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| TITLE | 102: Research Requiring HREB Review |
| SCOPE | The activities of the Human Research Ethics Board operating under the direct authority of Trinity Western University |
| RESPONSIBILITIES | The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator |
| APPROVAL AUTHORITY | The Vice-Provost, Research & Graduate Studies |
| EFFECTIVE DATE | November 14, 2019 |
| Supersedes documents dated | N/A |

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe research activities that require Human Research Ethics Board (HREB) review and research activities that do not.

2.0 DEFINITIONS

See Glossary of Terms.

3.0 PROCEDURE

All research involving human participants must be reviewed and approved by an HREB. No intervention or interaction with human participants in research, including recruitment, may begin until an HREB has reviewed and approved the research protocol, consent documents and recruitment materials. This includes all research undertaken by members of the university community including all faculty, visiting researchers, students, and staff irrespective of the source of financial support (if any) and irrespective of the location of the project.

Pilot studies, which assess the feasibility and/or inform the design of a subsequent study intended to address a research question, are also subject to HREB review. Undertaking pilot studies in research is distinct from the initial exploratory phase of research, which may involve contact with individuals or communities, but which does not require HREB review.

3.1 Research that Requires HREB Review

3.1.1 The following requires ethics review and approval by an HREB before the research commences:

- a) Research involving living human participants,
- b) Research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells.

This applies to materials derived from living and deceased individuals.

- c) Research using identifiable private information collected from human participants.
 - Photographs, videos and audio recordings of participants are to be considered identifiable information, whether collected in naturalistic research or any other research setting.
 - d) Research involving the secondary analysis of the following:
 - data collected for non-research purposes;
 - data collected for other purposes, including data collected through research previously approved by the HREB.
 - e) Research involving graphic, written or recorded information, including video or audio recordings, derived from identifiable human participants.
 - f) Research involving culturally sensitive objects, including but not limited to the clothing and personal effects of the dead. Researchers are expected to acquire the requisite knowledge about the beliefs and behaviours of cultural groups with which they are not familiar, in order to ensure that their research is conducted so as to exhibit respect for those cultures.
- 3.2 Research Exempt from HREB Review
- 3.2.1 Research does not require HREB review when it relies exclusively on information that is:
 - a) Publicly available through a mechanism set out by legislation or regulation and that is protected by law; or
 - b) In the public domain and the individuals to whom the information refers have no reasonable expectation of privacy;
 - 3.2.2 HREB review is not required for research involving the observation of people in public places where:
 - a) It does not involve any intervention staged by the Researcher, or direct interaction with the individuals or groups,
 - b) Individuals or groups targeted for observation have no reasonable expectation of privacy, and
 - c) Any dissemination of research results does not allow identification of specific individuals;
 - 3.2.3 HREB review is not required for research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information;
 - 3.2.4 The opinion of the HREB should be sought whenever there is any doubt about the applicability of the guidelines and regulations.
- 3.3 Activities Not Requiring HREB Review

- 3.3.1 Activities outside the scope of research subject to HREB review may still raise ethical issues that would benefit from careful consideration by an individual or a body capable of providing some independent guidance, other than an HREB;
- 3.3.2 Quality assurance and quality improvement studies, program evaluation activities, performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this SOP, and do not fall within the scope of HREB review;
- 3.3.3 Creative practice activities, in and of themselves, do not require HREB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to HREB review.

4.0 REFERENCES

See references.

5.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|-----------------|-----------------------|---------------------------|
| SOP 102 | November 14, 2019 | Original version |
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