Draft Tools to Operationalize Pre-Open Access Data Sharing

Distributed to participants of a 'Data Sharing' webinar coordinated by Gender and Agriculture Research Network held 29 September 2016. These Draft Tools shared by the System Management Office of CGIAR System Organization (SMO), are to be adapted with the assistance of SMO working with relevant Center counterparts and updated version will be included in the CGIAR Open Access and Open Data Support Pack. For further information or support please contact the presenters of the webinar: Leroy Mwanzia, CIAT (L.Mwanzia@CGIAR.ORG) and Rodrigo Sara, Systems Management Office (r.sara@cgiar.org)

Tool 1: Template for a Project-specific Data Sharing Protocol[1]

Data Sharing Protocol for <<PROJECT>>

(ideal 1-2 pages max to explain to prospective partner's requirements in a project specific manner)

1. *Background*
2. *Who is funding this research?*
3. *What is <<PROJECT>>*
4. *What data is used and generated in <<PROJECT>>*
   - *[identify any special considerations regarding the nature of the data]*
     a. *ethics/privacy consideration re research involving human subjects*
     b. *confidentiality considerations re partners' proprietary information or commercially sensitive information (e.g. patent applications)*
     c. *considerations concerning genotypic/phenotypic information (e.g. identification of native traits)*
     d. *considerations concerning traditional knowledge*
5. *What is the data used for?*
6. *Who owns the data?*
7. *Open Access to <<PROJECT>> data*
8. *Pre-open access sharing of <<PROJECT>> data*
9. *What are the basic principles governing Pre-open access sharing of data*
   - *Explain Protocol in lay terms*
10. *How do I obtain/request access to data?*
    - *Explain process for operationalizing and whether a data sharing license is to be used in support of each transfer*
11. *Can I refuse access to data?*
12. *How do I resolve a disagreement concerning a data transfer?*

[1] See example from the MalariaGen Genomic Epidemiology Network

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Tool 2: Sample Data Sharing Protocol

Part I Identify core elements relevant to the Data Sharing Protocol (relevance to be determined)

- Project
- Provider
- Recipient
- Data
- Data Manager
- Purpose
- Embargo Period (i.e. OA trigger)
- Credit
- Confidential Information
- Data Security
- Data Transfer
- Costs
- Standards/curation

[to be used in the coversheet of the draft data license, as per tool below]

Project	The <<PROJECT>> Project is [insert description]
Provider	[insert name and position] on behalf of [insert legal entity] with registered office at [insert]
Recipient	[insert name and position] on behalf of [insert legal entity] with registered office at [insert]
Data	[insert description of data subject matter including the following if applicable: (i) associated metadata; (ii) compliance with any data standards; (iii) methodology for collection/generation or other information pertaining to quality and/or interoperability]
Data Manager	[insert description of personnel at Provider who is responsible for permissions and queries related to the Data]
Purpose	[State the purpose(s) for which the Recipient is authorized to use the Data (consider what studies will be performed, what questions will be asked and what are the expected outcomes?). If Recipient is permitted to publish Data (or components thereof) or transfer Data to third parties (or components thereof) during Embargo period, this should be explicitly stated (included license terms) otherwise it is prohibited pursuant to Part II. (4). Additionally, if there are additional specific requirements concerning the use and management of the data which the Provider must flow down (e.g. policy or regulatory requirements concerning private information of human subjects), such requirements/limitations should also be explicitly stated in the Purpose)]
Embargo Period	**For unrestricted data: Identify the period according to the obligation to make the Data openly accessible as per the timeframes contained in Section 4.2.4 CGIAR Open Access Policy[2]]; AND/ OR** **For restricted data: embargo Period is perpetual so clearly identify the data or component thereof for which the embargo is not subject to expiry,** subject to the following: ▪ the basis for the perpetual embargo should be clearly identified (e.g. the obligation to make the Data openly accessible pursuant to Section 4.2.4 CGIAR Open Access Policy is not applicable due to…. (e.g. due to third party confidentiality requirements or credible risk of privacy breach)…… as approved by (e.g. as approved by the DDG in consultation with Center IP Focal Point]

[2] [Pursuant to Section 4.2.4 of OADM Policy the obligation arises as soon as possible and in any event within 12 months of completion of the data collection or appropriate project milestone, or within 6 months of publication of the information products underpinned by that data, whichever is sooner].

