

## **Data Access and Results Sharing Network Agreement**

This agreement including its annexes (the “Agreement”) is made by and between each of the Partners as defined below.

### *Background*

The Partners wish to collaborate to establish and operate a Data Access and Results Sharing Network (as further described in Annex 1) for the purpose of completing Data Analyses to address research questions of interest to Partners.

Therefore the Partners agree as follows:

### *Definitions and Interpretation*

1. The following expressions shall have the following meanings, unless context requires otherwise:
  - a. “Accession Form” in relation to each Partner means a form executed by that Partner and the Network Co-ordinator as set out in Annex 2.
  - b. “Agreed Role” means one of “Data Contributor” or “Data Harmonisation Lead” or “Topic Expertise Contributor” or “Methodological Expertise Contributor” or “Science Lead” or “Technical Lead” or “Network Co-ordinator”. The nature and contribution of each Role is described in Annex 2. For the avoidance of doubt, each Partner may perform more than one Role and each role may be performed by more than one Partner, except that at any one time there shall be only one Network Co-ordinator. The Agreed Role that each Partner may perform is listed in that Partner’s Accession form.
  - c. “Arising Intellectual Property” shall mean any Intellectual Property which is generated or first reduced to practice by any Partner or Partners directly as a result of the work undertaken in accordance with this Agreement.
  - d. “Background” means any Intellectual Property excluding Arising Intellectual Property owned or controlled by a Partner prior to commencement of or independently from the Network and which the owning Partner contributes or uses in the course of performing its obligations to the Network.
  - e. “Network Management Group” or “Group” shall mean the decision making body of the Network.
  - f. “Confidential Information” means any (i) Background; or (ii) other information disclosed by a Partner to the others for use in the Network, identified as confidential before or at the time of disclosure or which by its nature should reasonably be regarded as confidential. Arising Intellectual Property is Confidential Information of the Partner or Partners owning it.
  - g. “Data Access and Results Sharing Network” or “Network” means the collaborative grouping defined by the Partners who have executed an Accession Form with the Network Co-ordinator as further described in Annex 3.
  - h. “Data Analysis” means an analysis or series of related analyses to address a research question via “Data Access and Results Sharing” as further described in Annex 1.

- i. "Intellectual Property" means intellectual property of any description including all inventions, designs, specifications, formulae, improvements, discoveries, know-how, data, processes, methods, techniques and the intellectual property rights therein, including patents, copyrights, database rights, design rights (registered and unregistered), trademarks, trade names and service marks and applications and the right of enforcement for any of the above.
  - j. "Principal Investigator" and "Co-Investigator" in relation to each Partner means the individuals listed in that Partner's Accession Form, or such successor or successors as nominated by that Partner.
  - k. "Network Co-ordinator" means [initial co-ordinator name] or such other Partner as has replaced the Network Co-ordinator.
  - l. "Partner" means any party that has executed an Accession Form with the Network Co-ordinator and has not terminated participation in this Agreement.
  - m. "Procedures" shall mean the procedures set out in the Network Management Group's Terms of Reference attached as Annex 4.
2. This Agreement includes its Annexes. In this agreement:
- a. the plural shall include the singular and vice versa as context requires; and
  - b. the word "including" shall mean "including without limitation".

#### *The Network*

3. Each Partner shall use reasonable endeavours to diligently:
- a. collaborate in the Network and perform its Agreed Role;
  - b. provide such facilities, materials, equipment and personnel as are necessary to perform its part in the Network.
4. The Partners shall establish the Network Management Group, which shall follow the Procedures and each Partner shall participate in the Group.
5. The participation of each Partner in the Network shall be performed under the direction and supervision of the Principal Investigator at each Partner.
6. All Partners may, individually or in co-operation with other Partners, submit Data Analysis proposals. Each Partner will decide whether or not to participate in a Data Analysis and its Agreed Role(s) for each Data Analysis in which it decides to participate.
7. Each Partner shall bear the cost of its participation in the Network.

