mixing stable for: | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | |  | | | | Other (specify): | | | | | | | |  | | | | | | | | | | | | | |
|  |  |  | | | | minutes | | | | |  | | | | hours | | | | | | |  | | | | days | | | 13 | | | | USUAL DOSAGE RANGE: | | | | | | | | | | | | | | | |  | | | | | | | | |
|  |  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | After mixing store at: | | | | | | | | | | | | | | | | | | | | | | | | | | | 14 | | | | | | SPECIAL PRECAUTIONS (including drug | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | Room temp. at | | | | | | | | |  | | | | °C to | | | | |  | | | | | | °C | |  | | | | | | interactions and in-service requirements if necessary): | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | Refrig. temp. at | | | | | | | | |  | | | | °C to | | | | |  | | | | | | °C | |  | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
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| UH Cooperative IRB, version 10-29-14 | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| **FORM 6 / page 2of 2** | | | | | | | | | | | | |
| **UNIVERSITY OF HAWAII COOPERATIVE IRB**  **DRUG FORM FOR CLINICAL INVESTIGATIONS** | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| 15. POTENTIAL SIDE EFFECTS OR TOXICITIES | | | | 16. TIME OF ONSET | | | 17. DURATION | | | | | 18. ANTIDOTES |
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| 19. | OTHER AUTHORIZED PRESCRIBERS (Other than physicians listed on Form 1) | | | | | | | | | | | |
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| 20. | IN CASE OF ADVERSE REACTION, NOTIFY: | | | | | | | | | | | |
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|  | |  | | | | | |  |  | | | |
|  | | Principal Investigator (P.I.) | | | | | |  | Phone Number | | | |
|  | |  | | | | | |  |  | | | |
|  | | Designee of P.I. | | | | | |  | Phone Number | | | |
|  | |  | | | | | |  |  | | | |
|  | | Medical Director of Manufacturer | | | | | |  | Phone Number | | | |
|  | | | | | | | |  |  | | | |
| UH Cooperative IRB, version 10-29-14 | | | | | | End of Form 6 | | | | | | |

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| FORM 7 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **UNIVERSITY OF HAWAII COOPERATIVE IRB**  **INVESTIGATIONAL DEVICE FORM** | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name of Device: | | | |  | | | | | | | | | | | | | |  | | IDE / 510(k) / HUD#: | | | | | | | |  |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. | PROJECT TITLE: | | | | | |  | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2. | PRINCIPAL INVESTIGATOR: | | | | | | | | | | |  | | | | | | | | | | | | | | | | |
|  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3. | DURATION OF STUDY: | | | | | | | | | From | | |  | | | | | | To | | | | |  | | | | |
|  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. | SPONSOR/MANUFACTURER: | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | A. | Name: | | |  | | | | | | | | | | | | | | | | | | | | | | | |
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|  | B. | Address: | | | |  | | | | | | | | | | | | | | | | | | | | | | |
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|  | C. | Phone Number: | | | | | | |  | | | | | | | | | | | | | | | | | | | |
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| 5. | DEVICE DESCRIPTION: | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | A. | Name: | | |  | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | B. | Use of Device: | | | | | |  | | | | | | | | | | | | | | | | | | | | |
|  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | C. | Device Specifications (e.g., space, temperature, control, storage, electrical needs, etc.): | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 6. | STATUS OF DEVICE: | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | A. | Is device exempt from human subjects regulations? If yes, explain below: | | | | | | | | | | | | | | | | | | |  | Yes | | | |  | No | |
|  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | B | What risks are presented by the device? | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | C. | Are the risks presented by the device **significant** : | | | | | | | | | | | |  | | | or **nonsignificant** | | | | | |  | |  | | | |
|  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | D. | Has any other IRB reviewed and made decisions regarding this device ?: | | | | | | | | | | | | | | | | | | |  | Yes | | | |  | No | |
|  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | If yes, explain here: | | | | | | | |  | | | | | | | | | | | | | | | | | |
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|  | E. | What is the status of the device with the Food and Drug Administration (FDA)? | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | F. | Has the device been approved for marketing?: | | | | | | | | | | | |  | | Yes | | | | |  | No | | | | | | |
|  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | G. | Is the device approved for any other indications? If yes, explain below: | | | | | | | | | | | | | | | | | | |  | Yes | | | |  | No | |
|  |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | H. | Is the device now being studied for a different indication? If yes, explain: | | | | | | | | | | | | | | | | | | |  | Yes | | | |  | No | |
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| UH Cooperative IRB, version 10-29-14 | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |

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|  | | I. | Is an investigational device exemption (IDE) needed for this device? | | | | | | | | | |  | Yes | | | |  | No | |
|  | |  | | | | | | | | | | | | | | | | | | |
|  | |  | | If yes, has it been approved? | | | |  | Yes (Attach copy of approval) | | | | | |  | No | | | | |
|  | |  | | | | | | | | | | | | | | | | | | |
| 6. | | PROTOCOL REQUIREMENTS: | | | | | | | | | | | | | | | | | | |
|  | | A. | New Study? | | |  | Yes | | |  | | No | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | | | |
|  | | B. | Protocol Revision? | | |  | Yes | | |  | | No | | | | | | | | |
|  | |  | | | | | | | | | | | | | | | | | | |
|  | | C. | Emergency Use? | | |  | Yes | | |  | | No | | | | | | | | |
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| 7. | | SIGNATURE: | | |  | | | | | | | | | | | | Date: | | |  |
|  |  | | | | (Principal Investigator) | | | | | | | | | | | |  | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| UH Cooperative IRB, version 10-29-14 | | | | | | | | | | | End of Form 7 | | | | | | | | | |