

SWIMS DATA SHARING AND COLLABORATIVE RESEARCH

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Overview

The SWIMS team encourages collaborations and/or the sharing of Data collected by the SWIMS Project with well-matched high quality researchers, to ensure that the scientific potential of the SWIMS Project is maximised, provided that:

- The privacy of individuals is protected and any subsequent data-sharing agreement **prohibits** any attempt to (a) identify study participants from the released Data or otherwise breach confidentiality, (b) make unapproved contact with study participants.
- Ethical and legal consents where appropriate are obtained before the release of Data or any collaboration can proceed.
- The privilege of the SWIMS team to analyse the Data is not infringed by the proposal. Unnecessary duplication and competition is to be avoided.
- Data sharing must meet rigorous data security standards.

Release of the Data to the Applicant is dependent on the research plan being approved by the SWIMS Data-Sharing Committee; all appropriate ethical and legal approvals being obtained by the Applicant; a Collaboration/Data-Sharing Agreement being in place between the SWIMS team and the academic institution that employs the researcher; and SWIMS team resources being available.

To submit a data-sharing or collaborative request follow the guidance in this document and email a completed application form to swimsproject@plymouth.ac.uk with the heading DATA REQUEST or COLLABORATION REQUEST. Application forms can be downloaded from the SWIMS website:

<http://research.psmd.plymouth.ac.uk/cnrg/swims.php>

Alternatively, for an informal discussion of the suitability of an application, email swimsproject@plymouth.ac.uk with the heading DATA REQUEST QUERY and provide your name, Institution, Department, contact details and a brief summary of your research interests.

The SWIMS Team can also be contacted at:

SWIMS PROJECT
N16, ITTC Building 1
Plymouth Science Park
Derriford
PL6 8BX
01752 315246

Research Policy and Guidance Notes

Definitions

Agreement	Document signed by the Applicant and the SWIMS C.I setting out the terms and conditions for the sharing of Data
Applicant	Person applying for permission to collaborate / share data
Applicant's Representative	Person listed in a Data-Sharing Agreement by the Applicant as a Representative or as a person supervising, processing and/or having access to the shared data
C.I.	Chief Investigator of the SWIMS Project
CIS	Clinically Isolated Syndrome
Data	Data provided by the SWIMS Team or collected during collaboration with the SWIMS Team
Data Provider	The SWIMS Project
Derived Variables SWIMS	Data resulting from analysis of SWIMS Data or Data collected as a result of collaboration with the Team
MS	Multiple Sclerosis
MS Society	Multiple Sclerosis Society of Great Britain and Northern Ireland
PU	University of Plymouth (operating as Plymouth University)
PUPSMD	Plymouth University Peninsula Schools of Medicine and Dentistry
SWIMS	South West Impact of Multiple Sclerosis project

The SWIMS Project

Introduction

The South West Impact of Multiple Sclerosis (SWIMS) project is a longitudinal study following around 1600 people with MS or Clinically Isolated Syndrome (CIS) in Devon and Cornwall, providing new information about how MS changes over time.

The project began in Plymouth in 2004, with funding from the Peninsula Medical School Foundation and since 2008 the MS Society has kindly funded the continuation of SWIMS. Our major priority has always been recruitment and retention, in order to build up a unique longitudinal dataset to enable us to address our main research aims:

- 1) To understand the impact of MS from the perspective of people affected by MS
- 2) To find better ways of measuring outcomes in MS over time
- 3) To develop better methods to predict more accurately the future clinical course of the disease in any given person
- 4) To improve ways of measuring the cost-effectiveness of treatments for MS

Participants with MS complete questionnaire booklets twice per year. Participants with CIS complete similar but slightly shorter questionnaires once per year. Details of both MS and CIS questionnaires can be found in Tables A and B in Appendix 1. Patients with CIS who are subsequently diagnosed with MS are switched to the six-monthly MS data collection schedule.

In addition to the patient-completed questionnaires, the EDSS is assessed for some participants attending neurology outpatient clinics at the Plymouth neurology centres, but no specific clinic attendance is organised to evaluate clinical information.