#### *Intellectual Property Rights*

8. All Background shall remain the property of the Partner introducing it and nothing in this Agreement shall confer any right, title or interest to Background except as expressly granted in this Agreement.
9. Each Partner grants to the others a royalty-free, non-exclusive, non-sublicensable licence to use its Background solely for the purpose of, and limited to the duration of, participation in the

Network. Where the grant of such licence is subject to third party rights or statutory, legal or regulatory constraints each Partner shall, at the request of the Partner granting the licence, do such acts or execute such documents as are reasonably necessary to facilitate the grant of the licence, provided always that this provision shall not oblige a Partner do any act or execute any document that would significantly affect its legitimate interests.

10. Each Partner shall own the Arising Intellectual Property generated by its employees, students or agents through its participation in the Network and shall ensure that it secures such ownership from such employees, students or agents.
11. Each Partner shall promptly disclose to Partners all Arising Intellectual Property generated by it and shall co-operate, where required, in relation to the preparation and prosecution of patent or other applications relating to Arising Intellectual Property.
12. Where any Arising Intellectual Property is created by two or more Partners jointly and it is impossible to segregate each Partner's contribution (which, for the avoidance of doubt, includes the participation in a Data Analysis by a Data Contributor), such Arising Intellectual Property will be jointly owned by those Partners in equal shares. The owners may take such steps as they may decide from time to time, to register and maintain any protection for that Arising Intellectual Property, including filing and prosecuting patent applications, and taking any action in respect of any alleged or actual infringement of that Intellectual Property. If one or more of the owners does not wish to take any such step or actions, the other owner(s) may do so at their expense, and the owner not wishing to take such steps or action will provide, at the expense of the owner(s) making the request, any assistance that is reasonably required of it.
13. Each Partner is hereby granted an irrevocable, non-transferable, royalty-free, non-exclusive right to use all Arising Intellectual Property generated during that Partner's participation in the Network for academic and research purposes, including research funded by third parties provided that those third parties gain or claim no rights to such Arising Intellectual Property.

#### *Confidentiality and Publication*

14. Each Partner will use all reasonable endeavours not to disclose to any third party any Confidential Information, nor use for any purpose, except as expressly permitted by this Agreement any of another Partner's Confidential Information. This obligation shall not apply in respect of information which:
  - a. is already known to the receiving Partner before its participation in the Network;
  - b. is or becomes publicly known without the fault of the receiving Partner;
  - c. is obtained by the receiving Partner from a third party in circumstances where the receiving Partner has no reason to believe that there has been a breach of an obligation of confidentiality owed to the disclosing Partner;
  - d. is independently developed by the receiving Partner, as can be evidenced by contemporaneous written documentation;
  - e. is approved for release in writing by an authorised representative of the disclosing Partner; or

- f. the receiving Partner is specifically required to disclose by law including the order of a court of competent jurisdiction.
- 15. Publications resulting from a Data Analysis shall be sent to Partners for review at least thirty (30) days before submission for publication. The publishing Partner may be required to delay submission for publication if in another Partner's reasonable opinion such delay is necessary to seek patent or similar protection for material which it is entitled to seek protection, or to modify the publication in order to protect its Confidential Information. Such delay shall last no longer than is necessary and in any event shall not exceed three (3) months. Notification of the requirement of delay must be received within thirty (30) days of receipt of the proposed publication, failing which the publishing Partner shall be free to assume that no Partner objects to the proposed publication. Objections to publication will be referred to the Network Management Group for resolution.
- 16. Authorship of publications shall be in accordance with good academic practice and determined by Partners under the Procedures. Acknowledgement shall be made to [XXX]

#### *Accession*

- 17. A third party may, on signing an Accession Form become a Partner ("Joining Partner"), provided always, that no existing Partner, on being informed of the proposed addition of such third party to the Network, raises an objection to such third party's inclusion in the Network. In the event of such an objection being raised by an existing Partner, the Network Management Group shall be informed of said objection and shall at its sole discretion, determine whether any such objection is valid and ultimately, whether or not the third party in question shall be granted access to the Network as a Partner
- 18. A Joining Partner's obligations and rights under this Agreement shall take effect from the Starting Date shown on the Accession Form signed by the Joining Partner.

