Macquarie MINDS: Monitoring of Injury and psychosocial health outcomes, career trajectories and continuing educatioN, liveD experiences and Social connectedness

DATA ACCESS POLICY

1.   Purpose

1.1   Researchers at Macquarie University, students supervised by staff at Macquarie University, and members of the MQ-MINDS Steering Committee can apply to conduct research projects or sub-studies using data from the MQ-MINDS Cohort Study, provided the requirements of this policy are met.

1.2   The purpose of this policy is to describe the procedure and conditions for gaining access to data from the MQ-MINDS Cohort Study to conduct a research project or sub-study.

2.   Principles

2.1   This Policy is based on the following principles:

- The MQ-MINDS Cohort Study is to be used for the purposes of furthering the public good in relation to health and wellbeing.
- The MQ-MINDS Cohort Study is a collaborative resource, and data elements cannot be reserved by researchers for exclusive use.
- The MQ-MINDS Cohort Study is to be used for projects which are scientifically, methodologically, and ethically sound.
- The privacy of the MQ-MINDS Cohort Study participants is to be protected, only de-identified data will be provided.
- The MQ-MINDS Cohort Study participants are not to be subjected to any undue burden as a result of their participation in research projects or sub-studies.
- Approval to conduct a research project using data from the MQ-MINDS Cohort Study is to be granted through a transparent process which demonstrates accountability and equity.
- Research projects or sub-studies using data from the MQ-MINDS Cohort Study should be conducted in a timely fashion.

3.   Applications to access data

3.1   All applications to access data from the MQ-MINDS Cohort Study will be assessed in accordance with this policy.

3.2   The MQ-MINDS Steering Committee will appoint a Data Access Sub-Committee comprising three members, including at least two MQ-MINDS chief investigators. The Data Access Sub-Committee will be responsible for:

- reviewing and assess all applications for access to MQ-MINDS data; and
- making recommendations to the MQ-MINDS Steering Committee.

3.3   In the first instance, the Data Access Sub-Committee will undertake a short review of all applications to ensure that the access sought under the application is feasible and would be able to be provided if the application is approved. Where the Data Access Sub-Committee has questions about the feasibility of the proposed project, they will work with the applicant to address concerns regarding feasibility.

3.4   Where the application is feasible, and is for a project that is to be forwarded to a peer-reviewed funding agency, the Data Access Sub-Committee may provide a letter to the applicant (Stage 1

Endorsement) stating that, subject to the subsequent approval process, there are no feasibility obstacles to access being provided in relation to the application. The letter of Stage 1 Endorsement will note that this does not constitute approval to conduct the research project. Approval to conduct the research project will be subject to the approval process set out below (Stage 2 Approval).

3.5   In considering approval for access to data, the Data Access Sub-Committee will consider the following:

a) <u>Skills and capacity</u>. The Data Access Sub-Committee will assess whether the applicants have appropriate skills and capacity to conduct the proposed research.

b) <u>Scientific validity</u>. The Data Access Sub-Committee will assess whether the aim of proposed research is achievable and that the methods are appropriate.

c) <u>Exhaustion of the MQ-MINDS Cohort Study resource</u>. A principle of the MQ-MINDS Cohort Study is that access to the data is to be granted through a transparent process which demonstrates accountability and equity. Some projects using MQ-MINDS Cohort Study participants have the potential to limit or prevent the conduct of other projects that would involve the same participant group. The Data Access Sub-Committee will assess the potential for such exhaustion in light of other projects that may already be accessing the participants in question. The Data Access Sub-Committee may recommend against approval, or make approval conditional on changes to the design of the project, where the potential for exhaustion of the study resource is considered unreasonable.

d) <u>Burden on the MQ-MINDS Cohort Study participants</u>. A principle of the MQ-MINDS Cohort Study is that participants will not be subject to undue burden as a result of their participation in the study. The Data Access Sub-Committee will consider the burden that may be placed on participants as a result of the application and may recommend against approval where the burden placed on the participants is considered unreasonable, either by the MQ-MINDS Cohort Study itself, or in light of other sub-studies accessing the same participants.

e) <u>Public good considerations</u>. A principle of the MQ-MINDS Cohort Study is that the study is to be used for the public good. The Data Access Sub-Committee will consider the rationale of the application and how it contributes to the public good.

3.6   Following the considerations stated above, the Data Access Sub-Committee will make a final decision regarding the approval or non-approval of the application. The Data Access Sub-Committee will inform the MQ-MINDS Steering Committee of their decision as to whether Stage 2 Approval is granted.

4.   Ethical approval

4.1   All approvals will be subject to the applicant obtaining ethical approval, where this is required under the National Statement on Ethical Conduct in Human Research. Evidence of this approval must be provided before data are released to researchers. Please note the MQ-MINDS Cohort Study requires that certain wording must be included in sub-study materials, and this should be obtained by the applicant prior to seeking ethical approval.

5.   Data confidentiality agreement

5.1   A Data Confidentiality Agreement will not be issued until:

a) a Data Access Application Form has been completed and approved; and

b) evidence of ethical approval from the Macquarie University Human Ethics Review Committee has been forwarded to the Data Access Sub-Committee.

5.2   Data will not be transferred to Authorised Users until after a signed Confidentiality Agreement has been returned to Data Access Sub-Committee.

5.3   The Data Access Sub-Committee will be responsible for maintaining a register of all Authorised Users who have received data. This register will include:

- contact details of the Authorised Users;
- approved Data Access Application Forms; and
- signed Confidentiality Agreements.

6. Data access charges

6.1 There are no charges or fees associated with access to data from the MQ-MINDS Cohort Study.

6.2 All approvals will be subject to the applicant having the requisite funding to conduct the project.

7. Disposal of data

7.1 All MQ-MINDS data records will be securely stored for five years from the last publication, after which time all data will be destroyed/deleted.

8. Timeliness of research project or sub-study

8.1 Authorised Users are responsible for conducting research project or sub-studies using MQ-MINDS data in a timely manner.

8.2 Authorised Users are responsible for submitting research project or sub-study progress reports biannually.

9. Withdrawal of data access

9.1 Misuse or failure to observe the Confidentiality Agreement will result in the complete and immediate withdrawal of all MQ-MINDS data, information, and approvals.

9.2 Unsatisfactory progress and failure to complete research projects or sub-studies using MQ-MINDS data in a timely manner will result in withdrawal of all MQ-MINDS data, information, and approvals.

10. Review of this policy

10.1 This policy will be reviewed every two years from the date of approval, or more frequently if appropriate.

10.2 List of revisions to date:

Date	Description of revision(s)

Policy applies to	All persons working with MQ-MINDS data
Approval authority	MQ-MINDS Steering Committee
Governing authority	MQ-MINDS Data Access Sub-Committee
Approval date	13/12/2018
Effective date	13/12/2018
Date of last revision	13/12/2018
Date of next policy review	13/12/2020