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## 1. Introduction

The purpose of this document is to outline the publication and collaboration policies for the SMA REACH UK, based at the Dubowitz Neuromuscular centre, UCL Great Ormond Street Institute of Child Health.

This SOP has two sections: the first of these deals with the process for obtaining data from the SMA REACH UK database, and acknowledgement of SMA REACH UK in publications making use of these data collected; the second deals with use of SMA REACH UK - associated assessments (such as the Revised Hammersmith scale – RHS and Case report Forms – CRFs) in research studies external to SMA REACH UK.

## 2. Requesting and publishing SMA REACH UK data and acknowledging the network

This SOP applies to all requests for SMA REACH UK data, and any publications that make use of these data. It is designed to promote transparency on data use and authorship, and outline SMA REACH UK's policy for peer reviewed publications and open access to research data and metadata. Any publication using SMA REACH UK data should acknowledge support from the SMA REACH UK study and its network members.

### 2.1 Principles

Research using SMA REACH UK consortium data should:

- a. be collaborative, building on knowledge and data contributed by more than one site;
- b. be open, with research plans for shared data discussed and agreed by relevant SMA-REACH UK PIs and committees in advance of action being taken;
- c. be ethical, with data used only according to the terms of participant consent, and not used to address research questions that may be viewed as unethical, or which are outside the remit of the project application submitted to SMA REACH UK;
- d. minimise data transfer and storage security risks by executing cross-site, international analyses in the UK wherever possible;
- e. acknowledge the contribution(s) of the SMA REACH UK network and local investigators.

Principal investigators (PIs), co-investigators (Co-Is) and other bodies will notify the SMA REACH UK central coordinating team of any publications using SMA REACH UK data, or relevant grant applications submitted and/or awarded. This information will be used to support funder reporting.

### 2.2 Permissions

Permission from the SMA REACH UK steering committee must be obtained before network data are shared with either internal or external collaborators. Decisions on data sharing are made on a case-by-case basis, at regular or *ad hoc* steering committee meetings.

Requests to SMA REACH UK should be made using the SMA REACH UK data request form (annex 4.2).

### 2.3 Requesting and publishing SMA REACH UK data

Data may be obtained from the SMA REACH UK study database, and used in publications, via the following process:

- a. Requests for SMA REACH UK data, including proposals for use of those data in studies and/or publications should be sent by the study team (i.e. the team interested in obtaining data) to the SMA REACH UK coordinating team (based at the Dubowitz Neuromuscular Centre, UCL Great Ormond Street Institute of Child Health) by email – [ich.smareachuk@ucl.ac.uk](mailto:ich.smareachuk@ucl.ac.uk). These requests should use the data

request form in Annex 4.2 and include details of the research proposal and publication plans.

- b. The SMA REACH UK steering committee will regularly review proposed studies/publications to help identify areas of collaboration, overlap/conflict or IP publication between partners.
- c. If and when the steering committee agrees with the proposed study, data will be shared with the study team as necessary for the project.
- d. Any publications arising from studies using SMA REACH UK data should be shared with SMA REACH UK (via the coordinating team) at least 30 days in advance of publication. This stipulation covers publications including previously unpublished SMA REACH UK data, including (but not limited to) the following:
  - i. Original contributions, reports, reviews, editorials, commentaries, and letters in scientific journals.
  - ii. Books, book chapters, manuals, and publicly available electronic material.
- e. Conference abstracts and posters arising from studies using SMA REACH UK data should be shared with the SMA REACH UK network at least 7 days prior to submission and presentation, respectively.
- f. Members of the SMA REACH UK network should lodge any legitimate objections to data publication with the study team within 15 days of notification of intention to publish. Legitimate concerns could include:
  - i. Commercial sensitivity
  - ii. IP issues
  - iii. Desire to maximize scientific impact by delaying publication to integrate with data generated later in the project.
- g. The steering committee will mediate and resolve any disputes regarding publication.

