Ontario Cancer Research Ethics Board
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Memo

To: All OCREB Affiliated Centres

From: Ontario Cancer Research Ethics Board

cc: NCIC CTG

Date: October 29, 2015 (previous version: June 15, 2015)

RE: Pre-approved OCREB changes to the NCIC CTG ICF

In order to minimize or to eliminate changes at the centre level – consistent with OCREB's centre REB model – the Provincial Applicant should ensure that the pre-approved language (below) is added to the Provincial consent form for all NCIC CTG sponsored studies. None of the additions affect the integrity or consistency of the template and are added solely to address specific institutional requirements that have been approved by OCREB and subsequently incorporated into OCREB's current consent form template.

The NCIC CTG has approved the addition of the following statements in the appropriate sections of the consent form for all NCIC CTG sponsored studies. **Note: the addition of these statements does not require additional approval from NCIC CTG**:

1. STUDY PROCEDURES; (prior to the Experimental Procedures sub-section):

   If applicable:
   The following treatments and tests for this study may take place closer to your home at [*name of centre(s) to be entered in the centre-specific ICF*]:

   List the treatments and/or tests that are authorized to take place at the centre(s) listed above
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2. NON-EXPERIMENTAL PROCEDURES (HIV Testing sub-section added to the blood/urine bullet (if applicable):
   - blood/urine tests *[standard liver function, biochemistry, and other routine blood tests done as part of standard of care do not need to be specified or individually listed. If other tests (such as HIV, Hepatitis) are being done for study purposes only, they should be specified]*

If applicable:

HIV Testing

This study involves testing to determine your HIV status. This test is required for this research study to find out *if [provide reason for the test if not described elsewhere in the consent – e.g., you meet the eligibility requirements, etc.]*. If you test positive for HIV, you *[will not/will]* be able to participate in this study.

In order for you to be tested for HIV you will need to provide a separate consent for the testing. Before providing your consent you should know that you have the option of going to an anonymous HIV test site to get your test results privately, and you can choose not to share this information.

If you consent to be tested for the study, the results of your HIV tests, like all other laboratory test results, will be provided to the Sponsor, your study doctor and your usual doctor.

If you test positive, your doctor will be required to share your identity and your HIV status with Public Health. The people you may have exposed to HIV will have to be notified either by you, your usual doctor or by Public Health.

If you have concerns about being tested for HIV and the consequences of testing positive, you should speak to your study doctor or your usual doctor before providing your consent to be tested.

3. MANDATORY SAMPLE COLLECTION: (after the introductory description of the mandatory collection)

   If you are a First Nations or an indigenous person who has contact with spiritual 'Elders', you may want to talk to them before you make a decision about this research study. Elders may have concerns about some research procedures including genetic testing.

4. CONFIDENTIALITY: (list of authorized organizations)

   - The Ontario Cancer Research Ethics Board, the research ethics board which oversees the ethical conduct of this study in your clinic/hospital.

5. CONFIDENTIALITY: (optional information for centres using the CTMS) new item

Include the following statement if applicable (i.e., insert only if your centre is using the CTMS for clinical trial management)

- Your initials and medical record number may be entered into a clinical trial management system for research administration and quality assurance purposes only. The management system is a controlled access system to ensure the confidentiality and security of the data. The database of the system is housed at Ontario Institute for Cancer Research (OICR), in a secure environment. The management system assists sites in the project management of their trials and also enables the Canadian Cancer Clinical Trials Network (3CTN) to collect de-identified metrics for reporting on clinical trial activity in Canada. Access to the information in the system at this centre is limited to members of the research team. Information in the system will be used for the described purposes and the information/data will not be shared with any unauthorized parties or personnel.

6. CONFIDENTIALITY: (following the paragraph regarding informing the family doctor)

   A wallet card will be provided to you with information about how to contact the study staff when required.

7. COMPENSATION: (addition of the following statement to follow: 'You will not be paid for taking part in this study)

   You will be reimbursed for study-related expenses such as [specify, e.g., parking, etc.]. [Note: this statement may be removed/revised as per centre requirements]

8. CONFLICT OF INTEREST: (addition of the following statements)

   The doctor treating you also may be the doctor in charge of the study.

   If you would like additional information about the funding for this study, or about the role of the doctor in charge of this study, please speak to the study staff or to the Office of the Chair of the Ontario Cancer Research Ethics Board. (contact information below)

9. CONTACTS: (for questions about rights as a participant or about ethical issues related to this study)

   Please contact the Office of the Chair of the Ontario Cancer Research Ethics Board at:

   Telephone: 416-673-6648 Toll Free: 1-866-678-6427 ext. 6648

10. SIGNATURES: (becomes the 4th bullet)

    - I am aware of the risks to me of participating in the study and the risks to the fetus if I become pregnant or father a child during this study

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The Ontario Cancer Research Ethics Board operates in compliance with and is constituted in accordance with the requirements of: TCPS 2 - 2nd edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans; the International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada; and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations. OCREB is registered with the U.S. Department of Health & Human Service under the IRB registration number IRB00003960.

Richard Sugarman
Chair, Ontario Cancer Research Ethics Board