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Credit	[Identify how the Recipient or permitted downstream recipient(s) of the Provider's data must reference or acknowledge the Provider's Data or use of the Provider's Data (if applicable)]
Restricted Information	[Identify specific information, if any, that must remain confidential and should not be disclosed verbally or in writing to an unauthorized third party (i.e. during or after expiry of Embargo Period). Provider should be as specific as possible and flag (i) existence of known sensitive/personal data that identifies individuals; and (ii) safeguards in place to prevent sensitive information from becoming public.] OR [if the Embargo Period Expiry above is identified as "N/A" indicate "Any information embodied in or accompanying the Data identified/marked as restricted third party confidential information or which may disclose the identity of human research subjects"]
Data Security	[Identify any specific requirements, if any, that the Recipient must follow to maintain data security. E.g. if hard copies, are these required to be kept in a locked cabinet or room? If electronic copies, are these required to be password protected or kept on a secure disk? Will all Recipient staff be entitled to same level of access to data, or will some people have restricted access? What kind of password protections need to be put in place? Who will have physical access to the data, including the servers and the paper files? What will happen to the data after the data-sharing period ends?]
Data Transfer	[Identify the manner in which data will be transferred from the provider to the Recipient. Will data be transferred physically or electronically? If data are to be sent over the Internet, is a secure connection required? Will the data be encrypted before being transferred?]
Costs	[Identify any expenses related to the transfer of the data? If so, clarify who will cover the costs of sharing the data (e.g. Provider, Recipient, third party) and whether this is required in advance of the Data Transfer (e.g. prepayment vs reimbursement)]

Part II. Sample Protocol Requirements

1. Recipient shall not disclose **Confidential Information**

2. The **Recipient's** rights during the **Embargo Period**:
   i. Recipient may not, without prior approval:
      - use the Data beyond the scope of the Purpose
      - publish the Data
      - transfer the Data to third parties
   ii. Recipient may publish its findings resulting from their use of the Data, subject to Credit, Confidential Information and Data Security, Data Transfer, and Costs requirements
   iii. Recipient may transfer to third parties its findings resulting from their use of the Data, subject to Credit, Confidential Information and Data Security requirements as are applicable to Provider's Data contained therein.

3. The **Recipient's** rights upon expiry of the **Embargo Period** are as per the following permissions and constraints:

i. Except for Restricted Information for which obligations continue as per the Embargo Period, Recipient may use the Data for any purpose subject to the following:
   a. transfer Data to third parties *only if the Data has been published by Provider*, and subject to Credit, Confidential Information and Data Security requirements as may be applicable, including any downstream licensing requirements identified in the Protocol Elements [or otherwise communicated in writing by Provider]); and
   b. Recipient may publish its findings resulting from their use of the Data as per above
   c. Recipient may transfer to third parties its findings resulting from their use of the Data as per above

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Tool 3: Forms to Support Data Sharing

Annex 1 <<PROJECT>> Data Notification Form re Central Register

Provider	[Provider to identify]
Data Manager	[Provider to identify]
Data	[Provider to identify]
Embargo status	[Provider to identify]
Embargo Status Approval (if restricted for publication/transfer)	[name, position, signature]

Annex 2: <<PROJECT>> Data Sharing Request Form

Step 1: Recipient to submit to data owner identified in <<PROJECT>> data catalogue

Recipient	[Step 1: Recipient to identify]
Data	[Step 1: Recipient to identify]
Purpose	[Step 1: Recipient to identify]

Step 2: Provider to respond to Recipient

Provider	[Step 2: data owner to identify in response to data sharing request]
Data	[Step 2: Recipient to identify in data sharing request]
Purpose	[Step 2: Provider to propose in response to data sharing request]
Embargo Period	[Step 2: Provider to propose in response to data sharing request] [include approval if Data transfer/publication is to be embargoed?]
Credit	[Step 2: Provider to propose in response to data sharing request]
Confidential Information	[Step 2: Provider to propose in response to data sharing request]
Data Security	[Step 2: Provider to propose in response to data sharing request]
Data Transfer	[Step 2: Provider to propose in response to data sharing request]
Costs	[Step 2: Provider to propose in response to data sharing request]

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Step 3: Provider and Recipient to negotiate [Cross-CRP] License Re Data-Sharing Protocol for [<<PROJECT>>] on the basis of the information exchanged using this Data Sharing Request Form.

