

## Internal Medicine Program Guidelines for Research Activities Involving Resident Participation

### Background

Each year, there are many requests for Internal Medicine residents to participate in studies – some being done by residents or faculty within the Program, some coming from sources that are peripherally aligned with the Program, and other requests from sources that are external to the Department of Medicine and/or University of Toronto.

The Program leadership recognizes the importance of supporting and encouraging academic scholarship, yet has a duty to ensure that due diligence is done prior to Internal Medicine residents being asked to participate in research activities.

### Defining Research

- If a project is being completed for the primary purpose of publication, REB approval is required;
- If there is any potential for risk to participants, patients or staff, REB approval is generally required; and
- If in doubt, contacting the local REB for advice is strongly recommended.

Research, for this purpose, is defined as the purposeful collection of data from and/or about residents that falls outside the scope of direct patient care, where the intent is to utilize the data for scholarly activities including academic conferences and publications. A ‘research study’ includes but is not limited to surveys, clinical research activities, quality improvement interventions, and studies involving the educational components within and outside of the Internal Medicine Program.

The Tri-Council Policy Statement states "Quality assurance and quality improvement studies, program evaluation activities, and 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 Policy, and do not fall within the scope of REB review."

Tri-Council URL: <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

### Process

Prior to residents being asked to participate in any research activity, investigators are required to complete the **Request for Permission to Conduct Research Involving Residents as Participants form**, which details the nature of the project. The form must be accompanied by:

- Full research proposal and protocol
- Final copies of all materials to be used for recruitment (emails, posters, etc.)
- Consent forms
- Ethics approval certificate (if applicable)

- IMPORTANT: If you have submitted this proposal concurrent with a request for ethics approval, final approval by the Internal Medicine program will be delayed until the certificate is provided

Once received, all complete submissions will be reviewed by a subcommittee of the Internal Medicine program. The proposed research must:

- Appear to be relevant and important to the resident body (preference may be given to projects that are more relevant to the Internal Medicine program);
- Have the potential to benefit the educational process;
- Are feasible and meet the temporal constraints of the clinical and educational commitments of the Internal Medicine Program;
- Have appropriate methodology;
- Demonstrate a potential for significant benefit to patient care;
- Have ethics approval, when required, and follow principles outlined by local Ethics Review Boards
  - Protects confidentiality and privacy
  - Allows for voluntary participation/avoids coercion
  - Result in minimal time burden to resident research participants
- Do not impose undue hardship on residents or encroach on clinical duties

Once the proposed research is approved, researchers will be provided with a set distribution list including all PGY1-4 Internal Medicine residents\*, with the following instructions:

- The researcher must use their submitted and approved recruitment email
- The email must start with the subject line “Opportunity to participate in research:”
- The emails must be sent out at the agreed dates and a set number of times (usually three)
- The resident emails must be blind-copied
- The program director must be blind-copied on all recruitment emails
- The researcher must not share the email listing and must destroy the email listing immediately after the final recruitment email is sent. This excludes the email addresses of residents who agree to participate in the study and who need to be contacted in future as part of the study protocol (this email listing must be destroyed at the end of the study).

\*The program cannot provide further granularity in terms of a specific subset of Internal Medicine residents; therefore, the target audience will need to be clearly stated in the recruitment email. Note that Internal Medicine residents have the option to opt out of receiving recruitment emails; these residents will not be included in the distribution list.

### Reminders

Time will not be provided as part of the Academic Half Day (AHD) to approach residents for the purposes of study participation.

If a curricular initiative is embedded into the AHD and the educational leads of that initiative wish to study the merits of the educational endeavour, this will be reviewed by the program leadership and a decision will be brought forward on a case by case basis.