#### *Term, Termination and Withdrawal*

- 19. This Agreement comes into force from the Starting Date of the first Accession Form and shall remain in force, unless terminated earlier as provided for in this Agreement.
- 20. If all Partners other than the Network Co-ordinator have withdrawn or been excluded this Agreement shall terminate.
- 21. Any Partner (a "Withdrawing Partner") may by giving three (3) months written notice to the Network Coordinator withdraw from this Agreement.
- 22. Any Partner (a "Defaulting Partner") in material default of its obligations under this Agreement may be excluded from this Agreement by the Partners in accordance with the Procedures.
- 23. A Withdrawing Partner or Defaulting Partner shall:
  - a. remain liable for its acts or omissions prior to withdrawal or exclusion;
  - b. if so requested by the remaining Partners use reasonable endeavours to continue to provide access to its data and computer systems so far as is necessary for (i) the completion of any ongoing Data Analyses at the time of such withdrawal or exclusion

and /or (ii) the subsequent verification of results as may be required for research governance purposes; and

- c. grant any permissions to Arising Intellectual Property for research purposes as necessary for the continued performance of the Network or of obligations under this Agreement.

#### *Warranties and Liability*

24. The liability of any Partner for any breach of this Agreement, or arising in connection with this Agreement, will not extend to loss of business or profit or to any indirect damage or loss.

25. Each Partner warrants that:

- a. it has full power and authority to enter into this Agreement;
- b. it has taken all necessary actions and obtained all necessary authorisations, licences and consents to perform this Agreement including any local institutional approvals for use of data; and that
- c. it will comply with applicable law, and any regulatory and ethical licences, consents and approvals in its performance of this Agreement.

26. Each Partner assumes liability for all third party claims against the other Partners resulting from its breach of this Agreement or its negligence in connection with this Agreement, including any failure to perform its Agreed Role.

27. Nothing in this Agreement limits or excludes a Partner's liability for death or personal injury due to negligence; or any fraud or for any other sort of liability which, by law, cannot be limited or excluded.

#### *General*

28. Each Partner shall use all reasonable endeavours to do or procure to be done all further acts and execute or procure the execution and delivery of all other documents as another Partner may from time to time reasonably require for the purposes of giving that other Partner the full benefit of its rights under this Agreement.

29. Notwithstanding that each Partner executes a separate Accession Form with the Network Coordinator, this Agreement forms a single agreement made between all of the Partners.

30. Nothing in this Agreement shall create, imply or evidence any partnership, joint venture, or relationship of principal and agent between the Partners.

31. This Agreement is governed by National Law of the Network Co-ordinator. The courts of the country of the Network Co-ordinator shall have exclusive jurisdiction to deal with any dispute arising out of or in connection with this Agreement, except that any Partner may seek an interim injunction in any court of competent jurisdiction.

32. This Agreement constitutes the entire agreement between the Partners relating to its subject matter. This Agreement may not be varied or amended except by written agreement signed by the authorised signatory of each Partner.

33. The Network Coordinator's Principal Investigator shall be [ ]

#### *Notices*

34. The address for notices to the Network Co-ordinator is:

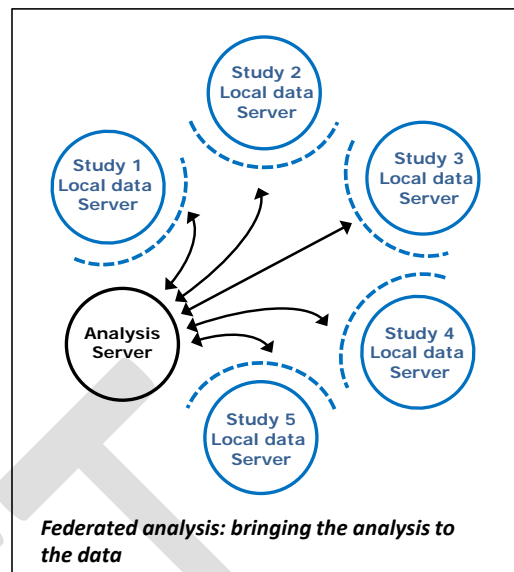
[ ]

35. The addresses for notices to other Partners are as specified in the Accession Forms.

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## Annex 1: Description of approach

The Data Access and Results Sharing Network (or Network) is the grouping of Partners that have agreed to work together to address research questions of interest to Partners using a process based on remote access to data held locally and sharing of summary results. This process is illustrated and described briefly below. At present the only informatics system that supports this analytic approach is DataSHIELD ([www.datashield.ac.uk](http://www.datashield.ac.uk)). However, should another approach with equivalent characteristics emerge, the Network may choose to use that new method in addition to - or instead of - DataSHIELD. In such a circumstance, the Data Access and Results Sharing Network Agreement that has been signed will remain in force with no modification.



