**APPENDIX 8**

**OKLAHOMA CHRISTIAN UNIVERSITY**

**DRUGS, AGENTS AND DEVICES**

**FORM**

Instructions: If this study involves the use of drugs, chemicals, nonhuman biological agents, or devices, the study is subject to Food and Drug Administration (FDA) regulations. Researchers planning to use these agents or devices in human subjects research must complete this form and include it with an original IRB application, as applicable.

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| --- | --- |
| **Responsible Project Investigator (RPI)** | |
| 1) RPI First Name | RPI Last Name |
|  | |
| 2) Project Title | |
|  | |
| 3) Will drug(s) be administered as part of this study?  ­\_Yes  \_No (If no, go to 4)  3a) Drug Name(s):  Trade: Generic:  3b) If the drug is investigational, provide the Investigational New Drug (IND) number:  IND#  3c) Who is the IND held by? (Check one)  ­\_Sponsor (provide a copy of the Investigator’s Brochure and the sponsor’s protocol)  \_Investigator (provide a copy of the IND application submitted to the FDA and safety information) | |
|  | |
| 4) Will biologic(s) be used as part of this study?  \_Yes  \_No (If no, go to 5)  4a) Biologic Name(s): | |
|  | |
| 5) Does the study involve the evaluation of investigational or marketed medical devices?  ­\_Yes  \_No  5a) Device Name(s) and functions:  5b) Investigational Device Exemption (IDE)# Date:  5c) Who is the IDE held by? (Check one)  ‘ Sponsor (provide a copy of the Investigator’s Brochure and the sponsor’s protocol)  ‘ Investigator (provide a copy of the IDE application submitted to the FDA)  5d) For a device with an IDE, check one of the appropriate categories:  ‘ 510 K Device (provide a copy of the FDA letter confirming the 510K status)  ‘ Non-significant risk device (provide justification of non-significant risk determination)  ‘ Marketed device | |
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