|  |  |  |  |
| --- | --- | --- | --- |
| Drug Information FormUse this form to give drug specific information to supplement the Protocol.

|  |  |
| --- | --- |
|  |  |

 | C:\Users\cbcholka\AppData\Local\Microsoft\Windows\INetCache\Content.Word\UNM_OfficeInstitutionalReviewBoard_Horizontal_RGB.PNG1805 Sigma Chi NE | Tel: (505) 277-2644 Website: irb.unm.edu | Email: IRBMainCampus@unm.edu |

|  |
| --- |
| Project Identification |
| Title of the project: |  |
| Principal Investigator: |  |

|  |
| --- |
| Drug Information |
| Drug name & manufacturer: |  |
| Dose & strength: |  |
| Route of administration (e.g. topical, oral, IV, etc.): |  |
| Is the drug a controlled substance? | [ ]  No | [ ]  Yes. Classification:  |

|  |
| --- |
| IND Requirements |
| Indicate whether the following apply to the research: |
|  | 1. The drug is FDA Approved and lawfully marketed in the United States. | [ ]  False | [ ]  True |
|  | 2. The research is not intended to be reported to the FDA as a well-controlled project in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug. | [ ]  False | [ ]  True |
|  | 3. The research is not intended to support a significant change in the advertising for the product. | [ ]  False | [ ]  True |
|  | 4. The research does not involve a route of administration or dosage level or use in a patient population or other factor (e.g. population) that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug. | [ ]  False | [ ]  True |
|  | Explain:  |
|  | 5. The research will be conducted in compliance with the FDA requirements for promotion and charging for investigational drugs (21 CFR 312.7); researchers and sponsors may not promote investigational new drugs as being safe and effective and they may not charge for, distribute, or test these drugs without FDA approval. | [ ]  False | [ ]  True |
| If all answers are true, project is exempt from IND requirements. **If any are false, the drug may require an Investigational New Drug (IND) application, and the OIRB should be contacted prior to submission to the IRB.** |

|  |
| --- |
| Handling of Drug |
| Describe the procedures for dispensing the drug: |  |
| Describe where the drug will be stored and how it will be secured (including limited access): |  |
| Indicate who is prescribing the drug, including contact information: |  |
| **IMPORTANT!** If applicable, submit a copy of all FDA or sponsor documents related to this drug including IND documentation. |

|  |
| --- |
| Certification |
| \* Signature below certifies that the information provided on this form is accurate and that the above titled research is in full compliance with the regulations, laws, and institutional requirements/policies governing human subject research. Exemption from the requirements for an IND does not in any way exempt you from complying with FDA requirements including the requirements for informed consent and initial and continuing review conducted by the UNM IRB.  |
| Principal Investigator |
|  |  |
| \* Signature | Date |