### Federated analysis

- A fundamental aspect of the approach is a federated process in which the 'analysis comes to the data'.
- Individual-level data from contributing studies are held securely on local, study-based servers.
- Analytical commands are sent as blocks of code to request each local computer to undertake an analysis and return summary results (i.e. results that are derived from the individual-level data, not the individual-level data itself).
- All analyses are performed locally, so all data stays at source and does not leave the originating institution.

### Privacy and confidentiality

- The output that is returned to the analysis server is designed to be non-disclosive; typically representing results summarised at the level of the study. The individual-level records that are held on the local server are neither visible nor physically accessible through the remote access process.
- Only the sub-set of variables (excluding participant identifiers) required for each Data Analysis are uploaded to the local data server at each study.
- Privacy and confidentiality is additionally addressed through data security methods including cell suppression (to avoid disclosure of sensitive tabular data), restrictions on the types of analyses permitted and limits on commands to prevent identification.
- Since the data stays at source, any breach of data traffic between the analysis computer and the local server can only yield non-disclosive results, not any individual-level data.

### Security

- The software tools use web security techniques, as used on internet banking, e-commerce and social networking sites, and include:
- Encryption - communication between users and servers cannot be intercepted and read by those who are not supposed to view that information.
- Authentication - the identity of users is verified either by login credentials or via a signed certificate so that they are only able to access data for which they have been given permission.
- Connection management - a firewall is used to ensure that only the intended clients with specific IP addresses can connect to the servers.
- Update management - to limit system security threats inherent to systems that are connected to the internet, software is regularly patched and updated.

## **Annex 2: Definition of roles**

The sections below further describe the tasks associated with each Agreed Role.

### *Network Co-ordinator*

- a) Co-ordinate the activities of the Network.
- b) Implement the decisions of the Network Management Group.
- c) Perform such administration, reporting, record keeping and communication with the Partners as is reasonably necessary for the Network Management Group's activities.
- d) Record decisions on the Data Analyses that will be addressed by the Network, which Partners have agreed to contribute to which Data Analyses and the Agreed Roles.

### *Data Contributor*

- a) Set up a local server following the SOP [Link] updated from time to time and follow the security measures defined therein.
- b) Maintain the security of the local data server and its on-going availability at the required performance specification.
- c) Upload relevant data for each Data Analysis to which the Data Contributor has agreed to participate and ensure that such data excludes personal identifiers or other data that is viewed as directly disclosive.
- d) Implement the directions of the Technical Lead in relation to access permissions and installed DataSHIELD functions and perform periodic software updates.
- e) Provide relevant meta-data and respond to queries to support the data harmonisation process.

### *Data Harmonisation Lead*

- a) Lead the process of understanding the data, defining the target variables for harmonisation, assessing harmonisation potential between participating studies and defining algorithms to transform relevant data into common scales.
- b) Ensure the decisions and steps in this harmonisation process are recorded for future re-use.

### *Topic Expertise Contributor*

- a) Contribute topic expertise to:
  - (i) Help define research questions and /or
  - (ii) Contribute to development of data analysis plans and /or
  - (iii) Contribute to the harmonisation of data and /or
  - (iv) Contribute to writing up results for publication.

### *Methodological Expertise Contributor*

- a) Contribute methodological expertise to:
  - (i) Help assess feasibility of research questions and /or
  - (ii) Contribute to development and execution of data analysis plans and /or

- (iii) Contribute to the harmonisation of data and /or
- (iv) Contribute to writing up results for publication.