Management

Professor John Zajicek is the Chief Investigator (C.I.) of the study. The SWIMS Project Team, who are responsible for the day-to-day running of the project, are based at the Plymouth University Peninsula Schools of Medicine and Dentistry (PUPSMD) in Plymouth, Devon. Plymouth University owns the Data contributed by participants for the SWIMS project.

Management of applications to collaborate or share Data.

The SWIMS Coordinator (SC) is the point of contact for Applicants and the SWIMS Data-Sharing Committee Members alike. The SC is responsible for tracking all applications and relevant documents; notifying Applicants about progress and decisions about their application; organising Data-Sharing Committee meetings; collating relevant documents; and reporting data-sharing activity to the SWIMS Project Steering Committee.

The SC will acknowledge receipt of an application and inform the Applicant if there are any obvious omissions. The SC will forward completed applications to the Data Sharing Committee, as a batch, once per month.

The SWIMS Data Sharing Committee (DSC)

The decision to approve or reject an application is made by the SWIMS Data-Sharing Committee. The Committee is comprised of:

- SWIMS C.I. (Chair)
- Statistician
- Independent academic Neurologist
- SWIMS Data Manager
- Patient representative

Review Process

DSC Members review applications independently and send their response to SC within three weeks of receipt where possible. SC collates Members' responses and sends a summary of responses to all DSC Members.

The DSC Members will each consider the Applicant's: affiliation; rationale for using SWIMS Data; hypothesis, aims, objectives; requirements, i.e. whether the SWIMS dataset contains the data requested; data analysis plan; data storage, security and management; funding status; and ethical approval status.

Where the DSC unanimously approves the application, the Applicant is notified by SC. A SWIMS Data-Sharing or Collaboration Agreement will then need to be completed by the Applicant and the SWIMS C.I.

Where the DSC unanimously rejects the application, the Applicant is notified of the decision and the reasons for rejection. If the DSC suggests amendment(s) to the application, the Applicant is notified accordingly.

Where there is not a unanimous outcome (including conflicting amendments suggestions) the Applicant is notified, and the DSC will discuss the application further, as soon as is practicable, to reach a consensus on the application.

Should the DSC be unable to reach a decision about an application, the application will be referred to the SWIMS Project Steering Committee, who will consider the application and the decisions of the DSC Members at the next scheduled meeting. The SWIMS Project Steering Committee will be required to recommend a course of action to the SWIMS C.I. regarding the application.

The processing of applications by the SWIMS Team and SWIMS DSC is summarised in Appendix 2.

Implementation of collaboration/data-sharing

Before proceeding with collaboration or data-sharing: a Data-Sharing or Collaboration Agreement must be signed by the SWIMS C.I. and the Applicant; all agreements and necessary permits or approvals MUST be obtained and evidence provided to the SC (if not previously provided given during the review process). The SWIMS team will provide an estimate of how long it will take to supply Data or set up SWIMS contribution to any collaboration (but will not undertake any such work until all agreements are in place).

Once all agreements and approvals/permits are in place, the SWIMS Team will extract, clean and dispatch the requested Data. The SWIMS Data Manager will liaise with the Applicant (or Applicant's Representatives) to ensure the Data are provided in a timely way and suitable format within the constraints of resources available to the SWIMS Team. Where appropriate, metadata documentation will be provided.

Applicants must acknowledge receipt of the Data and advise the SC of any problems as soon as possible.

Data Sharing and Collaboration Policy – Restrictions and Conditions

1. Research Priorities

The SWIMS Team encourages the sharing of Data with *bone fide* researchers to maximize the benefit of the study to those with MS provided:

Studies add to the understanding of MS and its impact upon the health and lives of those with the disease, without infringing the SWIMS Team's privilege to analyse the Data (see 1.1).

Requests to explore the SWIMS Data set must have clear aims and hypotheses; data mining requests are unlikely to be approved.

