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|  | **Purpose and Background** | **Yes** | **No** | **N/A** | **Notes** |
| 1 | Statement of purpose is adequate |  |  |  |  |
| 2 | Approval status of drug or device clearly explained |  |  |  |
| 3 | Preliminary data are adequate |  |  |  |
| 4 | Study personnel appear appropriate/qualified |  |  |  |
|  | **Scientific Review (only if not otherwise conducted)** | **Yes** | **No** | **N/A** |  |
| 1 | Procedures are consistent with sounds research design |  |  |  |
| 2 | Design is adequate to address research question |  |  |  |
| 3 | Rationale for the number of subjects is justified |  |  |  |
| *[Formal sample size is required except for pilot studies]* |  |  |  |
| 4 | Inclusion/exclusion criteria are appropriate |  |  |  |
| 5 | Study endpoints are well defined |  |  |  |
|  | Study Population and Recruitment Procedures | **Yes** | **No** | **N/A** |  |
| 1 | Selection of subjects is equitable |  |  |  |
| 2 | Screening procedures are acceptable |  |  |  |
| 3 | Recruitment methods and materials are appropriate |  |  |  |
| 4 | Payments/reimbursements are not coercive/unduly influential |  |  |  |
| 5 | Any coercion/undue influence to participate is avoided or minimized |  |  |  |
| 6 | Vulnerable subject populations\* are identified and adequately protected, and additional safeguards are provided where needed to protect subjects’ rights and welfare and minimize coercion or undue influence |  |  |  |
|  | *[\*E.g., children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons]* |
|  | **informed consent** | **Yes** | **No** | **N/A** |  |
| 1 | Consent will be sought from each prospective participant or their legal representative |  |  |  |
| 2 | If consent is waived, or consent process or documentation is altered from standard, appropriate justification is provided; consent or parental permission are not waived or altered in FDA-regulated research. |  |  |  |
| 3 | The consent process minimizes the possibility of coercion or undue influence |  |  |  |
| 4 | Consent form language is appropriate/understandable to subjects |  |  |  |
| 5 | Consent form is accurate and complete and includes all required elements [see checklist next page] |  |  |  |
| 6 | Consent procedure is described; sufficient time is allowed |  |  |  |
| 7 | Any exception to signed consent by adult subjects (e.g., surrogates, children) is justified in protocol and reflected in consent documentation |  |  |  |
| 8 | If those who do not use English as a primary language will be enrolled, application indicates whether translated consent forms or short form consent will be used |  |  |  |
| 9 | Communications with the participant, both written and verbal, will be in language understandable to the participant or representative |  |  |  |
| 10 | All translated consent documents are included with application |  |  |  |
| 11 | Information communicated during the consent process will not include exculpatory language through which the participant or representative is made to waive or appear to waive legal rights or release or appear to release the investigator, sponsor, institution, or their agents from liability for negligence. |  |  |  |
| 12 | Where surrogates/legally authorized representatives will consent, the required additional safeguards are in place, including VAMC requirements where needed |  |  |  |
| 13 | Modifications and renewals: If there are significant new findings or protocol changes that might relate to participants’ willingness to continue participation, there is an appropriate plan to inform subjects of this information. |  |  |  |
|  | **Procedures** | **Yes** | **No** | **N/A** |  |
| 1 | Study utilizes procedures already performed for diagnosis/treatment |  |  |  |
| 2 | Frequency and duration are stated |  |  |  |
| 3 | Research procedures are clearly differentiated from standard of care |  |  |  |
| 4 | Procedures are performed at acceptable facilities by trained staff |  |  |  |
| 5 | Data collection/recording methods are explained |  |  |  |
| 6 | Adverse Event reporting is addressed |  |  |  |
|  | **Risks and benefits** | **Yes** | **No** | **N/A** |  |
| 1 | Risks are well described, including physical, psychological, social, legal, or economic risks |  |  |  |
| 2 | Risks are minimized |  |  |  |
| 3 | Risks and benefits are well described |  |  |  |
| 4 | Risks are reasonable in relation to potential benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result |  |  |  |
| 5 | Injury/illness due to research is addressed |  |  |  |
|  | Data Analysis and Oversight | **Yes** | **No** | **N/A** |  |
| 1 | Plans for data/statistical analysis are defined and justified |  |  |  |
| 2 | Stopping rules are explained and sufficiently detailed |  |  |  |
| 3 | Provisions for monitoring safety data are adequate to ensure the safety of participants (Required for research over minimal risk) |  |  |  |
| 4 | When UCSF is the coordinating center or the prime grant holder provisions for communicating risks and material protocol changes between sites are adequate |  |  |  |  |
|  | Study Resources | **Yes** | **No** | **N/A** |  |
| 1 | Study personnel are sufficient in numbers and qualifications |  |  |  |  |
| 2 | Facilities are adequate |  |  |  |  |
| 3 | Medical or psychological resources that subjects may need as a consequence of the research are available |  |  |  |  |