## 2.4 Acknowledgement

Any publication that uses SMA REACH UK data should appropriately acknowledge the contribution of the network to the generation of the data used, using. This should involve inclusion of the network as an author on the publication, and acknowledgement of the network's membership in a fashion that allows any paper using SMA REACH UK data to appear in an online search (e.g. of PubMed) of any network member.

To properly acknowledge the SMA REACH UK network in a publication, please:

- a. Include "SMA REACH UK Network" as an author on the paper, and please **do not** include "on behalf of" before the network name.
- b. Include the acknowledgement statement in annex 4.1 (or similar) in the acknowledgements section of the paper.
- c. List the membership of the network (i.e. the clinicians and physiotherapists at each site) in the acknowledgments or collaborators section of the paper (as in the International SMA Consortium in, for example, this [Neurology paper](#), or this [J Clin Med paper](#)). An up-to-date list of network members can be obtained from the SMA

REACH UK central coordinating team. This list will be updated and audited on a regular basis.

- d. Specifically ask the publishing journal to make **all** the network members listed in the acknowledgments section searchable on PubMed.

Authorship of studies using SMA REACH UK data should be assigned according to [the recommendations of the International Committee of Medical Journal Editors](#).

### 3. Use of SMA REACH UK associated documents

This section of the SOP applies to research studies or external bodies interested in making use of SMA REACH UK-associated documents, such as assessment scales or case report forms (CRFs). This includes the Revised Hammersmith Scale (RHS) for Spinal Muscular Atrophy (SMA), a 36-item clinical outcome measure to assess physical abilities and motor performance of patients with type 2 and 3 SMA.

#### 3.1 Permissions

Interested study teams should contact the SMA REACH UK coordinating team by email, [ich.smareachuk@ucl.ac.uk](mailto:ich.smareachuk@ucl.ac.uk). In general, study teams may freely use the RHS for SMA and SMA REACH UK CRFs for clinical and research purposes, as long as suitable acknowledgement is given in publications arising from studies making use of them.

Study teams must ensure that the current version of each document – for the RHS in SMA, version 1.2 , dated 30 June 2021– and/or assessment manual(s) are used.

#### 3.2 Acknowledgement

Publications using the RHS for SMA or SMA REACH UK CRFs must acknowledge that these documents are licensed to the network in all associated publications and disseminated work resulting from the use of them.

All publications using the RHS for SMA must include the following copyright statement:

The Revised Hammersmith Scale (RHS) for spinal Muscular atrophy (SMA) is copyright © 2015 Great Ormond Street Hospital on behalf of the UK SMA Reach Network. You may print or use the RHS for academic or research purposes but any modification, translation or reproduction for redistribution or commercial exploitation of part or all of the contents in any form is strictly prohibited without our express written permission

The copyright statement and disclaimer can be made available from the authors of these publications.

#### 3.3 Translations

Study teams are free to translate the RHS or SMA REACH UK CRFs for use in non-English-speaking countries or populations. Study teams should understand that the copyright of translated versions of these documents remains with the SMA REACH UK Network

(although translators will be credited). A copy of any translated RHS or CRFs must be shared with the SMA REACH UK coordinating team.

The SMA REACH UK team recommends the following translation process, to ensure that the meaning of the original document is maintained in any translated version(s):

- a. An initial translation of the document, from English into the selected language, is performed by one individual or group.
- b. A fully-independent back translation of this initial translation, from the selected language into English, is performed independently of the initial translation by another individual or group.
- c. The SMA REACH UK team compares the back translation to the original English. Any discrepancies found at this stage are discussed with both the initial and back translators to establish a consensus on the correct wording, to maintain the intended meaning of the original document, and the translation is then revised.
- d. The final translation is shared with the SMA REACH UK coordinating team, to provide final specifications for use, so that organisations distribute permitted hard copies only.
- e. The approved translation will be available from SMA REACH UK for users of the selected language to access freely. Any work published in English or any translated language will need to follow this publication policy.
- f. Any translation should be for all the contents, not just sections. The translated copyright remains as per the original.

