

brisbane diamantina
health partners



Research Passport User Guide

Metro North
Hospital and Health Service

Metro South
Health

 **mater**

Children's Health Queensland
Hospital and Health Service



 **QIMR Berghofer**
Medical Research Institute

TRI
partnering for better health

West Moreton Health



Contents

Introduction.....	3
Background Information	4
Clinical research.....	4
Types of clinical research.....	4
Clinical research guidelines	4
Ethics.....	5
Research Governance.....	6
HRECs and Research Governance Office details for BDHP partners.....	6
Training.....	6
Good Clinical Practice (GCP) Training	6
The BDHP Passport Agreement.....	6
Purpose.....	7
Background.....	7
Current release.....	7
Future release.....	7
Passport FAQs.....	8



Introduction

The BDHP Research Passport Agreement is a collaborative agreement between all BDHP 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 BDHP Research Passport Agreement.

After reading this document, if you need further information please contact us by calling +61 7 3443 8059 or emailing info@diamantina.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 [ISO14155:2011](#).

For further information about clinical trials, visit the National Health and Medical Research Council's [webpage](#) and resources [webpage](#).

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 BDHP 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 BDHP 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 BDHP partners

[Metro North HHS](#)

[Metro South HHS](#)

[Children's Health Queensland HHS](#)

[West Moreton HHS](#) (single-site only)

[QIMR Berghofer Medical Research Institute](#)

[Mater Research](#)

[Queensland Department of Health](#)

[The University of Queensland*](#)

[Queensland University of Technology*](#)

**Please note 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, we advise you seek their HREC's approval first (i.e. before UQ or QUT).*

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](#).

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.



“By providing an existing, approved framework, the BDHP 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.

The BDHP Passport Agreement

Purpose

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

Background

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

BDHP 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 BDHP Research Passport Agreement, version 1, which researchers at all BDHP partner organisations can use.

BDHP 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 BDHP survey showed that the Agreement had been used over 280 times.

Current release

In mid-2018, in consultation with users, BDHP reviewed the BDHP Research Passport agreement and proposed changes to address intellectual property, student participation and third-party involvement. As it is a collaborative agreement, all Partners signed off on version 2 in April 2020. Version 2 of the BDHP Research Passport agreement supersedes version 1.

Future release

The BDHP Research Passport Agreement will require modifications and updates from time to time to ensure it continues to serve its purpose for the Partners. BDHP 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.

Passport FAQs

<p>What is the BDHP Research Passport Agreement?</p>	<p>It is a collaborative agreement designed to streamline research collaboration between BDHP Partners through the use of agreed legal terms. It consists of an umbrella agreement and an operating schedule.</p>
<p>What is the BDHP Research Passport Agreement used for?</p>	<p>Researchers can use this agreement for:</p> <ul style="list-style-type: none"> • 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.
<p>The BDHP Research Passport should not be used for:</p>	<ul style="list-style-type: none"> • 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.
<p>How does it work?</p>	<p>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.</p> <p>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.</p>
<p>Who can use this agreement?</p>	<p>Researchers at all BDHP Partner organisations can use this agreement at their sites and with other participating sites, including third-party collaborators.</p>

What is the current version in use?	Version 2 is the current version of the BDHP Research Passport Agreement in use.
Who are the BDHP Partners?	Visit our website to find a list of the BDHP partners.
Can other collaborators who are not BDHP partners use this agreement?	BDHP 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.
Is it compulsory to use the Research Passport Agreement for clinical research between BDHP 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 BDHP Partners have agreed to the use of this agreement and it has been approved by their lawyers.
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 BDHP Partner organisation as early as possible.
I am using Forensic Scientific Services (FFS) and Pathology Queensland for material transfer can I use the BDHP Research Passport?	Advice when using FFS and Pathology Queensland is not to use the BDHP Research Passport but use existing templates.
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 .

“It is really great to see the continuing evolution of the BDHP Research Passport, serving to facilitate ease of collaboration across Brisbane. With more than 60 investigators over all BDHP 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 BDHP 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)