1.1 *The privilege of the SWIMS team to analyse the Data should not be infringed*

The SWIMS C.I. reserves the right not to release Data where the Applicant's proposed analyses would infringe current work or planned work to be undertaken by the SWIMS Team.

Where the Applicant's proposed work duplicates or overlaps with the SWIMS C.I.'s current or planned work then the C.I. will consider a collaborative project.

A version-controlled document detailing the SWIMS C.I.'s current and planned research using the SWIMS data is available to Applicants and lodged with the SWIMS Data Sharing Committee to assess duplication or overlapping proposals.

2 Availability of the Data

The type of available Data is listed in Appendix 1. Data will become available for analysis one year after collection to allow time for the provision of a clean dataset. Within the SWIMS dataset there are variable levels of missing data and consequently the list in Appendix 1 cannot be used to accurately infer the amount of data available. The SWIMS team will advise Applicants of the number of participants completing particular instruments when processing a request although there may still be missing data at the item level.

Applicants should complete the checklist section of the application form (see sample in Appendix 3) to indicate which sets/subsets of the Data they wish to use. Applicants should also specify the following if appropriate:

- whether participants with MS, CIS or both are of interest,
- any demographic specifications e.g. age group, gender,
- the time period over which Data is requested, and
- any other restrictions e.g. all participants' ability to walk must score <6 on PDDS Instrument.

2.1. *Anonymised Data.*

Only anonymised Data will be available for data-sharing. Any requests for pseudonymous Data that would include details from which a study participant could potentially be identified will be referred by the SWIMS Data-Sharing Committee to the local NHS Trust Information Governance Manager, but are unlikely to be approved.

2.2 *Data Sharing / Collaboration Agreements*

The SWIMS C.I. and the Applicant shall ensure that a Data-Sharing or Collaboration Agreement is signed by both parties before Data are released or any collaborative activity commences.

3 Ethical and Legal Approvals

The Data, Derived Variables or parts thereof, may only be used for research that has appropriate ethical and legal approval. It is the Applicant's responsibility to ensure all approvals are obtained and no Data will be released until copies of such agreements have been seen by the SC.

4 Commercial purposes

In general, neither the Data, derived Data, nor any parts thereof, may be used for any commercial purpose or any purpose that is subject to consulting or licensing obligations to third parties unless those intentions were clearly and expressly stated in the original application and approved by the SWIMS Data-Sharing Committee.

5 Confidentiality

The Applicant shall ensure that: measures are in place to protect the confidentiality of study participants and the security of Data; and that practice complies with all legal and regulatory requirements and relevant best practice.

5.1. Representatives

The Applicant will provide a full list of all those individuals who will act as “Representatives” on behalf of the Applicant and all those persons who will be supervising, processing and/or have access to the shared Data.

The Applicant will ensure that they and their Representatives to whom the Data are disclosed are aware of their responsibilities in connection with the use of the shared Data.

The Applicant or their Representatives shall not use or divulge or communicate to any person or organisation any Data obtained from Plymouth University which they shall treat as private and confidential and safeguard accordingly.

5.2. Anonymity of study participants.

The Applicant will not use any Data provided as a means to re-identify individuals by associating the aforementioned Data with information from an alternative source. No attempt will be made to contact study participants

No direct or indirect access to SWIMS participants will be allowed.

6 Non-exclusive use of data.

The Applicant has non-exclusive use of the Data and may only use the Data for the research as detailed in the successful application.

7 Changes to research protocol.

Neither changes to the analyses of the Data, nor any additional processing beyond those agreed may be performed without the express written permission of the SWIMS C.I. Any changes or additional agreements must be submitted as a new application for consideration by the SWIMS Data-Sharing Committee.

8 Transfer of Data or Derived variables (in full or part)

The Applicant will not further transfer the Data, Derived Variables or any part thereof, to third parties without the third party having already entered into a separate Data-Sharing Agreement with the SWIMS C.I. Where such a third party agreement exists, only the Data specified in the third party agreement may be shared.

