Health Translation Queensland

Accelerating discovery into practice

Research Passport User Guide

Contents

Introduction

The Health Translation Queensland (HTQ) Research Passport Agreement is a collaborative agreement between all HTQ Partners. The agreement aims to streamline the approval process for researchers, saving them time and legal costs. This document provides some general information about clinical research and how researchers can use the HTQ Research Passport Agreement.

After reading this document, if you need further information please contact us by calling +61 7 3346 4637 or emailing research@healthtranslationqld.org.au.

Background Information

Clinical research

Clinical research refers to research carried out on humans, whether they are healthy or sick. This research helps to improve our knowledge of diseases, develop diagnostic methods and new treatments or medical devices for better patient care.

Types of clinical research

There are two main types of studies:

1. Observational
2. Interventional/Clinical Trials

1. In **observational studies** the researcher observes individuals without manipulation or intervention. Cohort studies and case control studies are two types of observational studies. A cohort study involves any group of people who are linked in some way (e.g. age). Researchers compare a common event in a select period. A case control study is one where people with an existing health problem are compared with a similar group without this problem (control group).

2. **Interventional studies** (also called clinical trials) involve testing an intervention, such as a new medicine, with a group of two or more study participants. Randomised controlled trials are considered the most rigorous intervention, where we are looking for the cause and effect of the intervention. Study participants are randomly allocated to one of two groups; the experimental group and the control group. Researchers follow the groups to assess the effectiveness of the intervention compared with the standard or placebo treatment.

Clinical trials to develop new interventions are conducted in phases. For more information, visit the Australian Clinical Trials webpage.

Clinical research guidelines

In Australia, research involving humans must comply with the principles set out in the following guidelines:

- National Statement on Ethical Conduct in Human Research (2007) – updated 2018
- Australian Code for the Responsible Conduct in Research (2018)
- State and territory guidelines

Clinical trials of medicines and devices also must comply with ICH Guideline for Good Clinical Practice. Medical devices must also comply with ISO14155:2020.

For further information about clinical trials, visit Australian clinical trials webpage and resources webpage.

Ethics

Failure to conduct your research in an ethical manor can invalidate your findings. Human Research Ethics Committees (HRECs) review research applications to ensure the research is treating people ethically. This means treating them with respect, dignity and care.

HTQ is committed to the highest standards of research ethics and integrity.

Most of our Partners have HRECs that review research proposals involving humans to ensure that they meet ethical standards and guidelines. The National Health and Medical Research Council (NHMRC) certifies HRECs for specific types of research, ranging from clinical trials to paediatric research. For a current list of HTQ Partners and the type of research they are certified for, please contact us.

Within the HTQ partnership, a number of HRECs are NHMRC-certified for the National Mutual Acceptance Scheme (NMA). This scheme supports a single scientific and ethical review for multi-centre human research. This means that one HREC can review a research proposal for multiple sites. However, there may be some exceptions, e.g. for research at private hospitals. It is often the case that research being carried out in a hospital will not accept an ethics review from a university. Therefore, if you are working with a university, it is advisable to obtain the hospital's ethics approval first and

then submit your proposal to the university. Often universities have an ethics ratification process, where an application need not have a full ethics review.

HRECs meet on set dates throughout the year to consider research proposals. For further information Queensland Health's website has a summary of their HRECs and meeting dates and an HTQ has created an interactive list of all Queensland HREC application and meeting dates.

Research Governance

Research governance is the process we use to ensure a project meets the highest standards. It includes the safety and quality of research, financial, legal and regulatory matters, and ethical approval.

All HTQ partners are accountable for the research conducted under their auspices and have research governance offices responsible for the oversight of research projects.

If you want to conduct a research project at a HTQ partner organisation, we recommend you contact their research ethics and governance office. If you're not sure where to get started, contact us.

HRECs and Research Governance Office details for HTQ partners

Queensland Department of Health

Children's Health Queensland HHS

Gold Coast Health

Mater Research

Metro North Health

Metro South Health

West Moreton HHS (single-site only)

Griffith University*

The University of Queensland*

Queensland University of Technology*

QIMR Berghofer Medical Research Institute

CSIRO

*Please note Griffith University, the University of Queensland and Queensland University of Technology are registered with (not certified by) the NHMRC. As the NHMRC-certified HRECs do not

accept the NMA, it might be more beneficial to have your research approved by an NHMRC-certified HREC and ratified by your registered HREC. Contact your HREC in the first instance to seek advice.

Training

There is a range of training available for researchers, governance officers and other clinical trial proponents. A list of training options is included in the Australian Government's Clinical Trial Toolkit. There is also comprehensive training at the Australian Clinical Trials Education Centre.

Good Clinical Practice (GCP) Training

Depending on the organisation you work in good clinical practice training for principal investigators involved in clinical research is mandatory. Check with your research governance office.

The Australian Clinical Trials Education Centre also provides a number of ethics and governance modules and GCP training free of charge.

The HTQ Passport Agreement

Purpose

The HTQ Research Passport Agreement is a collaborative agreement between all HTQ Partners. The agreement aims to streamline the approval process for researchers, saving them time and legal costs.

Background

Health Translation Queensland, formerly known as Brisbane Diamantina Health Partners (BDHP), formed in 2014 and was accredited as an Advance Health Research Translation Centre (AHRTC) by the NHMRC in 2017. The aim of the partnership is to integrate research within the health system through collaborations between clinicians, educators, researchers and academics.

