COVID-19 Pandemic Research Conduct & Requirements
Frequently Asked Questions

RESEARCH CONDUCT

1. **What are examples of essential onsite research activity involving patients, families, healthcare workers, and other hospital staff?**
   - *This could include COVID-19 related studies, or oncology clinical trial protocols where treatments are an important part of care.*
   - *This could also include large studies where substantial investment in cost and time has been made and are near completion.*
   - *Such studies will be reviewed on a case by case basis by Dr. Robert Reid to determine continuation of the protocol or if any change is appropriate at this time.*

2. **Does this apply to ALL research activities?**
   - *No – this does not apply to activities which do not touch our onsite patients, hospital clinical staff, or operations at this time. Study teams can continue with the written preparation of new grants, analysis of existing data, writing up of study results for publication, reporting or presentation.*

3. **What should I do if I change my protocol to align with this guidance?**
   - *Please see the guidance available in theTHP REB's communication on REB Review of Research During the COVID-19 Pandemic. Changes in protocol must be communicated to the REB.*

4. **Is THP still doing research? (or is everything at a stand-still)**
   - *Yes, research is still permitted and ongoing at THP. Under the current IBH Research Directive, all non-essential onsite research activity involving patients, families, healthcare workers, and other hospital staff are suspended until end of day Monday April 6th, 2020. On April 6, 2020 the directive will be revisited and a decision will be made whether to extend the directive as is or considering expanding permissions for non-COVID-19 related research studies.*

RESEARCH ETHICS

5. **Where can I locate information about REB review of research during the COVID-19 pandemic?**
   - *For information relating to REB Review of Research during the COVID-19 Pandemic, please visit the THP REB website: http://trilliumhealthpartners.ca/researchandinnovation/Pages/Research-Ethics-Board.aspx*

6. **What is the anticipated turnaround time for review of my study or REB submission?**
   - *At the current time the THP REB is operating on alternate review procedures due to the COVID-19 pandemic. New research relating to COVID-19 will be reviewed in an expedited manner once administrative*

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approval (THP COVID-19 Command Centre) is obtained. New research unrelated to COVID-19 will not be reviewed until further notice. For submissions relating to ongoing research, please review the Review of Ongoing Research section in the THP REB's communication on REB Review of Research During the COVID-19 Pandemic.

7. **My study is due for renewal during the COVID-19 situation. Should I submit to the REB, and what happens if my approval lapses?**
    - *The REB is requesting that our researchers submit for annual renewal. Our Board will do our best to ensure requests for annual renewal are reviewed. However, if the REB is unable to review or approve the renewal request ahead of the expiry date, when the approval is issued it will be effective retroactively to the expiry date so that there is no lapse period. If a renewal is submitted after the renewal date, the approval will be effective retroactively to the date of submission.*

8. **Is there a requirement for us to notify the REB if we are holding accrual at this time (per the IBH directive on halting nonessential, on-site research activities)? Can this be noted in the next renewal that the study was on hold due to the COVID 19 pandemic and institutional requirement, and when enrolment resumed?**
    - *Given the research directive that was issued by the Institute for Better Health (e.g. suspension of all non-essential on site research), it is reasonable to inform the REB of the hold on accrual at the next annual renewal. You do not need to submit an amendment to notify the REB of a hold on accrual.*

9. **Is there a contact for the REB during the COVID-19 situation?**
    - *Yes, please contact THPREB@thp.ca. Our REB Coordinator is available to help answer or direct questions and concerns you may have.*

10. **What happens with my research submissions that are/were under review by the REB at the time the IBH COVID-19 Pandemic research directive was issued?**
    - *All research studies that were actively in review at the time of the IBH COVID-19 Pandemic research directive will be dealt with individually taking into consideration the nature of the activity under review and ensuring alignment with the existing IBH research Directive*

11. **Are all REBs operating under the same model/restrictions as the THP REB?**
    - *The THP REBs approach to review of research during the COVID-19 pandemic is consistent with approach being used by other Toronto Academic Health Sciences Network (TAHSN) member hospitals and their respective REBs.*

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GENERAL RESEARCH ADMINISTRATION

12. Will all COVID-19 related research be approved?

- *All administrative approvals for COVID-19 related research are made through the THP Command centre. An internal vetting process for new COVID-19 related research has been put in place to facilitate administrative approvals. Please submit all new COVID-19 related research requests to Delilah Ofosu-Barko, Corporate Manager Research Operations & Project Management at delilah.ofosu-barko@thp.ca .*
- *For research ethics review of COVID-19 related research, THP has approved the use of the Clinical Trials Ontario Streamlined Ethics Review System for multi-centre clinical research studies, for information on how to submit your COVID-19 related multi-centre study for ethical review through CTO, please access the CTO website for specific details on CTO submission requirements through THP please review the THP SRERS form.*
- *For research ethics review of COVID-19 related research studies that do not meet the CTO requirements for review through CTO the THP REB will review and provide ethical oversight over these studies. For information relating to THP REB Review of Research during the COVID-19 Pandemic, please visit the THP REB website: http://trilliumhealthpartners.ca/researchandinnovation/Pages/Research-Ethics-Board.aspx*

13. Will research contracts continued to be negotiated?

- *Yes, our regular research administrative support activities will continue (including research agreement review and negotiation), however the timeline to completion may be longer than normal as we navigate executing our daily tasks remotely as a result of the current COVID-19 situation.*

14. Can new external (non-THP) research personnel get credentialed to support research activity at THP?

- *External research personnel supporting COVID-19 related research studies will be credentialed and cleared through existing processes. Under the current IBH Research Directive, all non-essential onsite research activity involving patients, families, healthcare workers, and other hospital staff are suspended until end of day Monday April 6th, 2020. On April 6, 2020 the directive will be revisited and a decision will be made whether to extend the directive as is or considering expanding permissions for non-COVID-19 related research studies, including credentialing of new external personnel supporting non-COVID-19 related research studies.*

15. Can we get remote access for our existing research associates (external non-THP personnel)?

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- *Under the current IBH Research Directive remote access will be granted, on an approval basis, solely for COVID-19 related research studies, activities required for continuity of care, activities required for patient safety until April 6, 2020 (end date for existing research directive). On April 6, 2020 the directive will be revisited and a decision will be made whether to extend the directive as is or considering expanding remote access request permissions for non-COVID-19 related research studies.*

- *If a researcher is requesting remote access for research purposes prior to April 6, 2020 they will need to ensure that the research activity:*
  - *Is required for continuity of care;*
  - *Is required for patient safety; or*
  - *Is tied to research on COVID-19*

16. Is CIHR going to change its requirements in light of the pandemic?

- *CIHR is currently examining how the COVID-19 pandemic is affecting various policies and operations. Guidance related to expectations for funding and the conduct of research will be released. CIHR is working with their Tri-Agency partners and will release an update to the research community soon. Any questions should be directed to the CIHR contact centre.*