|  |
| --- |
| The purpose of this worksheet is to provide support for reviewers in determining the appropriate pregnancy testing, contraception and semen exposure protection requirements for clinical trials. Committee members should consider the potential risk to a fetus should pregnancy occur, the available alternatives to study participation and the possible benefits of the research when determining requirements for contraception. Committee members should also consider whether women who have demonstrated compliance with a moderately effective form of birth control (e.g. oral contraceptives) should be permitted to continue that form of birth control (if the protocol permits) even when a “highly effective” form a birth control is required. Click [HERE](https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/images/figure.png?_=43140) to view the CDC’s Contraceptive Effectiveness Chart.  |
| **Section 1 – Inclusion of Women of Child-Bearing Potential (WOCBP)** |
|  |
| [ ]   | The study includes WOCBP.  *If yes, complete Sections 2-6* |
| [ ]   | This study does not include WOCBP. *If yes, complete Sections 3 and 7* |
|  | **Section 2 – Provisions for Pregnancy Testing** |
| [ ]  | The protocol includes adequate provisions for pregnancy testing. *If no – contact PI or Committee Analyst to discuss* |
|  | **Section 3 – Risks to Embryo/Fetus** |
| [ ]  | The risk of human teratogenicity/fetotoxicity has not been demonstrated or is unknown.  *If checked, contraceptive options should be based on available data, risks of drugs in same class and risk.*  |
| [ ]  | The risk of human teratogenicity/fetotoxicity has been demonstrated. *If checked, highly or moderately effective contraceptive options should be required unless there are no available treatment alternatives and the subject could lose an opportunity if she cannot comply with contraceptive requirements.* |
|  | **Section 4 – Available Alternatives**  |
| [ ]  | Alternative treatments with a risk/benefit ratio that is at least as favorable as the test article are available for WOCBP. *If checked, consider whether WOCBP should be required to use a highly effective contraceptive option.* |
| [ ]  | No alternative treatments with a risk/benefit ratio that is at least as favorable as the test article are available for WOCBP. *If checked, consider whether a requirement for a highly effective form of contraception would result in a loss of an opportunity for WOCBP.*  |
|  | **Section 5 – Contraceptive Options Required by Protocol and Consent Document** |
| [ ]  | The protocol requires highly effective contraception and:[ ]  The listed options are consistent with highly effective methods as defined by the CDC.[ ]  The listed options are NOT consistent with highly effective methods as defined by the CDC. |
| [ ]  | The contraceptive options include methods other than highly effective contraception as defined by the CDC:[ ]  The listed options are acceptable. [ ]  The listed options are NOT acceptable. *If checked, complete Section 6* |
|  | **Section 6 - Actions Required for Protection of WOCBP/Fetuses/Embryos** |
| [ ]  | The protocol/consent should be revised to require: [ ]  Highly effective contraception as defined by the CDC. [ ]  Highly or moderately effective contraception as defined by the CDC[ ]  Other:  |
| [ ]  | WOCBP should receive an Information Sheet describing the contraceptive requirements. |
|  | **Section 7 –Contraception and Semen Exposure Protection when the study includes Men who are Sexually Active** |
| [ ]  | This study includes men who may have partners who are WOCBP. If checked, c*onsider whether contraception should be required based on the risk of the test article and whether the test article is excreted in semen.*  [ ]  Men should agree to wear a condom to avoid partner test-article exposure through semen.[ ]  Men should agree to wear a condom because it is necessary for effective contraception.[ ]  Men should agree to not have sex with female partners who are WOCBP, unless the partner uses the following contraception while the man is exposed to the drug/biologic.[ ]  Highly effective contraception as defined by the CDC. [ ]  Highly or moderately effective contraception as defined by the CDC.[ ]  Other:  |
| [ ]  | Male subjects should receive an Information Sheet describing the contraceptive requirements. |
| [ ]  | Partners of male subjects who are WOCBP should receive an Information Sheet describing the contraceptive requirements. |