9. Data Security Measures

All Applicants must provide evidence that robust policies are implemented that conform to the Data Protection Act 1998 and that are consistent with legal and good policy requirements. In particular the Applicant will be required to provide copies of their Institution’s policies on data storage and system level security as well as policies and procedures for the secure destruction of data.

Data storage, management and security procedures will be stipulated in the Data-Sharing/Collaboration Agreement and the Applicant will list all those who will have access to the Data. The SWIMS Team must be informed in writing of any proposed alterations to these arrangements before they occur.

9.1 Data Storage

Data will be stored in a secure location and will not come into the possession or control of any other organisation or individual other than those who are listed in the Data Sharing Agreement.

The Applicant will be asked to specify: the format in which the Data will be stored, the arrangements for access to the Data, and the security systems employed (e.g. firewall/ antivirus security provision, any hard copy backups and how/where stored).

Data must not be stored on unencrypted portable devices, nor may copies of the Data be taken off site, nor shall Data be stored or used on any devices not listed in the Data-Sharing Agreement with SWIMS, nor may any Data be stored or transferred out of the European Economic Area.

9.2 Access to Data

Access will be limited to the Applicant and those listed by the Applicant in the original application form. At a minimum, access to the Data will be protected by password

10 Data Protection Act 1998

If the Shared Data includes personal Data the Applicant will receive and process that Data in accordance with the principles of the Data Protection legislation. Any unauthorised disclosure or breach of the Data Protection Act 1998 or of Data security must be reported to the SWIMS C.I. within one working day.

11 Ownership and Intellectual property Rights

11.1 Shared Data.

Any Data provided by the SWIMS team on behalf of Plymouth University remains the property of Plymouth University and is only provided for non-exclusive use by the Applicant. There is no transfer of licence or implied transfer of licence of rights in the Data from Plymouth University to the Applicant including intellectual property rights. Plymouth University retains all rights to distribute the Data to other institutions and the rights to publish any document relating to the Data. Intellectual Property Rights belong to Plymouth University.

11.2 Derived variables

All Derived Variables from analysis of the Data will be available to the SWIMS C.I. within one year of being cleaned or on termination of the study, whichever is sooner and will be incorporated into the SWIMS study and shall be owned by Plymouth University.

11.3 Other results

All other results generated by the research covered by this Agreement shall be the property of the Applicant save that the Applicant grants to Plymouth University a royalty-free, irrevocable, perpetual non-exclusive right to use such results for research and teaching.

12 Integrity of the Data

12.1 SWIMS obligations

The SWIMS Project Team will take all reasonable steps to ensure the accuracy of the Data prior to transfer.

Plymouth University accepts no liability in connection with the Applicant's use of the Data. The SWIMS C.I. does not represent that (i) the Data is fit for any particular purpose; or (ii) use of the Data is free from infringement of third party rights, including intellectual property rights. To the extent permissible by law the Applicant will indemnify and hold the SWIMS C.I. harmless for any damages howsoever arising from Applicant's use of the Data .

12.2 Applicants' and Representatives' obligations

The Applicant will ensure the preservation of the integrity of the Data provided.

13 Progress of proposed Research

13.1 Progress of research project

The Applicant will keep the SWIMS C.I. informed of progress by providing a summary of results every six months. The Applicant may also be required to provide a précis of progress, papers and/or results for the SWIMS newsletters, reports to funders or future grant applications.

13.2 Pre-publication of results

The Applicant will provide a fully documented electronic copy of the results to the SWIMS C.I. before publication in any form or within six months of completion of the study whichever is the sooner.

14 Publications

14.1 MS Society preview entitlement

The MS Society, as major funders, will be given the opportunity to preview any research output three months before publication (research posters, presentations and manuscripts).

14.2 SWIMS C.I. preview entitlement

The SWIMS C.I. will be given the opportunity to review any papers intended for publication at least 28 days prior to submission.

14.3 Post publication notification and copies

The Applicant will inform the SWIMS C.I. when a paper is published and provide an electronic copy of the final published version.