During 2014-2016, HTQ held workshops and open forums that aimed to identify essential ways to make the business of translational research easier. HTQ identified that one of the highest priorities was how to streamline research governance regulatory processes and reduce delays in contractual management.

HTQ established a Human Research Ethics and Governance Working Group to review the processes and timelines for ethics and governance approvals within the hospital, university and research institute partners and to develop an agreed framework. The outcome was the HTQ Research Passport Agreement, version 1, which researchers at all HTQ partner organisations can use.

HTQ launched the Agreement in early 2017. The Agreement consists of an umbrella agreement and an operating schedule. With agreed legal terms and schedule items, the Agreement reduces the number of legal reviews required for clinical collaborative research and speeds up the approval process.

By March 2019, a HTQ survey showed that the Agreement had been used over 280 times. A follow up evaluation of the Research Passport Agreement was carried out in 2022.

Current release

The HTQ Research Passport agreement has been updated a number of times to address proposed changes by the partners on issues such as intellectual property, student participation and third-party involvement. The current version of the HTQ Research Passport agreement is version 3.2. A version log can be found on our website which indicates the changes between versions.

Future release

The HTQ Research Passport Agreement will require modifications and updates from time to time to ensure it continues to serve its purpose for the Partners. HTQ is always interested in your feedback and ideas for improvements and implements a working group to support discussion and agreement on alterations to the Research Passport Agreement. If you have feedback email this to research@healthtranslationqld.org.au.

Guidelines for using the HTQ Research Passport Agreement

- The HTQ Research Passport Agreement is suitable for investigator initiated collaborative research projects only
- Do not use for
    - Clinical trial or interventional studies
    - Unapproved therapeutic goods / medical device trials
    - Establishing biobanks
    - Non-research, quality assurance activities

HTQ Research Passport FAQs

What is the HTQ Research Passport Agreement?

It is a collaborative agreement designed to streamline research collaboration between HTQ Partners through the use of agreed legal terms. It consists of an umbrella agreement and an operating schedule.

What is the HTQ Research Passport Agreement used for?

Researchers can use this agreement for:

- Research that is deemed low risk, including observational and other non-interventional studies that have negligible commercial value.
- Research that does not require other standard agreements, such as the Medicines Australia suite of agreements, NHMRC or GO8.
- Simple, straightforward research where there is no pre-existing or background intellectual property
- Projects involving biobanks, mouse models, or research that is of potential commercial value should consider whether the Passport is appropriate.

The HTQ Research Passport should not be used for:

- Research studies that include an international institution (due to the laws of Australia/Queensland)
- Clinical trials (use the Medicines Australia template) & NHMRC/ARC funded projects
- Commercial-in-confidence projects
- A postgraduate standalone project as it may involve terms of a scholarship agreement.

How does it work?

The agreement has standard legal terms covering intellectual property ownership, preservation of confidential information, and other rules for the responsible and compliant conduct of a research project. The schedule includes the specific project details.

If a project can be conducted on the standard legal terms, then no legal review of the agreement is required before the project can start. Legal consultation for special conditions will be included in the project schedule.

Who can use this agreement?

Researchers at all HTQ Partner organisations can use this agreement at their sites and with other participating sites.

What is the current version in use?

Version 3.2 is the current version of the HTQ Research Passport Agreement in use.

Who are the HTQ Partners?

Visit our website to find a list of the HTQ partners.

Can other collaborators who are not HTQ partners use this agreement?

HTQ Partners can add third parties, such as other Queensland Health HHS or private facilities, as Research Collaborators using the third-party agreement document. Third parties do not have to sign up to the terms in the umbrella agreement.

Another agreement which can be used is the National Multi-Jurisdictional Multi-Party non Clinical Trial Collaborative Research Agreement.

Is it compulsory to use the Research Passport Agreement for clinical research between HTQ partners?

No, but we encourage you to check if you can use it. It may save time and legal costs, which means you get started on your research sooner.

What are the advantages of using this agreement?

By using this agreement, you can avoid delays in research agreements being executed, speeding up your project's start-up time. All HTQ Partners have agreed to the use of this agreement and it has been approved by their legal teams.

Is a variation to the Research Passport Agreement allowed?

Yes. If a variation is required, please liaise with the legal teams at your organisation and the HTQ Partner organisation as early as possible. The special conditions section can be used for a variation.

Who can I contact for more information?

For enquiries about the Research Passport Agreement, please get in touch with your organisation's contact person or contact us.

Testimonials

"It is really great to see the continuing evolution of the HTQ Research Passport, serving to facilitate ease of collaboration across Brisbane. With more than 60 investigators over all HTQ sites, the Passport has been an enormous advantage in developing our collaborative research agreement for CPAC (Centre for Personalised Analysis of Cancers), which is a HTQ MRFF RART project."

Rik Thompson, Associate Director, Institute of Health and Biomedical Innovation (IHBI) @ Translational Research Institute (TRI) & Professor in Breast Cancer Research**,** School of Biomedical Sciences, Queensland University of Technology (QUT)

"By providing an existing, approved framework, the HTQ Research Passport Agreement reduces the lead time to implement new collaborations, and in turn, this stimulates more collaborations. QIMR Berghofer Principal Investigators find the associated schedules easy to use and reference when they're discussing potential collaborations with their counterparts in other organisations."

Mathias Kroll, General Manager Business Development, QIMR Berghofer Medical Research Institute.