#### Science Lead

- a) Lead the development of the research question and analysis plan
- b) Highlight to the Technical Lead the statistical methods required so that the functionality of DataSHIELD can be assessed and new functions developed as required
- c) Conduct agreed Data Analyses with support from the Technical Lead; alternatively guide the Technical Lead in running the analyses
- d) Make no attempt to identify or infer information about any individual, should disclosive data happen to arise. This will apply regardless of the cause of disclosure breach; for example, it will apply if the breach is consequent upon a mistake or malicious activity.
- e) Interpret results and lead the process of writing up results for publication

#### Technical Lead

- a) Provide guidance and advice to Data Contributors on the set up and maintenance of local study servers;
- b) Convert the harmonisation algorithms into programming code and apply remotely through the Opal web interface to remotely transform data to comparable scales;
- c) Identify the required DataSHIELD functions to complete the agreed Data Analyses using only functions that are described as non-disclosive on [link]
- d) Where a Data Analysis calls for functionality that is not currently available, determine whether new non-disclosing functions can be developed and within what time-frame; and if so, to implement such functions when available;
- e) Advise each participating Data Contributor on the permissions and DataSHIELD functions required for a Data Analysis;
- f) Provide and maintain the Analytical Computer; conduct agreed Data Analyses in co-ordination with the Science Lead.
- g) Maintain the security of the Network, informing Partners of required patches and software upgrades;
- h) Make no attempt to access data through any means other than DataSHIELD (for analysis, via remote access through the Analytical Computer) and the Opal web interface (for harmonisation, via direct remote access); and
- i) Make no attempt to identify or infer information about any individual, should disclosive data happen to arise. This will apply regardless of the cause of disclosure breach; for example, it will apply if the breach is consequent upon a mistake or malicious activity.

### **Annex 3 – Accession Form**

#### **FORM OF ACCESSION FOR [NEW] PARTNERS**

ACCESSION of a [new] Partner to the Data Access and Results Sharing Network Agreement.

[Name of [New] Partner] (the “Joining Partner”) of [registered address]

agrees to become a Partner to the Agreement identified above and accepts all the rights and obligations of a Partner starting [date] (the “Starting Date”).

The Agreed Role(s) and Data Collection(s) for each Data Analysis that the Partner agrees to participate in shall be determined by procedures established by the Network Management Group and said Roles and Data Collections shall be documented and listed on the InterConnect website.

The Joining Partner’s Principal Investigator shall be:

The Joining Partner’s Co- Investigator(s) shall be:

The Joining Partner’s address for notices shall be:

Agreed by the parties through their authorised signatories:

For and on behalf of the Network Co-ordinator

Signed: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

For and on behalf of [new partner]

Signed: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

## **Annex 4 –Network Management Group Terms of Reference**

### *Purpose*

The Group exists to coordinate and manage the Network on behalf of the Partners and to ensure that Data Analyses are ethically and scientifically valid and in keeping with the overall scientific objectives of the Network.

### *Membership*

The Group will consist of representatives of each Partner (usually that Partner's Principal Investigator). Co-Investigators from each Partner may also participate in meetings.

The Group's Chairperson will be nominated by the Network Co-ordinator or otherwise as agreed by the Group.

### *Role*

All significant operational matters relating to the Network will be decided by the Group, which shall also put in place any structures or processes to manage the Network that it agrees.

In particular, the Group shall establish procedures for submitting, reviewing and recording Data Analysis proposals and the process by which Partners decide whether or not to participate in a Data Analysis, the Agreed Role(s) of participating Partners within that Data Analysis and the contributing Data Collections.

### *Quorum*

The quorum for a meeting shall be not less than 50% of the Partners.

### *Meeting Frequency*

The Group will meet in person or virtually (by telephone or video conference) on a quarterly basis or when reasonably considered necessary at the request of any Partner. Meetings shall be convened with at least twenty-one days written notice, which shall include an agenda. Minutes of a meeting shall be prepared and circulated by the Chairperson without delay and in any event within fifteen days of the meeting. The Chairperson shall prepare such progress reports as are reasonably required by the Group.

### *Voting*

Group decisions will usually be made by consensus but in the event of disagreement, voting will take place. Each Partner shall be entitled to cast one vote. Votes on exclusion of a Defaulting Partner must be unanimous amongst all Partners other than Defaulting Partners. Other votes require a quorum and will be determined by simple majority, with the Network Co-ordinator having the deciding vote in the event of a tie.