14.4 Open Access publication of papers

The Applicant will ensure that all papers are freely available in Open Access to meet the requirements of the MS Society. Currently, the requirements are to publish in a forum that ensures an automatic archive with PubMed Central, or allows “self-archive” of final manuscripts (author’s copy) with Europe PubMed Central.

15 Authorship of publications

All publications and presentations should acknowledge significant contributions of all parties to the work.

16 Acknowledgements in publications

16.1 Acknowledgment of SWIMS Project

The Applicant will include the following acknowledgement:

“The author/authors is/are grateful to the SWIMS Project participants for allowing <name of applicant> of <affiliation of applicant> to have access to Data they provided for the SWIMS Project. The author/authors acknowledge the SWIMS Project Team for delivering these Data. This publication is the work of the authors and <insert name(s)> will serve as guarantors for the contents of this publication. This publication does not necessarily reflect the views of the SWIMS Project Team nor the SWIMS Data-Sharing Committee.”

16.2 Acknowledgment of funders of SWIMS Project

All funders of the SWIMS Project must be properly acknowledged in publications or presentations resulting from data-sharing with the SWIMS C.I. The following acknowledgment must be used:

“The <insert funders> provided support for the SWIMS Project.”

Currently the funders are: The Multiple Sclerosis Society of Great Britain and Northern Ireland (awards XXX, 931), and the Peninsula Medical School Foundation.

17 End of Research

17.1 End date of study

The Applicant will inform the SWIMS C.I. as soon as the end date of the study is known and will provide any required documents and copies of manuscripts or reports prior to the final study closure.

17.2 Data destruction.

Data and Derived Data will be returned to the SWIMS C.I., or destroyed, using a specified method, at the end of the study.

In addition, the Applicant will ensure that the Data are returned to the SWIMS C.I., or destroyed if: a reasonable request is made by the SWIMS C.I., the Applicant breaches the Data-Sharing Agreement; and/or a study participant withdraws consent.

If the Data are destroyed, the Applicant will confirm the destruction in writing to the SWIMS C.I.

18 Costs

Funding for SWIMS does not extend to support for external researchers or projects.

18.1 Cost of Data

The Data are supplied without cost.

18.2 Cost of preparing Data for sharing

Should the resources required to meet an Applicant’s request exceed the aforementioned resources, the Applicant will be required to reimburse SWIMS for these additional. Once a formal application has been received, any additional cost to the SWIMS project of meeting the request will be calculated and the Applicant advised.

19 Breach of Agreement / Termination

Plymouth University retains the right to demand the return of all Data and Derived Data if any of the terms of the Data-Sharing or Collaboration Agreement are breached by the Applicant or their Representatives.

Any breach of security or such Agreement which has led / could lead to disclosure must be reported to SWIMS C.I., and copied to the SC, within one working day.

Either party can terminate this Agreement by giving the other party 30 working days' notice.

On termination of this Agreement the Applicant will return all Data and Derived Data to the SWIMS C.I. or confidentially and securely destroy all Data, such action to be confirmed in writing to the SWIMS C.I. within 5 working days of the termination of this Agreement.

APPENDIX 1: Data collection in SWIMS booklets

Table A: General questions about each participant’s MS included in SWIMS questionnaire booklets

Questions	MS booklets		CIS booklets	
	Baseline	Frequency of follow-up	Baseline	12 monthly follow-up
Date of First symptoms	✓	<i>n/a</i>	<i>n/a</i>	<i>n/a</i>
Date of First visit to GP	✓	<i>n/a</i>	✓	<i>n/a</i>
Date diagnosed with MS	✓	<i>n/a</i>	✓	<i>n/a</i>
Relapses*:				
Number/date/duration* of relapses (*included from May 2005)	✓	6 monthly	<i>n/a</i>	<i>n/a</i>
Hospital admission/use of steroids	✓	6 monthly	✓	<i>n/a</i>
Effect upon work/other activities	✓	6 monthly	✓	<i>n/a</i>
Visits to specialists (contact with health and social care professionals)	✓	6 monthly	✓	✓
Medications (updated with new medication as available for prescription)	✓	annually	✓	✓
Current symptoms (n.b. items differ according to MS or CIS)	✓	6 monthly (from Mar 2008)	✓	✓
Investigations:				
Brain scan/MRI/CT/Lumbar puncture/electrical tests	✓	6 monthly	✓	✓
Type of MS**	✓	annually	<i>n/a</i>	<i>n/a</i>
Worsening? (does participant feel that s/he has deteriorated in previous six months)	✓	6 monthly	<i>n/a</i>	<i>n/a</i>
Assistance Help needed to complete form? (included from March 2008)	✓	6 monthly	<i>n/a</i>	<i>n/a</i>
Change of diagnosis?				✓