Step 4: If a data sharing request is turned down the data owner will the record reasons for refusal and report to [insert] for information keeping purposes concerning the implementation of the <<PROJECT>> Data Sharing Protocol.

Recipient	[Provider to identify]
Data	[Provider to identify]
Purpose	[Provider to identify]
Reasons for Refusal (if applicable)	[Provider to identify]
[Refusal Approval]	[name, position, signature]

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Tool 4: Template Data Sharing Declaration[3]

<<PROJECT>> Participant Data Sharing Declaration

Background:

- <<PROJECT>> is [insert description and link if relevant]
- <<PROJECT>> Participants agree that [indicate why data sharing is important to achieving the <<PROJECT>> objectives]
- <<PROJECT>> Participants agree to implement a Data Sharing Protocol as a means to fulfilling the objectives of the <<PROJECT>>

To implement the <<PROJECT>> Data Sharing Protocol, <<PROJECT>> **Participants agree to**:

- Implement appropriate institutional **data governance** procedures including: [e.g. adequate PIC/ethics review and mark third party restricted data accordingly]
- Provide adequate **training** to data providers and recipients involved in <<PROJECT>> regarding the Data Sharing Protocol and the Data Sharing License.
- **reciprocate data sharing** in accordance with the ***Data Sharing Protocol (as per Annex x)***

To operationalize the <<PROJECT>> Data Sharing Protocol, <<PROJECT>> **Participants agree to**:

- maintain a **central register** of data sets related to <<PROJECT>> project
- prospective Provider to use <<PROJECT>> ***Data Notification Form (as per Annex x)*** to notify <<PROJECT>> participants of data set availability ([including internal approval for embargo status which restricts transfer/publication])
- prospective Recipient to use <<PROJECT>> ***Data Sharing Request Form (as per Annex x)*** (to be sent directly to Data Manager?) to request data from Provider
- Provider **entitled to refuse request** in following circumstances [e.g. to be exercised in good faith at the discretion of the Provider):

To **resolve disagreements or disputes** that may arise pursuant to the <<PROJECT>> Data Sharing Protocol, <<PROJECT>> **Participants agree to**:

- Procedure for handling disagreements concerning access to data
- Escalation to a third party (non-binding opinion), if requested by a participant).
- Further escalation will be as per Data License

Upon signature of this declaration the following <<PROJECT>> Participant agrees to abide by the above data sharing protocol concerning <<PROJECT>> datasets vis-à-vis all other <<PROJECT>> Participants.

Signed on [insert date] by [insert name, position] as a duly authorized representative of **[insert organization]**: _____

[3] To be used when the core elements underpinning data sharing cannot be built into the contract underpinning the research collaboration (e.g. by explicit reference or annexing template data sharing license to be used by project participants)

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Tool 5: Data License pursuant to [<<PROJECT>>] Data Sharing Protocol

[generic draft developed by Rodrigo Sara (Legal Officer, System Management Office of CGIAR System Organization) and Itzel Saldivar (IP Counsel, CIMMYT]

The data-sharing protocol for the Project (the Protocol) provides a licensing framework to facilitate [cross-CRP] data transfer between Project participants and has been developed having regard to the CGIAR Open Access Policy requirements (and comparable institutional requirements as may apply) concerning CRP related data and publications.

This license comprised of Part I Protocol Elements, Part II Protocol Requirements and Part III General Terms and Conditions constitutes the terms and conditions pursuant to which Project participants have voluntarily agreed to transfer and receive data and is legally binding on Recipient and Provider upon signature.

