RESEARCH DATA GOVERNANCE AND SHARING FRAMEWORK ("FRAMEWORK")

1. Introduction

1.1 The sharing of research data promotes open scientific inquiry that expedites the translation of research findings into knowledge and applications, to improve human health and healthcare. It promotes novel research that may not have been envisioned by the original researchers, allows synergies from multiple data sources, and enables the sharing of unique data that cannot be easily replicated (such as studies on unique populations).

1.2 The timely sharing of research data allows other researchers to leverage on past research findings and facilitates collaboration to make research more robust.

1.3 Unless otherwise defined in this Framework or indicated to the contrary, all terms used herein shall have the meanings as ascribed to them in the NMRC Research Grant Terms and Conditions available at https://www.nmrc.gov.sg/policy-guideline/research-grant-terms-conditions, as may be revised from time to time.

2. Applicability

2.1 This Framework shall apply to Contracts which fulfil the following criteria:

(a) the Contract is for the Funding of the Research listed in **Annex A**, where the Grantor is providing Funding of at least S$250,000[1] of direct cost; and

(b) the Application is submitted to the Grantor on or after the Effective Date.

2.2 Notwithstanding Clause 2.1 above, this Framework, in consultation and agreement with the Lead Principal Investigator, shall apply to Contracts where the Application is submitted to the Grantor before the Effective Date ("**Prior Contracts**"), upon notification by the Grantor in writing from time to time. Notwithstanding any other terms in those Prior Contracts, any notice given under those Prior Contracts in relation to the applicability of this Framework shall be deemed to have been duly given if delivered via electronic mail.

2.3 In this Framework, the "Effective Date" means 1 January 2024.

3. Research Data to be Shared

3.1 Subject to Clause 3.3 below, the Host Institution and the Lead Principal Investigator shall ensure that all Final Research Data and its associated metadata (including but not limited to a list of all data variables collected in the Research) are Shared under the Framework.

3.2 The Host Institution shall ensure that all applicable legislation that prescribes requirements in relation to data (including the Personal Data Protection Act 2012 and the Human Biomedical Research Act 2015) are complied with, when sharing the Final Research Data.

3.3 Clause 3.1 above shall not apply where the Host Institution and the Lead Principal Investigator have obtained approval from the Grantor to Share only a limited scope of the Final Research Data, in which case, the Host Institution and the Lead Principal Investigator shall Share that limited scope of Final Research Data under the Framework.

[1] The Grantor may be the sole party providing Funding for the Research, or it may be co-funding the Research with other public/non-public organisations.

3.4 The Host Institution and Lead Principal Investigator are required to submit a data sharing plan ("**Data Sharing Plan**") with the Application, for the Grantor's approval, in the format required by the Grantor. The Host Institution and the Lead Principal Investigator shall inform the Grantor of any change to the Data Sharing Plan that was submitted together with their Application, in the Final Report.

3.5 The Data Sharing Plan will be reviewed and assessed separately from the other components of the Application, by the Grantor's review panel or equivalent body, in accordance with the relevant guidelines in place from time to time. Upon the review and assessment, the Grantor's review panel or equivalent body may request for the Data Sharing Plan to be revised. If so, the Lead Principal Investigator and the Host Institution shall ensure that the Data Sharing Plan is revised accordingly and submitted to the Grantor, within the timeframe indicated by the Grantor.

3.6 For the purposes of this Framework: -

"**Final Research Data**" means, in relation to the Research, recorded factual material commonly accepted in the scientific community as necessary to document and support research findings, regardless of whether the data is used to support publications. Final Research Data that are clinical in nature shall include the human subject's basic demographics (including but not limited to the human subject's age, gender and race), disease and condition (i.e. the diagnosis), unless the information is not collected in the Research. Final Research Data shall not include laboratory notebooks, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects such as gels or laboratory specimens.

4. Timeframe for Final Research Data to be Shared

4.1 Subject to Clause 4.2 below, the Host Institution and the Lead Principal Investigator shall ensure that Final Research Data are Shared by the dates set out below (each, a "**Deadline**"): -

(a) research data not included in a publication: no later than 24 months from the last date of the Term; or

(b) research data included in a publication: no later than 12 months from the date of that publication.

4.2 The Host Institution may submit a written request at least three (3) months before each Deadline to the Grantor to extend the Deadline, for the Grantor's approval. The written request shall include comprehensive and cogent reasons as to why the Deadline should be extended. To avoid doubt, each Deadline in Clause 4.1 shall continue to apply in the absence of any approval by the Grantor to extend that Deadline.

4.3 For the purposes of this Framework: -

"**Share**" means to submit to the Research Data Repository in accordance with and for the purposes set out in this Framework (and "Shared" shall be construed accordingly).