* Relapse defined as “a worsening of existing neurological symptoms which lasts for at least 48 hours, or the appearance of a new neurological symptom which lasts for at least 48 hours”.

**Examples of MS sub-types are represented graphically in order to assist participants in selecting a classification.

Table B: Validated Instruments included in SWIMS questionnaire booklets

Patient Reported Outcome Measures (Instruments)	Date first included	MS Baseline	MS follow-up Version A*	MS follow-up Version B*	CIS Baseline	CIS follow-up
EuroQol (EQ-5D)	Sep 2004	✓	✓	n/a	✓	✓
Fatigue Severity Scale (FSS)	Jul 2005	✓	✓	n/a	n/a	n/a
General Health Questionnaire-30 (GHQ-30)	Sep 2004	✓	✓	n/a	✓	✓
MS Disease Impact Scale-29 (MSIS-29)	v1 Sep 2004, v2 Jul 2005	✓	✓	n/a	n/a	n/a
MS Walking Scale (MSWS-12)	v1 Sep 2004, v2 Sep 2006	✓	✓	n/a	n/a	n/a
Patient Determined Disease Steps (PDDS)	May 2013	✓	✓	✓	n/a	n/a
Functional Assessment of MS (modified 44-items scale) (FAMS)	Sep 2004	✓	n/a	✓	n/a	n/a
MS Neuropsychological Screening Questionnaire (MSNQ)	Sep 2004	✓	n/a	✓	n/a	n/a
Postal Barthel Index (PBI)	Sep 2004	✓	n/a	✓	n/a	n/a
Medical Outcomes Study Short Form 36 Item Health Study (SF-36)	v1 Sep 2004, v2 May 2005	✓	n/a	✓	✓	✓