Part I. Cover sheet Identifying Protocol Elements [and instructions for completion by researchers of Provider and Recipient]

Project	The <<PROJECT>> Project is [insert description]
Provider	[insert name and position] on behalf of [insert legal entity] with registered office at [insert]
Recipient	[insert name and position] on behalf of [insert legal entity] with registered office at [insert]
Data	[insert description of data subject matter]
Data Manager	[insert description of personnel at Provider who is responsible for permissions and queries related to the Data]
Purpose	[State the purpose(s) for which the Recipient is authorized to use the Data (consider what studies will be performed, what questions will be asked and what are the expected outcomes?). If Recipient is permitted to publish Data (or components thereof) or transfer Data to third parties (or components thereof) during Embargo period, this should be explicitly stated (included license terms) otherwise it is prohibited pursuant to Part II(4). Additionally, if there are additional specific requirements concerning the use and management of the data which the Provider must flow down (e.g. policy or regulatory requirements concerning private information of human subjects), such requirements/limitations should also be explicitly stated in the Purpose)]
Embargo Period	Identify the period according to the obligation to make the Data openly accessible as per the timeframes contained in Section 4.2.4 CGIAR Open Access Policy[4]] OR [indicate (i) "Embargo is perpetual: the obligation to make the Data openly accessible pursuant to Section 4.2.4 CGIAR Open Access Policy is not applicable due to…. as approved by….."; (ii) identify the basis on which an exemption applies to the obligation to make the Data openly accessible arises pursuant to the CGIAR Open Access Policy (e.g. due to third party confidentiality requirements or credible risk of privacy breach), AND (iii) identify the source of approval for the exemption (e.g. as approved by the DDG in consultation with Center IP Focal Point]

[4] [Pursuant to Section 4.2.4 of OADM Policy the obligation arises as soon as possible and in any event within 12 months of completion of the data collection or appropriate project milestone, or within 6 months of publication of the information products underpinned by that data, whichever is sooner].

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Credit	[Identify how the Recipient or permitted downstream recipient(s) of the Provider's data must reference or acknowledge the Provider's Data or use of the Provider's Data (if applicable)]
Restricted Information	[Identify specific information, if any, that must remain confidential and should not be disclosed verbally or in writing to an unauthorized third party (i.e. during or after expiry of Embargo Period). Provider should be as specific as possible and flag (i) existence of known sensitive/personal data that identifies individuals; and (ii) safeguards in place to prevent sensitive information from becoming public.] OR [if the Embargo Period Expiry above is identified as "N/A" indicate "Any information embodied in or accompanying the Data identified/marked as restricted third party confidential information or which may disclose the identity of human research subjects"]
Data Security	[Identify any specific requirements, if any, that the Recipient must follow to maintain data security. E.g. if hard copies, are these required to be kept in a locked cabinet or room? If electronic copies, are these required to be password protected or kept on a secure disk? Will all Recipient staff be entitled to same level of access to data, or will some people have restricted access? What kind of password protections need to be put in place? Who will have physical access to the data, including the servers and the paper files? What will happen to the data after the data-sharing period ends?]
Data Transfer	[Identify the manner in which data will be transferred from the provider to the Recipient. Will data be transferred physically or electronically? If data are to be sent over the Internet, is a secure connection required? Will the data be encrypted before being transferred?]
Costs	[Identify any expenses related to the transfer of the data? If so, clarify who will cover the costs of sharing the data (e.g. Provider, Recipient, third party) and whether this is required in advance of the Data Transfer (e.g. prepayment vs reimbursement)]

Part II. Protocol Requirements

4. **Provider** transfers **Data** to **Recipient** as per the definitions contained in the Part I Protocol Elements and subject to the rights and obligations contained in this Part II Protocol Requirements and the Part III General Terms and Conditions below.

5. **Recipient** queries or clarifications concerning the use of the **Data** or any aspect of the Part I Protocol Elements related to the **Data** should be directed to the **Data Manager**.

6. Recipient shall not disclose **Confidential Information** and shall ensure internal controls are in place to restrict access and dissemination to staff and consultants that have been trained in the management of confidential data and this Protocol.

7. The **Recipient's** rights to use and transfer the **Data** and related information during the **Embargo Period** are as per the following permissions and constraints:
   i. **Recipient** may not use the **Data** beyond the scope of the **Purpose** unless approved in writing by the **Provider**;
   ii. **Recipient** may not publish the **Data** unless approved in writing by the **Provider**;
   iii. **Recipient** may not transfer the **Data** to third parties unless approved in writing by the **Provider**;
   iv. Subject to ii above, **Recipient** may publish its findings resulting from their use of the **Data** subject to **Credit, Restricted Information and Data Security, Data Transfer,** and **Costs** requirements as may be identified in the Part I Protocol Elements which are applicable to **Provider's Data** contained therein;
   v. Subject to iii above, **Recipient** may transfer to third parties its findings resulting from their use of the **Data** subject to **Credit, Restricted Information** and **Data Security** requirements as are applicable to **Provider's Data** contained therein.

