

## **What is research?**

Research is defined in TCPS2 (2022) as ‘an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation’. A link to TCPS2 (2022) online follows:

[https://ethics.gc.ca/eng/policy-politique\\_tcps2-eptc2\\_2022.html](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html)

## **When is NYGH REB approval needed?**

Before a research study involving **human participants** and **any NYGH resources** may commence, either the NYGH REB or the REB delegated by NYGH through Clinical Trials Ontario must grant approval. This REB is called the **NYGH REB of Record**. Per TCPS2, REB approval is required before any aspect of a study may commence, even if the involvement of human participants is deferred to a later phase. Please appreciate that the resources category is broad and includes NYGH personnel, for example.

Consequently, an NYGH employee on the team for a study taking place entirely at another hospital needs to obtain REB approval from the NYGH REB of Record. NYGH REB applications are through our online submission system, called ARIEL (<https://apply-ariel.nygh.on.ca>).

Research studies requiring REB review are those that involve **human participants** (including information from living human participants and human biological materials for both living and deceased individuals) **at any point** during a particular research study. Please see Article 2.1 in TCPS2 (2022) for additional details regarding what constitutes a human participant. Our Standard Operating Procedures (which can be found on ARIEL (<https://apply-ariel.nygh.on.ca>) under ‘Help’ and then ‘Templates’) and other regulations such as PHIPA may also be useful in terms of what constitutes research with human participants.

## **Are there any exceptions?**

There are a few rare exceptions to this rule requiring REB approval for research, as per TCPS2 (2022), which can be found in TCPS2 (2022) Articles 2.2 to 2.4. Other non-research activities that are similar to research, include those listed in Articles 2.5 and 2.6. Please consult the NYGH REB office if a determination and documentation is needed regarding these rare exemptions.

The NYGH REB issues determinations (as per Article 2.5 of TCPS2 2022, referenced, above) regarding when a project constitutes research versus when it is solely a quality improvement project in the hospital. These QI determinations may be useful for future use in documenting that REB approval was not required.

## **What constitutes valid REB approval for NYGH involvement in an offsite study?**

Approval by the NYGH REB of Record (see above) is required for any recruitment, screening, and/or enrollment of human participants in research ‘under the auspices of NYGH’, even when the research is primarily being conducted at another site and that site has obtained REB approval. If the study uses any NYGH resources, including staff as co-investigators, etc., approval by the NYGH REB of Record is still required. Approval by an REB selected by Clinical Trials Ontario through the CTO Stream application process is acceptable by NYGH only if the application recognizes NYGH as a site or centre and identifies the NYGH personnel on the application or approval letter.

## **How do I apply for NYGH REB approval?**

Through our online submission system, ARIEL (<https://apply-ariel.nygh.on.ca>). Start with the institutional authorization for research from in ARIEL, which goes to the Office of Research and Innovation, then complete the Initial Application for a new study. If you're going to go through a CTO Stream REB, you still must start with an institutional authorization application in ARIEL. Then, you'll apply as a centre in CTO Stream with a local investigator named and forward a copy of the REB approval to the Office of Research and Innovation after it has been obtained. If your work might be a QI project as opposed to research, you can submit just the QI Checklist in ARIEL first, with a project overview, for a determination from the REB.

**Who do I ask if I have questions?**

You can contact the REB office with questions anytime at [REB@nygh.on.ca](mailto:REB@nygh.on.ca). Our REB team is here to help!

**Are there additional requirements for approvals required for research at NYGH?**

Yes. Institutional authorization is required for all research studies conducted at NYGH and is the first step in our online submission system, ARIEL. Other departmental and/or resource approvals, permissions, contracts, and requirements for finance and/or HR may apply, depending on the research and/or QI project. Please contact the Office of Research and Innovation at [research.innovation@nygh.on.ca](mailto:research.innovation@nygh.on.ca) with any questions. Further, depending on the study, Health Canada applications for clinical trials of drugs or devices may be involved, with additional requirements for international studies. The sponsor of the study will know about these requirements.