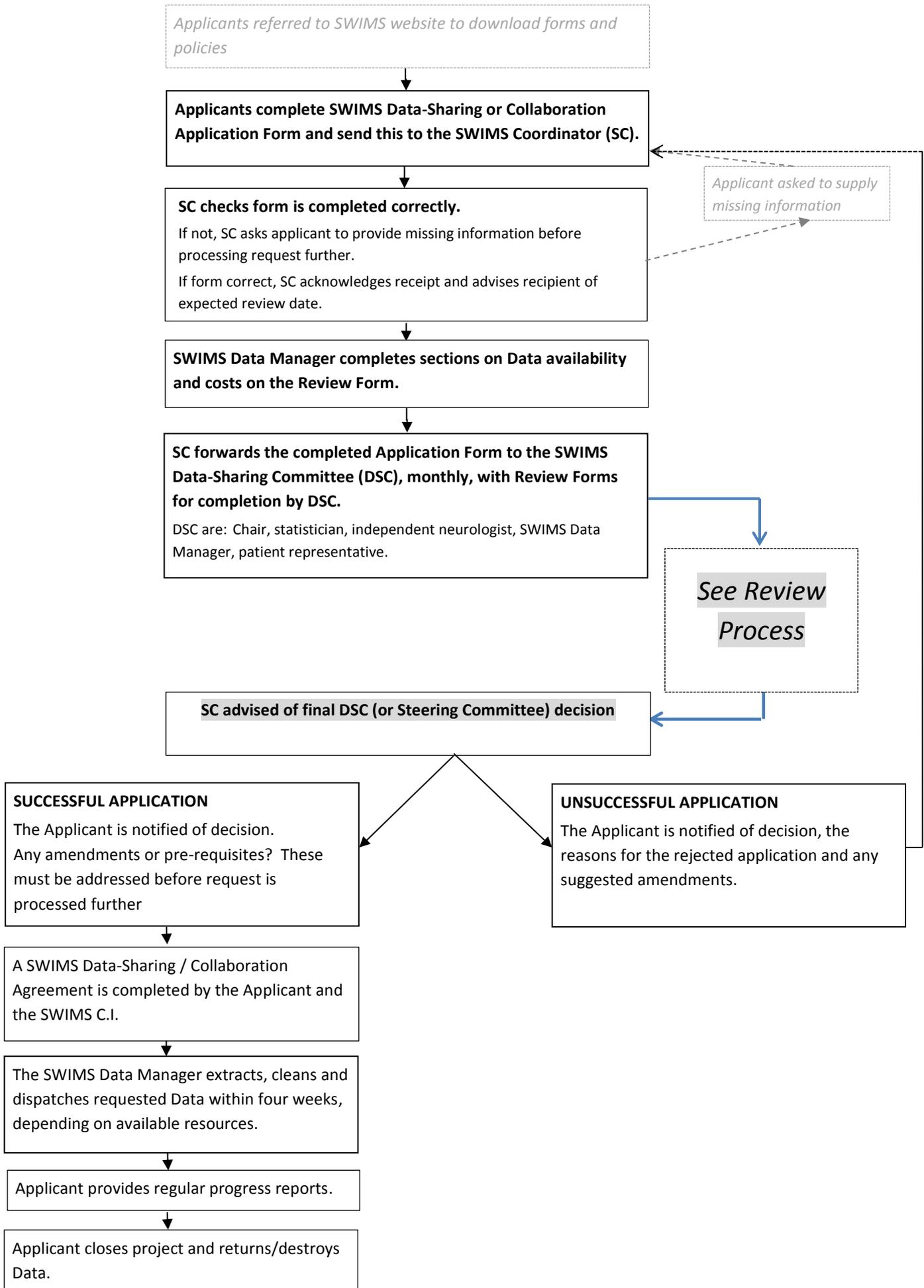
*To minimise the risk of overburdening participants, MS participants are randomly allocated to receive either Version A or Version B booklets 6 months after completion of the Baseline. Participants then receive alternate versions (A / B) every six months so that each instrument is collected on one of the following time lines:

Baseline, +6 months A, +12 months B, +18 months A, + 24 months B +30 months A etc.

