

AMENDMENT 1 TO THE CLINICAL TRIAL MASTER RESEARCH AGREEMENT
between Primary and Satellite Sites (hereinafter referred to as “Amendment 1”)

BETWEEN:

INSTITUTION

Address

(Hereinafter referred to as “INSTITUTION”)

and

INVESTIGATOR

Address

(Hereinafter referred to as “INVESTIGATOR”)

and

STUDY SPONSOR

Address

(Hereinafter referred to as “SPONSOR”)

WHEREAS the parties entered into a Clinical Trial Agreement for the project entitled “**TITLE**” (the “Study”) effective **DATE** (hereinafter referred to as the “**Agreement**”);

WHEREAS, the Institution and Investigator are participating in CRAFT (Canadian Remote Access Framework for clinical Trials), a Canadian-wide initiative to bring oncology care outside of tertiary centers at a community hospital;

WHEREAS, the parties want to implement CRAFT principles into the Study;

WHEREAS, the parties wish to amend the Agreement to reflect this change;

AND WHEREAS this Amendment 1 will take effect as of the date of last signature;

NOW THEREFORE, IN CONSIDERATION of the mutual covenants and promises herein contained the sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. The parties add the following to the Agreement at clause **X (or to the recitals)**:

The parties agree to implement the CRAFT principles into the Study. Sponsor agrees that Institution and Investigator may subcontract with satellite sites (the “Satellite Site”) to achieve this purpose.

Note to satellite sites: clause X should be at the start of the agreement or in the recitals. (remove this text from agreement)

2. The parties add the following to the Agreement at clause **Y**, regarding Representations and Warranties:

The parties agree that the Institution and Investigator may state in any Subsite agreement that the Sponsor has provided this warranty. Institution and Investigator may further include this warranty verbatim in any such Satellite Site agreement.

Note to satellite sites: if there is a study drug, you should have a warranty from the Sponsor that the drug has been manufactured and packaged in accordance with good manufacturing practices. This new clause should go after the warranty paragraph, Y. (remove this text from agreement)

3. The parties add the following to the Agreement at clause Z, regarding Indemnity:

The words: "Satellite Site and Satellite Site Investigators" shall be added after the words "Institution, Investigator" and before the words "as well as its/his/her respective".

Note to satellite sites: the indemnity language varies broadly. Your agreement should ask the Sponsor to provide the same indemnity to the satellite site as they are providing to the primary site. (remove this text from agreement)

4. All other terms of the Agreement remain in full force and effect.

This Amendment 1 may be signed in counterparts, and each counterpart may be delivered by facsimile or signed PDF by email. Each counterpart shall constitute as an original, and when taken together, shall constitute one and the same instrument.

[Signatures to Follow]

IN WITNESS WHEREOF, the parties have executed this Amendment 1 through their duly authorized representatives.

INSTITUTION

By: _____
Name: _____ Date _____
Title: _____

I have authority to bind the organization.

INVESTIGATOR

Dr. _____ Date _____
Principal Investigator

SPONSOR

Name: _____ Date _____
Title: _____

I have authority to bind the organization.