## 4. Annexes

### 4.1 SMA REACH UK network acknowledgement statement

Publications using SMA REACH UK data should acknowledge the network with the following statement (or similar):

- a. SMA REACH UK:

*The author of this [INSERT PUBLICATION DETAIL] would like to acknowledge the work of the SMA REACH UK Team for their contribution in the collection and provision of the data used within this [INSERT PUBLICATION DETAIL]. Prof Francesco Muntoni is the Chief Investigator of the SMA REACH UK Project in the UK (REC Reference 13/LO/1748, IRAS project ID: 122521), via University College London and Great Ormond Street Hospital for children.*

*SMA REACH UK would like to acknowledge the contribution of current commercial funders Biogen, Roche and Novartis. SMA REACH UK is also grateful to historic funders of the project. The funders had no role in study design, data collection and analysis, decision to publish or preparation of the [INSERT PUBLICATION DETAIL].*

### 4.2 SMA REACH UK audit data request form V3.1



## REQUEST FOR DATA FROM SMA REACH UK

**Please note that following review of your request, only anonymised data can be provided.**

### Applicant Details

Title and Name:		Role:	
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Affiliation (e.g. NHS Hospital / Academic Institution / Company) and Address	
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### Request Details

Please make your request by ticking the appropriate boxes below and enclose the relevant documents:

<p><b>I am requesting data for:</b></p> <p><input type="checkbox"/> Audit project</p> <p><input type="checkbox"/> Research project, approved by a Research Ethics Committee and registered with an NHS Trust/Academic Institution</p> <p><input type="checkbox"/> Healthcare Commissioning project</p> <p><input type="checkbox"/> Other, please specify:</p> <p><b>The data I am requesting will be published in the form of an:</b></p> <p><input type="checkbox"/> Abstract</p> <p><input type="checkbox"/> Poster</p> <p><input type="checkbox"/> Publication</p> <p><input type="checkbox"/> Not published</p> <p><input type="checkbox"/> Other, please specify:</p>	<p><b>The following documents are enclosed:</b></p> <p><input type="checkbox"/> A description/summary of the audit/research project (page 2 of this document)</p> <p><input type="checkbox"/> Confirmation that the audit project has been registered with a relevant hospital/academic department</p> <p><input type="checkbox"/> Research Ethics Committee approval</p> <p><input type="checkbox"/> Statistical Analysis Plan (if relevant; page 2 of this document)</p> <p><input type="checkbox"/> Other relevant documentation, please specify:</p>
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## Supporting Information

I am requesting anonymised data for the following purpose(s) (include further details on a separate sheet if more space is required):

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## Statistical analysis plan

a. Please list/ describe the primary and secondary objectives of the study.
b. What are the inclusion criteria?
c. What are the exclusion criteria?
d. What is the primary outcome measure and on which form is this recorded?
e. What are the secondary outcome measures and on which forms are they recorded?



f. Details of analysis method to be used. Include the analysis endpoint, statistics methodology and planned subgroup analyses. Please address and consider sample size.
g. Detail statistical packages to be used for analyses.
h. How will this data analyses be presented?

_____	_____	_____
Name	Signature	Date

### After the data request

As part of this data request, any publication (or similar) arising from the use of the supplied SMA REACH UK provided will be expected to include appropriate acknowledgement of the SMA REACH UK, as laid out in the SMA REACH UK publication policy (see section 2.4 – acknowledgement). This includes inclusion of the network as an author on the publication, acknowledgement of the network’s membership, and the acknowledgement statement as per Annex 4.1.

### Follow-up

The SMA REACH UK coordinating team will follow-up with the requestor listed above 6 months after the data is provided, for an update on use of the data and any subsequent publications. By submitting this form, you agree to provide an update as required.