



## ETHICS COMMITTEE CERTIFICATE OF APPROVAL

*This is to certify that*

**Project Number:** 94074 (Local Reference: Project 128/23)

**Project Title:** Integrative approaches for Optimizing Recognition, Management and Education of concussion at the community sports level (INFORMED-1)

**Coordinating Principal Investigator:** Professor Biswadev Mitra

*was considered under the Victorian Streamlined Ethical Review Process (SERP) by the Ethics Committee on 23-Mar-2023, meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and was **APPROVED** on 11-May-2023.*

---

It is the Coordinating Principal Investigator's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

***The Coordinating Principal Investigator is required to notify the Secretary of the Ethics Committee, via amendment or progress report, of***

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Coordinating Principal Investigator to continue in that role, or any other change in research personnel involved in the project;
- Any expiry of the insurance coverage provided with respect to sponsored clinical trials and proof of re-insurance;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

***Additionally, the Coordinating Principal Investigator is required to submit***

- A Progress Report on the anniversary of approval and on completion of the project.

The Ethics Committee may conduct an audit at any time.

**All research subject to the Alfred Hospital Ethics Committee review must be conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007).**

**The Alfred Hospital Ethics Committee is a properly constituted Human Research Ethics Committee in accordance with the National Statement on Ethical Conduct in Human Research (2007).**

### **SPECIAL CONDITIONS**

All research projects approved by the Alfred Hospital Ethics Committee are subject to, and must be carried out in compliance with, the most recent applicable COVID-19 government and relevant institution's restrictions.

## APPROVED DOCUMENTS

Documents reviewed and approved at the meeting were:

Document	Version	Date
Protocol	5.0	16-Mar-2023
Participant Information Sheet & Consent Form	3.1	4-Apr-2023
INFORMEDTBI Website	2	18-Apr-2023
Flyer	2.0	16-Mar-2023
GP Letter Template	-	1-Mar-2023
Data Collection Sheets	-	20-Feb-2023

Additional documents considered:

Document	Version	Date
Letter of Support from Victorian Amateur Football Association (VAFA)	-	1-Feb-2023
Researcher CVs	-	-
Researcher GCPs	-	-

## APPROVED SITES

Approval is given for this research project to be conducted at the following sites and campuses:

- School of Public Health and Preventative Medicine – Monash University (Coordinating Principal Investigator: Prof Biswadev Mitra)
- Alfred Health (Site Principal Investigator: Prof Biswadev Mitra)

*The Alfred Hospital Ethics Committee has approved the study but does not take responsibility for research governance processes at the participating sites. It is the responsibility of each participating site to create and implement research governance practices to adequately authorise, monitor and oversee the conduct of the study at their site.*

### Site-Specific Assessment (SSA)

SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

The completed Site-Specific Assessment Form and a copy of this ethics approval letter must be submitted to the Research Governance Officer for authorisation by the Chief Executive or delegate. This applies to each site participating in the research.

The HREC wishes you and your colleagues every success in your research.

**SIGNED:**

**Chair, Ethics Committee (or delegate)**

***Please quote project number and title in all correspondence***