brisbane diamantina health partners

Research Passport User Guide

THE AUSTRALIAN E-HEALTH RESEARCH CENTRE

mater

Metro North Health

Metro South Health

Queensland Children's Hospital

QUT the university for the real world

The University Of Queensland AUSTRALIA CREATE CHANGE

QIMR Berghofer Medical Research Institute

TRI partnering for better health

West Moreton Health

Queensland Government

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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 3346 5524 or emailing info@bdhp.com.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** (can also be 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 control.

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

Some studies will only involve collecting samples and clinical data, the BDHP Research Passport agreement can be used for these studies.

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.

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.

BDHP 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 BDHP Partners and the type of research they are certified for, please contact us.

Within the BDHP 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, for example research at private hospitals. It is often the case that research being conducted in a hospital will not accept a HREC review from a non-certified HREC such as a university HREC. 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 HREC for ratification.

HRECs meet on set dates throughout the year to consider research proposals. You can find a list of Queensland Health HREC information and meeting dates here.

Research Governance

Research governance refers to the processes used by institutions to ensure that they are accountable for the research conducted under their auspices. To be properly governed, research must be conducted according to established ethical principles, guidelines for responsible research conduct, relevant legislation and regulations and institutional policy. Research governance is also about credentialing and training of researchers and managing institutional risk.

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 are not sure where to get started, contact us.

HRECs and Research Governance Office details for BDHP partners

Children's Health Queensland HHS
CSIRO Social Science
QIMR Berghofer Medical Research Institute
Mater Research
Metro South HHS
Queensland University of Technology*
Queensland Health Forensic Scientific Services*
Royal Brisbane & Women's Hospital
The Prince Charles Hospital
The University of Queensland (HREC A & B)*
West Moreton HHS (single-site only)

**Please note the University of Queensland, Queensland University of Technology and Forensic Scientific Services 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, and research administrative staff - 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 GCP training for researchers and research staff involved in clinical research is mandatory. Check with your research governance office.

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 Advisory 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. As each partners' legal team have already reviewed the clauses and signed off on the current version, it is only the schedule that need be signed off by governance departments. The BDHP Research Passport agreement will only need to be legally reviewed if any of the standard terms have been varied. To vary the terms the special conditions section is used in the Schedule.

"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.

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.

In June 2020 CSIRO e-Health joined the BDHP Partnership and on 4 December 2020 a Deed of Accession was fully executed to include CSIRO on the agreement and version 2.1 was launched.

The Research Passport agreement is intended to be used for research collaborations between two or more BDHP partners. It is to be used for low risk projects. Where more complex collaborations are proposed, and the Research Passport agreement cannot be utilised it is advised to use alternative agreements.

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

What is the BDHP Research Passport Agreement?	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.
What research is the Research Passport suitable for?	• Collaborative research projects (Note: If a project arises from an NHMRC funding agreement the Go8 multi-institutional agreement is preferred) • Including but not limited to research which is low risk to the organisation • Facilitate transfer of data or biological materials • Research requiring Human Research Ethics (HREC) and Site-Specific Assessment (SSA) approval • Research with commercial potential or studies with background intellectual property (IP). *Use the special conditions to vary the level of detail as necessary.* • Projects involving Forensic Scientific Services (FSS) and Pathology Queensland (PQ) • Accessing material from a biobank • Student research without a scholarship agreement • Aboriginal and Torres Strait Islander (ATSI) research. *This type of research is considered high-risk by HRECs, but not in terms of governance*
The research passport should be used with caution	• Student research which involves terms of a scholarship agreement • Studies including international institutions *(due to laws of Australia and Queensland)*
The BDHP Research Passport should not be used for:	• Clinical trial research / interventional trials that assigns participants to one or more health-related interventions to evaluate effects of health outcomes (as defined by the World Health Organisation) - use Medicine's Australia suite of clinical trial agreements • Establishing Biobanks • Non-research quality assurance projects

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 BDHP Partner organisations can use this agreement at their sites and with other participating sites, including third-party collaborators.
What is the current version in use?	Version 2.1 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 clauses 1 and 2 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. This means only the project schedule needs to be approved by governance and there is no need for a legal review when none of the terms are varied.
Is a variation to the Research Passport Agreement allowed?	Yes. If a variation is required, please liaise with the research governance teams at your organisation as early as possible. A variation is to be made in the project schedule's special conditions.

I am using Forensic Scientific Services (FSS) and Pathology Queensland for material transfer can I use the BDHP Research Passport?	Yes. Forensic Scientific Services and Pathology Queensland encourage the use of the BDHP Research Passport agreement.
Who can I contact for more information?	For enquiries about the Research Passport Agreement, 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)