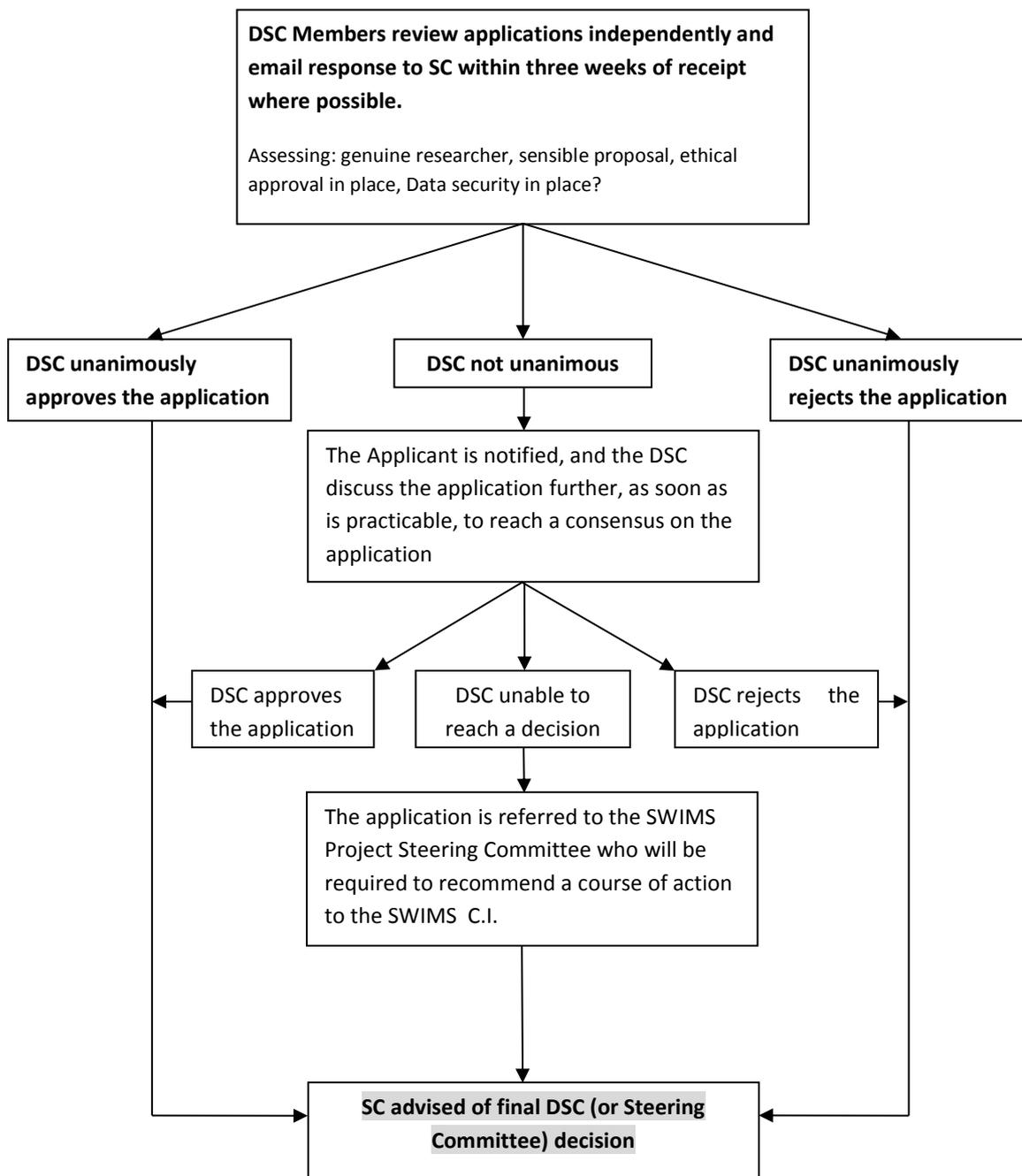
or

Baseline, +6 months B, +12 months A, + 18 months B, +24 months A , +30 months B etc.

APPENDIX 2 Processing of Collaboration and Data-Sharing Requests



SWIMS Data-Sharing Committee (DSC) Review Flow Chart for Collaboration and Data Sharing Requests



APPENDIX 3 Data Request Checklist

MS Data, CIS Data or both? Please tick appropriate boxes

MS?

CIS?

General questions:	Tick if requested	Raw data or summary? e.g. total number of symptoms	Time points	Restrictions or exclusions? e.g. age 45 or over; PDDS < 6
Date of first symptoms				
Date of first visit to GP				
Date diagnosed with MS				
Relapses*				
Number/Date/Duration of relapses				
Hospital admission/use of steroids				
Effect upon work/other activities				
Visits to specialists: contact with health and social care professionals				
Medications				
Current symptoms				
Investigations				
Brain scan/MRI/CT/Lumbar puncture/electrical tests				
Type of MS***				
Worsening? does participant report deterioration in previous six months				
Assistance: Help needed to complete form?				
Change of diagnosis?				
PROM DATA:				
EuroQol (EQ-5D)				
Fatigue Severity Scale (FSS)				
Functional Assessment of MS (modified 44-items scale) (FAMS)				
General Health Questionnaire-30 (GHQ-30)				
Medical Outcomes Study Short Form 36 Item Health Study (SF-36)				
MS Disease Impact Scale-29 (MSIS-29)				
MS Neuropsychological Screening Questionnaire (MSNQ)				
MS Walking Scale (MSWS-12)				
Patient Determined Disease Steps (PDDS)				
Postal Barthel Index (PBI)				