5. Research that Involves Human Subjects

5.1 For Research involving human subjects, the Institutions, the relevant IRBs, and the Lead Principal Investigator shall ensure that: -

(a) the rights and confidentiality of the human subjects (including their data) are sufficiently protected;

(b) the Final Research Data is Shared only in the following forms and subject to the conditions stipulated below: -

(i) a robustly anonymised form free of identifiers that would link to, or lead to deductive disclosure of the identity of the human subject. The anonymisation standards used shall be equivalent to or more robust than the government recognised anonymisation standards (for example, the Framework on Anonymisation Standards for the Public Healthcare Sector or the Personal Data Protection Commission anonymisation guidelines); and

(ii) appropriate consent from the human subjects for the following shall be obtained: -

(A) to use and disclose the Final Research Data for the purposes of wider or future research to maximise the value of the Final Research Data, with adequate safeguards for the human subjects;

(B) to contact the human subject should the Research and/or future research show that clinical intervention is needed in respect of the human subject; and

(C) to collect the human subject's clinical data from national-level databases, such as the National Electronic Health Record (NEHR). There shall be in place an anonymisation framework, data governance frameworks and protocols, and consent processes to ensure the proper handling of that clinical data.

5.2 Where the Research involves human subjects, the Lead Principal Investigator and the Host Institution shall ensure that the Data Sharing Plan is reviewed and endorsed by the relevant IRB before any work requiring the IRB's approval may commence. The Lead Principal Investigator and the Host Institution shall ensure that the Data Sharing Plan is consistent with the scope of consent of the human subjects from whom the Final Research Data will be obtained, and that there is adequate protection of the human subjects.

6. Storage of Final Research Data

6.1 The Host Institution and the Lead Principal Investigator agree to have a copy of the anonymised Final Research Data stored in the Research Data Repository for a minimum duration of ten (10) years from each Deadline, subject to the Research Data Repository's archival protocol.

6.2 For the purposes of this Framework, "**Research Data Repository**" means the data repository provided by the Grantor and developed by Synapxe Pte. Ltd.

7. Governance of and Access to Final Research Data stored in the Research Data Repository

7.1 Where the Lead Principal Investigator and/or any Institutions become aware that any Final Research Data needs to be removed from the Research Data Repository for any reason (for example, if any consent for the use of Final Research Data is withdrawn), the Lead Principal Investigator or the Host Institution (as the case may be) shall inform the Grantor as soon as possible.

7.2 The Lead Principal Investigator and the Host Institution acknowledge that data requestor and his/her institution may request to access and use the Final Research Data stored in the Research

Data Repository by submitting a duly completed data request form ("**Data Request Form**"), in the form required by the Grantor and endorsed by that data requestor's institution, to the Grantor. The Data Request Form will be reviewed and approved by the Data Contributing Institution. The Grantor will inform the data requestor and his/her institution of the outcome of their data request and whether they are granted permission to access and use the Final Research Data.

7.3 The Lead Principal Investigator and the Host Institution acknowledge that the Data Contributing Institution may, in deciding whether to grant a request for access and use of Final Research Data, take into account (1) whether the proposed use of the Final Research Data in the Research Data Repository (as stated in the Data Request Form) is scientifically and ethically appropriate, and (2) whether the data request conforms to the Framework and is consistent with any limitations on the use of the Final Research Data in the Research Data Repository (including legal restrictions). For the avoidance of doubt, the above shall not in any way curtail the discretion of the Data Contributing Institution as to whether to grant the data requestor's request.

7.4 The Lead Principal Investigator and the Host Institution acknowledge that a data requestor may appeal against a decision by the Data Contributing Institution to reject the data requestor's request to access the Final Research Data stored in the Research Data Repository. Any such appeal shall be considered by the NMRC Data Access Oversight Committee in consultation with the Data Contributing Institution. The decision of the NMRC Data Access Oversight Committee shall be final.

7.5 The Lead Principal Investigator and the Host Institution agree that upon approval, data requestors and their institutions may access and use the Final Research Data in the Research Data Repository, in accordance with any terms and conditions set out by the Grantor and the Terms of Use of Final Research Data in the Research Data Depository.

7.6 For the purposes of this Framework: -

"**Data Contributing Institution**" means a Host Institution that has contributed data to the Research Data Repository in accordance with the Framework.

Annex A

RESEARCH WHICH THIS FRAMEWORK APPLIES TO

All Research funded under the following:

1. Clinician Scientist – Individual Research Grant
2. Clinical Trial Grant
3. National Innovation Challenge on Active and Confident Ageing
4. Open Fund – Large Collaborative Grant
5. Open Fund – Individual Research Grant
6. Open Fund – Young Individual Research Grant
7. Population Health Research Grant
8. Singapore Translational Research Investigator Award
9. Clinician Scientist Award
10. Clinician Innovator Award
11. HPHSR* Clinician Scientist Award
12. Transition Award

**HPHSR: Health Promotion, Preventive Health, Population Health and Health Services Research*