#  HDEC TEMPLATE FOR REPRODUCTIVE RISKS AND CONTRACEPTIVE ADVICE

# PARTICIPANT INFORMATION SHEETS FOR CLINICAL STUDIES

## Reproductive Risks for Sexually Active Participants of Child-Bearing Potential

***[Modify if required]*** The effects of [drug] in pregnancy and breastfeeding are unknown, but there is a risk it may cause birth defects or fetal deaths, [and/or] be passed on in breast milk. If you are pregnant or breastfeeding, you cannot take part in this study.

If you are sexually active and of child-bearing potential (able to become pregnant), it is very important that you do not become pregnant during this study. You must use one of the methods of contraception listed below, from at least [*insert duration*] before your [*first*] dose of study drug until at least [*insert duration*] after your [*last*] dose:

A highly effective method (less than 1 pregnancy per 100 women using the method for one year) e.g.:

* Implant contraceptive (e.g. Jadelle®)
* Intra-uterine device (IUD) containing either copper or levonorgestrel (e.g. Mirena®)
* Male sterilization (vasectomy)
* Female sterilization (e.g. bilateral tubal ligation (‘clipping or tying tubes’) or hysterectomy)

OR an effective method (5 - 10 pregnancies per 100 women using the method for one year) e.g.:

* Injectable contraceptive (e.g. Depo Provera)
* Oral Contraceptive Pill (combined hormonal contraceptive pill or progestogen-only ‘mini-pill’)
* Vaginal contraceptive ring (e.g. NuvaRing®)

**[*If hormonal contraceptives are not acceptable in the study, e.g. because of interactions with the study drug, this should be stated here and these methods deleted from the lists above.]***

***[Add if a barrier form of contraception must also be used]*** You / your partner must also use a barrier form of contraception, from your [*first*] dose of study drug through until [*insert duration*] after your [last] dose. Barrier methods of contraception include:

* Male condoms
* Female condoms
* Female diaphragm (‘cap’)

Please note that barrier methods alone are not highly effective methods of contraception.

***[Add if applicable]*** You must also agree not to donate eggs, from dosing until at least [*insert duration*] after your [last] dose of study drug.

**If you do become pregnant during the study, you must tell the study doctor** **as soon as possible. *[Add detail regarding whether participant may stay in the study (or not) and how participant will be monitored. A statement should be included about the collection of information about the pregnancy and outcomes, including that of the infant].***

**Reproductive Risks for Sexually Active Participants able to Father a Child.**

***[Modify if required]*** The effects of [drug] if passed on through semen are unknown, but there is a risk it may cause birth defects or fetal deaths. **You are responsible for informing your sexual partner** of these possible risks.

***[Add If the study involves male and female participants]*** If you are sexually active and have any partner who is of child-bearing potential (meaning a partner who may become pregnant) it is very important that you use contraception during this study.You and your partner must use one of the contraception options listed above for participants of child-bearing potential, from at least [*insert duration*] before your [first] dose of study drug through until at least [*insert duration*] after your [last] dose. **[*Please note that if hormonal contraceptives are not acceptable for female participants, e.g. because of interactions with the study drug, it is still acceptable for hormonal methods to be used by sexual partners of male participants. If this is the case, please add:*** A hormonal method of contraception (e.g. pill, implant, injection) is also acceptable.]

***[Add if the study involves male participants only]*** If you are sexually active and have any partner who is of child-bearing potential (meaning a partner who may become pregnant) it is very important that you use contraception during this study.You and your partner must use one of the methods of contraception listed below, from at least [*insert duration*] before your [first] dose of study drug through until at least [*insert duration*] after your [last] dose:

A highly effective method (less than 1 pregnancy per 100 women using the method for one year) e.g.

* Implant contraceptive (e.g. Jadelle®)
* Intra-uterine device (IUD) containing either copper or levonorgestrel (e.g. Mirena®)
* Male sterilization (vasectomy)
* Female sterilization (e.g. bilateral tubal ligation (‘clipping or tying tubes’) or hysterectomy)

OR an effective method (5 - 10 pregnancies per 100 women using the method for one year) e.g.

* Injectable contraceptive (e.g. Depo Provera)
* Oral Contraceptive Pill (combined hormonal contraceptive pill or progestogen-only ‘mini-pill’)
* Vaginal contraceptive ring (e.g. NuvaRing®)

**[*Add if a barrier form of contraception must also be used]*** You / your partner must also use a barrier method of contraception, from your [first] dose of study drug through until [duration] after your [last] dose.Barrier methods of contraception include:

* Male condoms
* Female condoms
* Female diaphragm (‘cap’)

Please note that barrier methods alone are not highly effective methods of contraception].

***[Add if applicable]* If a pregnancy occurs, you must report this to the study doctor as soon as possible.** Your partner will be asked to give consent for her information and her infant’s information to be collected for monitoring purposes.

***[Add if applicable]*** You must also agree not to donate sperm, from dosing until at least [duration] after your [last] dose of the study drug.