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8. The **Recipient's** rights to use and transfer the **Data** and related information upon expiry of the **Embargo Period** are as per the following permissions and constraints:
    i. Recipient's rights and obligations regarding **Restricted Information** continue as per the **Embargo Period** otherwise **Recipient** may use the **Data** for any purpose subject to the following:
        a. **Recipient** may transfer Provider's Data to third parties only if the Data has been published by Provider and subject to **Credit, Restricted Information** and **Data Security** requirements as may be applicable, including any downstream licensing requirements identified in the Protocol Elements [or otherwise communicated in writing by Provider]); and
        b. **Recipient** may publish its findings resulting from their use of the **Data** subject to **Credit, Restricted Information and Data Security, Data Transfer,** and **Costs** requirements as are applicable to **Provider's Data** contained therein;
        c. **Recipient** may transfer to third parties its findings resulting from their use of the **Data** subject to **Credit, Restricted Information** and **Data Security** requirements as are applicable to **Provider's Data** contained therein.

Part III. General Terms and Conditions

1. Mutual Obligations: The **Provider** agrees to transfer the **Data** to the **Recipient** and the **Recipient** agrees to use the **Data** as per the Part I Protocol Elements and subject to the rights and obligations contained in the Part II Protocol Requirements and this Part III General Terms and Conditions.
2. Term: The Provider and Recipient shall be bound by the terms of this License until such time as the Data that is the subject of the License is published by the Provider or [3] years, whichever is earlier, provided however that Recipient's obligations concerning Confidential Information survive termination of the agreement.
3. Ownership and IP: This Agreement constitutes a license by the **Provider** to the **Recipient** to use the data solely for the purposes set forth in this Agreement. The **Provider** is the owner of the **Data** and the license shall not be deemed a grant of any intellectual property rights or other rights to use the data for any purpose other than as expressly permitted. The **Recipient** is the owner of the findings resulting from their use of the **Data** and the use of such data by the **Provider** should be the subject of a separate license.
4. Warranty and liability: The **Data** is provided as is without warranty of any sort, expressed or implied, and including without limitation warranties of merchantability and fitness for a particular use. The **Provider** shall not be liable in any manner to the Recipient or any third parties the **Recipient** may distribute the **Data** or to any person whomsoever, for any losses, damages (direct or indirect), costs, liabilities, expenses, claims, or demands resulting from any delays, inaccuracies, errors in the **Data** or its transmission, including, without limitation, loss of profits, business or revenues.
5. Indemnity: The Recipient will indemnify Provider against all actions, claims, demands, proceedings, liabilities or expenses (including all legal and other fees and disbursements) arising from the use of the Data by third parties who have accessed the Data as a result of the **Recipient's** distribution of the **Data**.
6. Data integrity and third party rights: Provider is responsible for conducting appropriate due diligence and communicating to Recipient in relation to any (i) ethics related approvals and/or prior informed consent in relation to the Data if required pursuant to institutional policy or regulatory framework concerning research involving human subjects; (ii) third party rights, including intellectual property rights. The Recipient shall ensure that the **Data** is not misrepresented or displayed in such a way as may create a false or misleading impression as to the source, value or implication of the **Data** or any component thereof.
7. Disputes: Any disagreements between the **Provider** and **Recipient** concerning the interpretation or application of this Agreement will be settled amicably by negotiation [, failing which all disputes arising out of or in connection with this grant shall be finally settled under the Rules of Arbitration of the United Nations Commission on International Trade Law (UNCITRAL) by one or more arbitrators appointed in accordance with the said Rules. To assist in amicable resolution of a despite either party to the License may seek a non-binding opinion from the Legal Office of the CGIAR Consortium (including its successor in title)].

8. Governing Law: This License shall be governed under general principles of law to the exclusion of any national system of law. Such general principles of law shall be deemed to include the UNIDROIT Principles of International Commercial Contracts 2004.
9. Amendment of License: This License may be amended in written agreement signed by both parties.

Signed [insert date] by [insert name, position] on behalf of **Provider**:

Signed [insert date] by [insert name, position] on behalf of **Recipient**: