



Northern Ontario
School of Medicine
École de médecine
du Nord de l'Ontario
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Access to PGME Learners for the Purpose of Research				Class: B	
Approved By:	Associate Dean, PGME				
Approval Date:	2021 04 08	Effective Date:	2021 04 08	Review Date:	2024 04 08
Responsible Portfolio/Unit/Committee:	PGME				
Responsible Officer(s):	Associate Dean, PGME & HS				

1.0 Purpose

These guidelines describe the principles and procedures by which PGME Learners should be invited to take part in approved research activities as participants within these scholarly activities (research subject).

2.0 Scope

These guidelines apply to all PGME Learners and all scholars wishing to access the broader PGME Learner group as part of an approved research project or approved scholarly activity. Consideration and decisions related to discipline specific requests will take place at the program level. These guidelines do not apply to Program Evaluation activities carried out by NOSM which fall within the definition of such activities described in Article 2.5 of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (2018) (TCPS) and NOSM generated feedback surveys (eg. Resident Exit Survey, Annual Wellness Survey, Strategic Plan Input). In addition, these guidelines do not apply to industry-based research projects seeking to determine the opinion of PGME Learners about individual products or product lines for the purpose of marketing. Such projects are not supported by the PGME office.

3.0 Definitions

- 3.1 Research is defined as per the Article 2.1 of the TCPS being “an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation”.
- 3.2 Approved Research is defined as research activities that have obtained Research Ethics Board approval at their host academic institution.
- 3.3 Research Ethics Board (REB) is an institutional body capable of reviewing the

ethical acceptability of research which acts in accordance with Article 6 of the TCPS.

4.0 Principles

- 4.1 The Associate Dean Postgraduate Medical Education and Health Sciences (AD PGME & HS) must ensure that:
- (i) PGME Learners acting in the role of research study participants must be performed in accordance with the TCPS
 - (ii) the study represent an acceptable safety risk to any members of the NOSM community
 - (iii) the study does not impede the delivery of a PGME Learner's PGME training
 - (iv) participation in research has no effect, in any way whatsoever, on a PGME PGME Learner's academic standing or participation in PGME training
 - (v) Participation by postgraduate medical education learners in research is voluntary. A postgraduate medical education learner declining or electing not to participate in research has no effect, in any way whatsoever, on a PGME resident's academic standing or participation in PGME training.

5.0 Procedures

- 5.1 Any person wishing to recruit PGME & HS PGME Learners as research participants must apply in writing to the Associate Dean, PGME & HS via postgrad@nosm.ca . The request must include:
- (i) a copy of the written approval of the Research Ethics Board (REB) having jurisdiction over the research study e.g. from the researcher's university or hospital REB
 - (ii) a copy of the research protocol approved by the REB including any associated documentation e.g. Participant Information Sheets, which formed part of the protocol reviewed by the REB
 - (iii) a copy of any other institutional approvals required such as biosafety approval
 - (iv) a short (< 150 words) summary of the research study
 - (v) disclosure of the source of any in-kind or actual funding for the research project
 - (vi) any actual or perceived conflict-of-interest
 - (vii) a detailed summary of which PGME Learners are being asked to participate along with timelines associated to this participation
- 5.2 On receipt of this information the Associate Dean, PGME & HS (or delegate) may ask for additional information, as required in order to grant or deny the request. For example, if in the opinion of the Associate Dean, PGME & HS (or delegate) specific approvals are required (e.g. biosafety, which are not included in the application, the Associate Dean, PGME may request that such approvals be provided).
- 5.3 The Associate Dean, PGME & HS will decide to grant the researcher(s) access to PGME PGME Learners for the purpose of research if the following conditions have been met:
- (i) the researcher(s) have obtained the necessary (as determined by the Associate Dean, PGME & HS) institutional approvals e.g. REB approval, biosafety approval
 - (ii) any actual or perceived conflict-of-interest (as determined by the Associate Dean, PGME &

- HS or other regulatory bodies) will be clearly stated in the invitation to participate sent to PGME students
- (iii) the research study is not, in the opinion of the Associate Dean, PGME & HS intended to promote the use of a commercial product
 - (iv) the planned research will not hinder the delivery of PGME Learners PGME training
 - (v) the planned research will not affect PGME Learners academic standing or participation in PGME training
 - (vi) the research protocol has measures in place that protect the anonymity and privacy of PGME PGME Learners, other members of the NOSM community, and the medical school as an institution
- 5.4 The Associate Dean, PGME & HS will be at liberty to consult with other persons who will be asked to use professional discretion when discussing details of the intended research.
- 5.5 The Associate Dean, PGME & HS (or delegate) will communicate their decision to the researcher(s) within 20 business days of receipt of the application stating whether the application is granted or not granted. No other information will be provided. On the request of the researcher(s) the Associate Dean, PGME will provide a copy of this letter to regulatory bodies such as a REB.
- 5.6 On request of the researcher(s) the Associate Dean, PGME & HS will consider a request for an agreement-in-principle to the proposed research based on preliminary submissions if this is required to obtain, for example, REB approval. Such agreement in principle does not constitute a binding agreement to grant access to PGME PGME Learners to the researcher. Actual access will require the submission of a full application which includes all regulatory approvals as described in paragraph 5.1. The Associate Dean, PGME & HS will complete a request for an agreement-in-principle within 20 business days and will communicate their decision in writing to the researcher(s).
- 5.7 The decision of the Associate Dean, PGME & HS will be final and binding.
- 5.8 If the application is granted, the Associate Dean, PGME & HS will request that a short introductory invitational text be supplied by the researcher(s) which will be included in a communication to the PGME Learners which will be limited to inclusion in The 'Script. The introductory text will include details of the research study and how to participate.
- 5.9 The researcher(s) will never be granted direct access to PGME Learners (providing email addresses or access to group email list) for the purpose of inviting PGME Learners to be a participant in research studies.
- 5.10 The PGME will not be responsible for research participation including compliance with deadlines or follow ups, or receiving back completed surveys.
- 5.11 Please be aware that any electronic survey used to collect data must meet the Personal Information International Disclosure Protection Act. (Survey Monkey is not permitted).

