

MEMORANDUM

From: Dale Dewhurst, Chair Health Research Ethics Board of Alberta Cancer Committee
Date: 18 January 2019
Subject: **January 21, 2019 implementation of the 2018 Common Rule**

On January 21, 2019, the 2018 revision of the Federal Policy for the Protection of Human Subjects (the “Common Rule”, found in [45 CFR 46](#)), will be implemented. Research that is sponsored or monitored by the United States Department of Health and Human Services (US DHHS – NIH, NCI, OHRP) is subject to this revised regulation, within the confines of existing Canadian regulations and laws. Sites which submit research to the HREBA Cancer Committee (HREBA-CC) for review will be most impacted by a) the updated requirements for waiver of informed consent, and b) the updated requirements for informed consent.

Below is an overview of the updated requirements; for full details refer directly to the regulations.

A. Updated Requirements for Waiver of Consent

For the HREBA-CC, where a waiver of consent is requested by the site, justification must be provided in Question 1.1 of the ‘Informed Consent Determination’ section of the IRISS application. In addition to meeting all items specified in [TCPS2 Article 3.7A](#), sites must also meet the new Common Rule requirement:

- If the research involves using identifiable private information or identifiable biospecimens, the Principal Investigator must justify that the research could not practicably be carried out without using such information or biospecimens in an identifiable format

If this justification is not provided when applicable, submissions will be returned for correction prior to being sent for review (administrative review stage).

B. Updated Requirements for Informed Consent

The following suggested actions assume that the HREBA templates are being followed, as applicable:

- HREBA Informed Consent Form Template for Participation in a Research Study
- HREBA Informed Consent Form Template for Non-Clinical Trial Research
- HREBA Optional Research Consent Template

At this time, if suggested actions are not taken changes will be requested in the pending approval letter; however, as of April 1st submissions may be returned for correction at the administrative review stage.

New Requirement	Suggested Action
For all research:	
<p>45 CRF 46.116 (a)(5)(i): Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.</p> <p>The Federal Register (v. 82; no. 12; 19Jan2017; page 7214) provides the following guidance (not legally binding) for what would generally encompass key information:</p> <ol style="list-style-type: none"> 1. The fact that consent is being sought for research and that participation is voluntary 2. The purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research 3. The reasonably foreseeable risks or discomforts to the prospective subject 4. The benefits to the prospective subject or to others that may reasonably be expected from the research 5. Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject. 	<p>Much of what these Common Rule changes require in this provision is already covered in the HREBA-CC templates. There is no need to summarize or repeat what is contained in the body of the consent again at the start of the consent form; it will be sufficient to add an introductory paragraph outlining where key information can be found within the consent form.</p>
<p>45 CRF 46.116 (c)(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.</p>	<p>Follow HREBA ICF Template(s), which already address this issue.</p>
<p>45 CRF 46.116 (b)(9) For any research that involves the collection of identifiable private information or biospecimens, one of the following statements is needed:</p>	
<p>(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative; or</p> <p>(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.</p>	<p>Follow HREBA ICF Template(s), which already address this issue.</p>

New Requirement	Suggested Action
<p>45 CRF 46.116 (c) As applicable, for any research that involves biospecimens, the following additional elements of consent need to be included:</p>	
<p>(7) the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit</p>	<p>Follow HREBA ICF Template(s), which already address this issue. All consent form templates indicate that there are no plans to provide payment to participants if research leads to the development of commercial products. Additionally, the main consent form only allows for use of biospecimens for research purposes, while the optional consent form indicates that “no samples or information/ data will be sold”.</p>
<p>(9) whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)</p>	<p>If hereditary genetic testing may/will be done:</p> <ul style="list-style-type: none"> • For Clinical Trials, immediately after template wording “Hereditary genetic testing (to look at whether cancer runs in your family) [may <i>or</i> will] be done on these samples”, clarify the extent/focus of this testing (i.e. will it be limited to the disease or include whole genome sequencing). • For non-clinical trials include the above-specified clinical trial template wording and clarification in the WHAT WILL HAPPEN DURING THIS STUDY? section.