Trinity Health Of New England

Department of **<insert here>**

**Important Information about Reproductive Risks**

**WoMen**

**<insert here>** drugs such as the ones offered as part of this clinical trial can affect an unborn child. If you are a woman able to have children, it is important that you do not become pregnant while you are taking part in this study, and perhaps even for some time after you stop taking the study drugs. Your doctor will discuss this in detail with you. Women who are breast feeding should stop breast feeding while taking part in this study.

Trinity Health Of New England sites are dedicated to your health and well-being. While abstinence is the most effective way of preventing a pregnancy, we understand that women may also decide to use other methods of pregnancy prevention. Sites within Trinity Health Of New England will not provide contraception products as part of this study, nor does it endorse, approve, or intend contraception, other than abstinence, by complying with the requirements of this study.

The “Reproductive Risks” section of this Informed Consent Form discusses what forms of pregnancy prevention are adequate for use in this study and which forms are not. You are encouraged to ask your study doctor or research nurse for more information about reproductive risks and pregnancy prevention.

As a Catholic Healthcare system, Trinity Health Of New England abides by the Ethical and Religious Directives for Catholic Health Care Services, as determined by the United States Conference of Catholic Bishops. As such, Trinity Health Of New England neither endorses nor provides medical practices and/or procedures that contradict the moral teachings of the Roman Catholic Church.

Patient Initials \_\_\_\_\_\_\_\_\_