

DATA ACCESS AGREEMENT TERMS & CONDITIONS

These terms and conditions govern access to the managed access datasets to which the User Institution has requested access.

After the request from the User Institution, IRST will evaluate it and the data access will be granted only after the subscription of a Data Access Agreement form that will include the following definitions and terms and conditions.

Any further details about specific project, dataset or authorization will also be included in the Data Access Agreement form.

Definitions

Authorised Personnel	The individuals at the User Institution to whom IRST grants access to the Data . This includes the User and any other individuals for whom the User Institution subsequently requests access to the Data .
Data	The managed access datasets to which the User Institution has requested access.
Data Producers	IRST and the collaborators responsible for the development, organisation, and oversight of these Data .
External Collaborator	A collaborator of the User , working for an institution other than the User Institution .
Project	The project for which the User Institution has requested access to these Data .
Publications	Includes, without limitation, articles published in print journals, electronic journals, reviews, books, posters and other written and verbal presentations of research.
Research Participant	An individual whose data form part of these Data .
Research Purposes	Research seeking to advance the understanding and state of the art of the specific field of interest.
User	The principal investigator for the Project .
User Institution(s)	The Institution that has requested access to the Data .
IRST	IRCCS Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori" - IRST S.r.l.

Terms and Conditions

1. The User Institution agrees to only use these Data for the purpose of the Project and only for Research Purposes. The User Institution further agrees that it will only use these Data for Research Purposes which are within the limitations (if any) set out in the Project description.
2. The User Institution agrees to preserve, at all times, the confidentiality of these Data. In particular, it undertakes not to use, or attempt to use these Data to compromise or otherwise infringe the confidentiality of information on Research Participants.
3. The User Institution agrees to protect the confidentiality of Research Participants in any research papers or publications that they prepare by taking all reasonable care to limit the possibility of identification.
4. The User Institution agree that in handling this Data it will follow an up-to-date information technology (IT) policy that must include, at a minimum, the following items:
 - a. Logging and auditing of Access to the Data and to the computer network;
 - b. Password protection to computer network and/or strong data encryption;
 - c. Virus and malware protection to computers on the computer network;
 - d. Secure backup procedure.
5. The User Institution agrees not to attempt to identify Research Participants. The User Institution agrees not to link or combine these Data to other information or archived data available in a way that could re-identify the Research Participants, even if access to that data has been formally granted to the User Institution or is freely available without restriction.
6. The User Institution agrees only to transfer or disclose these Data, in whole or part, or any material derived from these Data, to the Authorised Personnel. Should the User Institution wish to share these Data with an External Collaborator, the External Collaborator must complete a separate application for access to these Data.
7. The User Institution agrees that the Data Producers, and all other parties involved in the creation, funding or protection of these Data: a) make no warranty or representation, express or implied as to the accuracy, quality or comprehensiveness of these Data; b) exclude to the fullest extent permitted by law all liability for actions, claims, proceedings, demands, losses (including but not limited to loss of profit), costs, awards damages and payments made by the Recipient that may arise (whether directly or indirectly) in any way whatsoever from the Recipient's use of these Data or from the unavailability of, or break in access to, these Data for whatever reason and; c) bear no responsibility for the further analysis or interpretation of these Data.
8. The User Institution agrees, when applicable, to follow the *Fort Lauderdale Guidelines*¹ and the *Toronto Statement*². This includes but is not limited to recognising the contribution of the Data Producers and including a proper acknowledgement in all reports or publications resulting from the use of these Data.

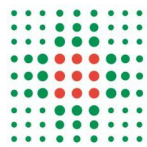
¹ http://www.wellcome.ac.uk/stellent/groups/corporatesite/@policy_communications/documents/web_document/wtd003207.pdf

² <http://www.nature.com/nature/journal/v461/n7261/full/461168a.html>

9. The User Institution agrees to follow this *Publication Policy*:
- User Institution intends to publish the results of their analysis of this dataset and do not consider its deposition into public databases to be the equivalent of such publications. IRST anticipates that the dataset could be useful to other qualified researchers for a variety of purposes. However, some areas of work are subject to a publication moratorium.
 - User Institution respects the moratorium period for the Data Producers to publish the first peer-reviewed report describing and analysing these Data.
 - The publication moratorium covers any publications (including oral communications) that describe the use of the dataset. For research papers, submission for publication should not occur before 6 months after these data were first made available on the relevant hosting database, unless IRST has provided written consent to earlier submission.
 - In any publications based on these data, please describe how the data can be accessed, including the name of the hosting database and its accession numbers, and acknowledge its use in a form agreed by the User Institution with IRST.
10. The User Institution recognizes that nothing in this Agreement shall operate to transfer any intellectual property rights to the Data and agrees not to make intellectual property claims on these Data and not to use intellectual property protection in ways that would prevent or block access to, or use of, any element of these Data, or conclusion drawn directly from these Data.
11. The User Institution can elect to perform further research that would add intellectual and resource capital to these data and decide to obtain intellectual property rights on these downstream discoveries. In this case, the User Institution agrees to implement licensing policies that will not obstruct further research and to follow, when applicable, the U.S. National Institutes of Health *Best Practices for the Licensing of Genomic Inventions (2005)*³ in conformity with the Organisation for Economic Co-operation and Development *Guidelines for the Licensing of the Genetic Inventions (2006)*⁴.
12. The User Institution agrees to destroy/discard the Data held, once it is no longer used for the Project, unless obliged to retain the data for archival purposes in conformity with audit or legal requirements.
13. The User Institution will notify IRST within 30 days of any changes or departures of Authorised Personnel.
14. The User Institution will notify IRST prior to any significant changes to the protocol for the Project.
15. The User Institution will notify IRST as soon as it becomes aware of a breach of the terms or conditions of this agreement.
16. IRST may terminate this agreement by written notice to the User Institution. If this agreement terminates for any reason, the User Institution will be required to destroy any Data held, including copies and backup

³ https://www.icgc.org/files/daco/NIH_BestPracticesLicensingGenomicInventions_2005_en.pdf

⁴ <http://www.oecd.org/science/biotech/36198812.pdf>



copies. This clause does not prevent the User Institution from retaining these data for archival purposes in conformity with audit or legal requirements.

17. The User Institution accepts that it may be necessary for the Data Producers to alter the terms of this agreement from time to time. As an example, this may include specific provisions relating to the Data required by Data Producers other than IRST. In the event that changes are required, the Data Producers or their appointed agent will contact the User Institution to inform it of the changes and the User Institution may elect to accept the changes or terminate the agreement.
18. If requested, the User Institution will allow data security and management documentation to be inspected to verify that it is complying with the terms of this agreement.
19. The User Institution agrees to distribute a copy of these terms to the Authorised Personnel. The User Institution will procure that the Authorised Personnel comply with the terms of this agreement.
20. This agreement (and any dispute, controversy, proceedings or claim of whatever nature arising out of this agreement or its formation) shall be construed, interpreted and governed by the laws of the laws to which the User Institution must comply and by the laws of Italy, and is subject to the exclusive jurisdiction of the courts of of the courts that will be defined by the User Institution and of the courts of Forlì (Italy). The Parties undertake to amicably settle any disputes that may arise from this agreement. In the event of disputes arising between the Parties regarding the interpretation, execution and termination of this agreement, the place of jurisdiction will be the Court of the defendant.