Required Element		Present?	
ALL TRIALS – CGSB RE			
#	RE	Main	Optional
1A	A statement that the research subject is being invited to participate in a clinical trial	Choose	Choose
1B	An explanation of the purposes of the clinical trial	Choose	Choose
1C	The expected duration and nature of the research subject's participation	Choose	Choose
1D	A description of the clinical trial interventions and the probability of assignment to each intervention	Choose	Choose
1E	A description of the procedures to be used as part of the clinical trial, including a clear indication of which procedures are experimental	Choose	Choose
1F	A description of available alternative procedures or courses of treatments outside the scope of the clinical trial	Choose	Choose
1G	A description of the known risks to the research subjects and to other persons, as applicable, including pregnant mothers, nursing infants or the fetus	Choose	Choose
1H	A statement that the particular treatment or procedure may involve risks to the research subject (or to the embryo or fetus, if the research subject is or may become pregnant) which are currently unforeseeable	Choose	Choose
1I	A description of any possible foreseeable benefits to the research subject or to others; when there is no known clinical benefit to the research subject, the research subject shall be informed	Choose	Choose
1J	A description of how the confidentiality of research records identifying the research subject will be maintained, and any limits to their confidentiality	Choose	Choose
1K	A statement to the effect that monitors, auditors, the REB, and regulatory authorities will be granted direct access to the research subject's medical and research records for verification of the clinical trial data, as well as organization officials for legitimate purposes, including quality management	Choose	Choose
1L	A description of the compensation, if any, that will be provided to the research subject in the event he or she is injured during the clinical trial	Choose	Choose
1M	A statement that the research subject does not waive any legal rights that he or she would otherwise have but for being a research subject in the clinical trial. Any offers of compensation in the event of injury shall not limit recourse to other legal remedies	Choose	Choose
1N	A description of the type of response that will be undertaken if injury occurs to the research subject during the clinical trial (for example, that treatment will be made available and covered by the clinical trial funding), or that no such response is planned	Choose	Choose
1O	A statement that participation in the clinical trial is voluntary and that refusal to participate or, once agreeing to participate, a decision to withdraw from the clinical trial at any time, involves no loss of any benefit to which the research subject is otherwise entitled	Choose	Choose
1P	A statement that outlines the process involved for termination of participation	Choose	Choose

1Q	The circumstances or reasons under which the research subject's participation in the clinical trial may be terminated by the qualified investigator and a statement identifying any other persons with the authority to modify the research subject's participation, such as the sponsor	Choose	Choose
1R	A statement that new findings discovered during the clinical trial which may affect the research subject's willingness to continue participation shall be provided to the research subject in a timely fashion	Choose	Choose
1S	The research subject's responsibilities	Choose	Choose
1T	Any anticipated expenses associated with participation in the clinical trial	Choose	Choose
1U	Any payments or incentives for participation in the clinical trial	Choose	Choose
1V	The identity of the sponsors and qualified investigator(s)	Choose	Choose
1W	The approximate number of research subjects in the clinical trial	Choose	Choose
1X	The person to contact for further information about the clinical trial	Choose	Choose
1Y	The person or office to contact for further information about the rights of research subjects in clinical trials	Choose	Choose
1Z	The person to contact in the event of clinical trial related injuries	Choose	Choose
1 AA	A statement concerning any personal benefits that may accrue to the qualified investigator, if applicable and deemed necessary by the REB.	Choose	Choose
ALL TRIALS - CTG POLICY POINTS			
2A	Compliance with NCIC CTG policies regarding drug provision	Choose	Choose
2B	Compliance with NCIC CTG policies regarding compensation/ indemnification	Choose	Choose
2C	Compliance with NCIC CTG policies regarding confidentiality and privacy	Choose	Choose
2D	Compliance with NCIC CTG tumour banking policies	Choose	Choose
2E	Signature and date block for Person Conducting the Consent Discussion	Choose	Choose
2F	Signature and date block for Participant	Choose	Choose
2G	Signature and date block for witness	Choose	Choose
2H	Study Title and/or Code	Choose	Choose
2I	Version control	Choose	Choose
TRIALS SUBJECT TO 21CFR50			
3A	A statement … that notes the possibility that the Food and Drug Administration may inspect the records	Choose	Choose
3b	"A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."	Choose	Choose