

MS Stem Governance Committee – Terms of Reference

1. Title

The Multiple Sclerosis (MS) Stem governance committee (GC).

2. Purpose

Menzies exists to perform internationally significant medical research leading to healthier, longer and better lives for Tasmanians. The Multiple Sclerosis (MS) Research Flagship carries out research to reduce the impact of MS on individuals and the community.

MS Stem is a biobank of induced pluripotent stem cells (iPSCs) generated from people with and without MS. The biobank provides national and international researchers with access to fully characterised iPSC lines on a cost-recovery basis. MS Stem provides researchers with a suitable human, cellular model of MS for advancing research into the biological causes of MS and identification of potential new treatments. MS Stem GC will act as the custodian of MS Stem, on behalf of the Menzies and MS Research Flagship.

3. Scope

The MS Stem GC reports to the MS Research Flagship Steering Committee and Menzies Advisory Board.

MS Stem GC is responsible for:

- 3.1 Ensuring the MS Stem biobank repository is operating in accordance with current human research ethics (HREC) approvals, laboratory standard operating procedures (SOP's) and/or clinic safe work procedures (SWP's) and prevailing Tasmanian and/or Australian regulatory requirements [Appendix 1].
- 3.2 Granting or denying requests to source iPSCs from the biobank after reviewing the application form, confirming that the research is being carried out by researchers in a not-for-profit organisation and evaluating the recipient's ethical approval provided.
- 3.3 The GC will make a determination about the status of the recipient's ethic committee by considering registration with a national ethics certification scheme, e.g. National Health Medical Research Council in Australia, or similar in other countries. Alternatively, they will assess the REC against the World Health Organisations agreed international standards [3].
- 3.4 Maintaining a register of applicants and recipients and making annual contact with any research group that receives cells under the conditions stipulated in the '*Outgoing Materials Transfer Agreement (MTA) MSStem Cells.doc*'.
- 3.5 Evaluating the annual status reports received from recipients, and adherence to the terms of the MTA.

- 3.6 Conduct PubMed reviews of recipient researchers to ensure that MS Stem iPSCs and their derivatives are being appropriately referenced in publications as specified in the MTA.
- 3.7 Monitoring, evaluating and updating the ongoing risk profile of MS Stem.
- 3.8 Monitoring, evaluating and updating the ongoing financial viability of the resource.
- 3.9 Making recommendations to the MS Research Flagship steering committee and Menzies advisory board with regards to ongoing and future development of MS Stem.

4. Membership

The membership of the MS Stem GC will endeavour to maintain fifty percent independent membership.

The GC comprises:

- 4.1. MS Stem Director (Chair)
- 4.2. MS Research Flagship Program Manager
- 4.3. MS Stem scientist*
- 4.4. Human stem cell ethicist (independent)*
- 4.5. Biobanking expert (independent) *
- 4.6. MS consumer/s (independent)*

* To be appointed by the Director for a fixed term of up to 3 years.

The Director may invite other staff or experts to meetings for specific agenda items.

5. Meetings

- 5.1 The GC will be supported by the Menzies MS Research Flagship Program Manager. The Program Manager will be responsible for preparing and distributing agendas, minutes of meetings, reports and other relevant and related correspondence, following consultation with the MS Stem Director. Meeting documents will be distributed one to two weeks in advance.
- 5.2 In making decisions or recommendations, the GC should aim for a consensus view. Where this is not achievable, the GC Chair will have the casting vote.
- 5.3 The GC will meet according to an annual schedule negotiated by members at the initial and subsequent meetings. Additional meetings will be called on an as needed basis when iPSC requests are received.
- 5.4 Meeting quorum is a minimum of 75% of members present in person, by phone or videoconference. In the absence of the Chair, the Chair will either nominate a deputy chair or request the meeting be re-scheduled.

6. Conflict of Interest

Members of the GC must declare all perceived or actual conflicts at the commencement of the meeting or during the course of the meeting should one arise. The Chair will manage conflicts of interest as required.

7. Term, Amendment, Modification or Variation

These Terms of Reference are effective from September 2023 and continue until terminated by the MS Stem Director in agreement with the Menzies Director.

These Terms of Reference may be amended, varied, or modified in writing after consultation and agreement between MS Stem Director and the Menzies Director.

Appendix 1: References

1. The National Statement on Ethical Conduct in Human Research 2018 (Australia)
<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>
2. National Health and Medical Research Council, Human Research Ethics Committees
<https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Committee/HREC-Human-Research-Ethics-Committees-registered-with-NHMRC-LIST.pdf>
3. World Health Organisation (WHO), Standard and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
<https://www.who.int/publications/i/item/9789241502948>
4. The Human Tissue Act, 1985 (Australia)
<https://www.legislation.tas.gov.au/view/html/inforce/current/act-1985-118#GS7@EN>
5. Customs (Prohibited Exports) Regulations 1958 (Australia)
<https://www.legislation.gov.au/Series/F1996B03403>
<https://www.tga.gov.au/resources/resource/guidance/export-human-substances>
6. The Privacy Act 1988 (Australia)
<https://www.legislation.gov.au/Details/C2022C00361>
7. Personal Information Protection Act 2004 (Tasmania)
<https://www.legislation.tas.gov.au/view/html/inforce/current/act-2004-046>
8. The general data protection regulation (GDPR) (European)
<https://gdpr-info.eu/>
9. The future of EU privacy regulations on biobanks and iPSC research
https://www.eurostemcell.org/sites/default/files/documents/did-you-know/1206_13_FM-RME-2017-0068%20-%20Michael%20Morrison_FINAL.pdf