a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

SOP 801

TITLE	**801: Researcher Qualifications and Responsibilities**
SCOPE	All research submitted to the University of British Columbia's Research Ethics Boards
RESPONSIBILITIES	The Vice-President, Research & Innovation, delegated to the Director, Office of Research Ethics, all Research Ethics Board (REB) Chairs and members and all REB Office Personnel and all Researchers
APPROVAL AUTHORITY	The Vice-President, Research & Innovation
EFFECTIVE DATE	May 2018
Supersedes documents dated	May 2011; April 2009; July 2003

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the qualifications and responsibilities of the Researcher who engages in research involving human participants.

2.0 DEFINITIONS

See the Glossary of Terms.

3.0 PROCEDURE

Research involving human participants must be conducted by individuals appropriately qualified by education, training, and experience to assume responsibility for the proper conduct of the research and for the protection of human research participants. The REB must have assurance that the qualifications of new Researchers, for the conduct of research, are appropriate.

Researchers are required to conduct the research in compliance with applicable regulations and guidelines, and to comply with all REB policies.

3.1 Researcher Qualifications

3.1.1 The Researcher must make available, upon request, to the REB his/her current CV and medical license number (if applicable) and his/her relevant training and experience, in sufficient detail for the REB to make an objective judgment regarding the Researcher's qualifications, if necessary[1];

3.1.2 If applicable, the Researcher must be a physician with a specialty qualification in their field and with current professional qualifications entitling them to provide health care under the applicable laws;

3.1.3 The Researcher must have completed appropriate training regarding the requirements of conducting and overseeing research;

3.1.4 The Department Head or his/her designee must approve the application to the REB;

3.1.5 The Department Approver's signature attests that:

- He/she is aware of the proposal and supports its submission for REB review,
- The application is considered to be feasible and appropriate,
- Any internal requirements have been met,
- The Researcher is qualified and has the experience and expertise to conduct this research,
- The Researcher has sufficient space and resources to conduct this research;

3.1.6 Any concerns raised in the REB review of the Researcher's qualifications will be communicated to the Researcher and must be satisfied prior to REB approval of the application.

3.2 Researcher Responsibilities

3.2.1 The Researcher is responsible for complying with the decisions and responsibilities set out by the REB. In addition, it is the Researcher's responsibility to comply with all applicable regulations and ensure that (if applicable)[2]:

- He/she and his/her staff members are appropriately qualified by education, training and experience to assume responsibility for the proper conduct of the research and for protection of human research participants,

- He/she has adequate resources to properly conduct the research and conducts the research following written SOPs,
- All real, potential, or perceived conflicts of interest are declared to the REB at the time of the initial application, and as they arise[3],
- The REB review and approval is obtained before engaging in research involving human participants,
- All necessary documentation is signed by the responsible Researcher, as applicable,
- Informed consent, when required, is obtained from participants in accordance with applicable regulations prior to their enrollment into the research, and using the most current informed consent document(s) approved by the REB (as applicable)[4],
- He/she personally conducts or supervises the described investigation(s),
- The research is conducted in compliance with the approved research and applicable reporting criteria are reported to the REB, including deviations, serious, unexpected adverse events and privacy breaches,
- Any changes in the approved research are not initiated without REB review and approval, except where necessary to eliminate an immediate hazard(s) to the participant(s)[5],
- Premature termination or suspension of the research is reported to the REB,
- Accurate and complete records are maintained according to applicable regulatory requirements,
- Written summaries of the research status are submitted to the REB at least annually, or more frequently if required by the REB, and an application for continuing review is submitted to the REB prior to the expiration of REB approval[6],
- Any other unexpected finding or new research knowledge that could affect the risk/benefit ratio of the research is reported to the REB[7],
- The REB is notified if there is a change in Researcher,
- The REB is notified immediately if his/her medical or dental license or hospital privileges are suspended, restricted or revoked (if applicable) or should his/her qualifications otherwise no longer be appropriate,
- The REB is notified when the research is complete;

Note: When applicable, the obligations of a Researcher holding a Clinical Trial Application (CTA) with Health Canada (i.e., sponsor-Researcher) include both those of a sponsor and those of a Researcher[8];

3.2.2 The Researcher's primary Department/Division within the University is responsible for maintaining current CVs and medical licenses (if appropriate) for each of its Researchers. The Researcher's Department/Division is also responsible for immediately advising the REB should it become aware of any information that would indicate that the qualifications of the Researcher may no longer be appropriate.

4.0 REFERENCES

1. *Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline*, ICH Topic E6, 1997, Section 3.1.3:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6r2-step4-eng.php#a3.1

2. *Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline*, ICH Topic E6, 1997, Section 3.1.2:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6r2-step4-eng.php#a3.1

3. *UBC Policy 97*:
https://universitycounsel.ubc.ca/files/2012/02/policy97.pdf
The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 7.4*:*
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter7-chapitre7/#toc07-1d

4. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans,* Article 3.5*:*
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#toc03-1a

5. *Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline*, ICH Topic E6, 1997, Section 4.5.2:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6r2-step4-eng.php#a4.5
The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.16*:*
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#ch6_en_a6.16

6. *Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline*, ICH Topic E6, 1997, Section 3.1.4:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6r2-step4-eng.php#a3.1
The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 6.14*:*
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#ch6_en_a6.14
The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Article 2.8*:*
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2_en_a2.6

7. *The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans,* Article 6.15*:*
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#ch6_en_a6.15

8. *Health Canada Guidance for Industry, Good Clinical Practice: Consolidated Guideline*, ICH Topic E6, 1997, Section 5.6:
http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6r2-step4-eng.php#a5.6
Government of Canada, Canadian General Standards Board. CAN/CGSB -191.1-2013 Research ethics oversight of biomedical clinical trials (2013), Section 4.2.3.1:
http://publications.gc.ca/collections/collection_2017/ongc-cgsb/P29-191-001-2013-eng.pdf