| 4 | Letters of support from involved units are provided or appropriate co-investigators from those units are named |  |  |  |  |
|  | **Privacy and Confidentiality** | **Yes** | **No** | **N/A** |  |
| 1 | Privacy protection measures are adequate |  |  |  |
| 2 | Confidentiality of identifiable data measures are adequate |  |  |  |
| 3 | Data to be retained in subject’s medical record is explained |  |  |  |
| 4 | For FDA regulated research, disclosure that FDA may inspect records |  |  |  |
| 5 | Certificate of Confidentiality is warranted |  |  |  |
|  | **Drugs, Biologics & Devices** | **Yes** | **No** | **N/A** |  |
| 1 | IND or IDE provided, or meets exemption |  |  |  |  |
| 2 | NSR Acceptable |  |  |  |  |
| 3 | Test article control is adequate |  |  |  |  |
|  | **Other** | **Yes** | **No** | **N/A** |  |
| 1 | References are appropriate |  |  |  |  |
| 2 | Frequency of review is stated if less/greater than standard 12 months |  |  |  |
| 3 | Federal grant and CHR application are consistent |  |  |  |  |
| 4 | For research conducted outside of California, including internationally, local legal issues, IRB approvals and coordination are adequately considered. (Ask for consultation from Legal Affairs if necessary.) |  |  |  |  |

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|  | **Continuing Review and Modifications** | **Yes** | **No** | **N/A** |  |
| 1 | The current or proposed consent document is accurate and complete |  |  |  |  |
| 2 | Do significant new findings that may relate to a participant’s willingness to continue taking part in the research study need to be provided? |  |  |  |  |
| If so, is the plan to provide new findings to participants acceptable? |  |  |  |
| 3 | Is it necessary to obtain verification from sources other than the investigator to ensure that no material changes have occurred since previous IRB review? |  |  |  |  |

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|  | **Basic Elements of Informed Consent**  **[45 CFR 46.116(a) and 21 CFR 50.25(a)]** | **Yes** | **No** | **Notes** |
| 1 | A statement that the study involves research; |  |  |  |
| an explanation of the purpose of the research; |  |  |
| an explanation of the expected duration of the research; |  |  |
| a description of the procedures to be followed; and |  |  |
| identification of any procedures that are experimental. |  |  |
| 2 | A description of any reasonable foreseeable risks or discomforts to the subject (including ineffective treatment). |  |  |  |
| 3 | A description of the benefits to the subject or to others that may 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 the records identifying the subject will be maintained; and |  |  |  |
| A statement that the records may be inspected by the Sponsor (CRO or other designee), the FDA (for FDA-regulated research), the CHR or other authorized parties. |  |  |
| 6 | For research involving more than minimal risk, an explanation as to whether any compensation will be paid, whether any medical treatments are available if injury occurs, and, if so, what those treatments consist of or where further information may be obtained. |  |  |  |
| For VAMC research, inclusion of VA-specific wording regarding research-related injury and payment for care. |  |  |
| 7 | An explanation of whom to contact: |  |  |  |
| for questions about the research; |  |  |
| for questions about rights as a research subject; and |  |  |
| in the event of a research-related injury. |  |  |
| 8 | A statement that participation is voluntary, and |  |  |  |
| that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue at any time without penalty. |  |  |
|  | **Additional Elements (IF APPLICABLE)**  **[45 CFR 46.116 (b) and 21 CFR 50.25(b)]** | **Yes** | **No** | **Notes** |
| 1 | A statement that the particular treatment/procedure may involve risks to the subject (or to the fetus or embryo, 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. |  |  |  |
| 3 | Any additional costs to the subject that may result from participation in the research. |  |  |  |
| 4 | The consequences of and procedures for withdrawing from the research study. |  |  |  |
| 5 | A statement that significant new findings that may affect subject’s willingness to continue participation [such as safety risks] learned during the course of the research will be provided to the subject. |  |  |  |
| 6 | The approximate number of subjects in the study. |  |  |  |
|  | **Documentation of Informed Consent**  **[45 CFR 46.117 (b) and 21 CFR 50.27]** | **Yes** | **No** | **Notes** |
| (a) | Except as provided in (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. |  |  |  |
| (b) | Except as provided in (c) of this section, the consent form may be either of the following: |  |  |  |
|  | (1) A written consent document that embodies the elements of informed consent required by 45CFR46.116 and 21CFR50.25 for FDA regulated research. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or |  |  |  |
|  | (2) A short form written consent document stating that the elements of informed consent required by 45CFR46.116 and 21CFR50.25 for FDA regulated research have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form. |  |  |  |
| (c) | An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either: |  |  |  |
|  | (1) 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 |  |  |  |
|  | (2) 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. |  |  |  |