University of Nebraska Medical Center

Please complete this checklist and submit to WCG with your submission

Any deviation from the language contained within this document requires pre-approval from the UNMC IRB Office. If written approval is not provided the language deviations will be removed.

**Please note: Purple text = site to determine if applicable to study. Please complete fill-in fields if applicable**

**Blue text = WCG IRB can complete for you**

**Black Grey shaded text = must be included verbatim in your consent form as applicable. If different language is submitted to WCG IRB, it must be accompanied by sign-off from UNMC IRB Office.**

**Purple Grey shaded text = If language is included in your consent form, it must be verbatim.**

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| Header/Logo  *Make the appropriate selection to the right of which logo to include on your ICF.* | Option A:  Option B:  Option C: |
| Pregnancy Risk Language  *Make the appropriate selection to the right.* | Option A:  It is possible that the medicines used in this study could injure a fetus if you, or your partner, become pregnant while taking them. You have already been told what is known about this possibility, and you are encouraged to ask further questions.  Option B:  It is possible that the medicines used in this study could injure a fetus if you, or your partner, become pregnant while taking them. You have already been told what is known about this possibility, and you are encouraged to ask further questions.  You may want to discuss this with others before you agree to take part in this study. If you wish, we will arrange for a doctor, nurse, or counselor who is not part of this study to discuss the potential risks and benefits with you and anyone else you want to have present.  Because of the potential risks, you, or your partner, must not become pregnant while you are participating in this study. Women must have a negative pregnancy test before entering the study.  If you are sexually active and can get pregnant, or can get your partner pregnant, you must use [ONE or TWO (site will select as appropriate)] appropriate method of birth control every time you have sex, or you must not have sex.    You can get additional information about methods to avoid pregnancy by calling the UNMC Research Subject Advocate’s Office at (402) 559-6941.  You will need to continue to use birth control to avoid pregnancy for [Site will indicate number] months after finishing the research.  By signing this and being in the study, you are agreeing to not get pregnant while you are on the study and for [Site will indicate number] months after. Should you become pregnant while on this study, you should immediately notify the study personnel. The investigator will assist you in finding appropriate medical care. The investigator also may ask to be allowed to continue getting information about your pregnancy. You can refuse to provide this information. |
| Subject Payment  Is SSN required for payment?    *Yes*  *No* | In order to pay you, you will have to provide your social security number. You can choose not to provide this and still participate in the research but we will be unable to pay you. |
| Tissue Bank  Is this applicable to your study?    *Yes*  *No* | We do not plan to pay you if any new drugs or products are made using the sample(s) you donated. It is our policy that all donated samples belong to the organization. |
| Subject Injury Language  Is your study greater than minimal risk?    *Yes*  *No* | Your health and safety is our main concern. If you are injured or have a medical problem because of this study call someone listed at the end of this consent form. You can get emergency medical treatment at Nebraska Medicine. You can also go to your doctor, the nearest emergency room or call 9-1-1.  We have no plans to pay for your treatment or give you any other money or compensation.  Signing this does not mean you have given up any of your legal rights. |

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| HIPAA Language  *Complete the applicable language selections to the right.* | PHI may be shared with the following entities (indicate which options apply):  The Food and Drug Administration (FDA) [if study involves FDA regulated drug, device, or biologic]  National Institutes of Health (NIH) [if study is funded by the NIH]  Researchers at [insert the name of the institution(s) involved in the study if this is a multi-institution study where PHI will be shared with other researchers]  Your health insurance company [if the Institution expects third party payers to pay for clinical procedures performed during the course of the research]  The Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC) [if the research involves patients with cancer]  [insert name of CRO] which has been hired by the sponsor to help run the research  [name of NCI National Cooperative Group]  The National Cancer Institute's (NCI) Clinical Trial Reporting Program  In addition to the above, choose one of the statements that appropriately represents your study:  Option 1: You are letting us use and share your PHI for as long as the research is going on.  Option 2: You are letting us use and share your PHI for as long as the sponsor needs so it can get approval from the FDA.  Option 3: There is currently no plan to end this study. You are letting us use and share your PHI for as long as we want. |

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| Other special instructions | ***If specific language needs to be added anywhere else in the consent form-[Name] will list it out here.***  *[provide additional language, if applicable]* |

FOR UNMC IRB OFFICE USE ONLY:

***By signing below, I confirm I have reviewed the above and approve of any deviations to the institutional language in the following sections [list here]:***

Signature of UNMC IRB Office

Date