

Synapse Commons Data Sharing Policy

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Introduction	<p>Sage Bionetworks is driving a systems change in data-intensive healthcare research by enabling a collective approach to information sharing and analysis. Sage Bionetworks is building a broadly accessible computational 'Commons' platform where large-scale datasets can be shared and interconnected researchers can jointly develop and evolve informative models of disease.</p> <p>Sage Bionetworks believes that scientific and community-based collaborations are essential for real innovation and that no one academic or commercial entity has the financial or intellectual resources to adequately exploit the current explosion of genetic information. Sage Bionetworks also believes that patients should be fully empowered partners in order to expedite data collection, analysis and application to healthcare advances.</p> <p>Sage Bionetworks acts as steward for the data, tools and analyses available through the Commons and this document summarizes the rules that govern the use of the Synapse Commons.</p>
Definitions	<p>A Data Contributor (“Contributor”) is the original Data producer or depositor who has institutional, funder, and regulatory permission (in each case, to the extent applicable) to provide the Data to the Commons. Contributors can also be individuals who wish to participate in research by submitting their own Data to a collective pool of Data.</p> <p>“Data” is any human or non-human dataset that contains genomic, molecular and/or phenotypic data. A “User” is an individual who has registered with Synapse and has agreed to adhere to all Sage Bionetworks Policies and Terms of Use.</p> <p>The Sage Bionetworks Synapse (“Synapse”) is a computational and storage platform enabling collaborative, data-driven research on integrative genomic datasets. Synapse is composed of both a private and a public environment. The Synapse Commons (“Commons”) is the open, public environment of Synapse, designed to encourage and promote the distribution and collaborative analysis of Data and predictive models of diseases.</p> <p>The Access and Compliance Team (“ACT”) implements Sage Bionetworks’ Data sharing policies and handles requests for access to Data. The ACT is composed of senior Sage Bionetworks staff with relevant scientific, bioethics, and human subject research expertise.</p> <p>The Sage Bionetworks Ethics Advisory Team (“SB-EAT”) is a group of independent experts providing guidance on implementing the Synapse Commons</p>

	Data Access and Use Procedures and on evaluating the ethical, social and policy implications of the Sage Bionetworks Commons.
Access and Use of Data	<p>Access to Data deposited in the Commons will be granted to registered Users for research and training purposes without restriction due to citizenship, affiliation or academic credentials. Sage Bionetworks will record and make available information about Users including name, e-mail address and User-provided intended use of the Data / project description. Sage Bionetworks will also require User agreement to the specific Terms of Use for data access including: the commitment to protect the Data from misuse that could potentially harm, marginalize or discriminate against individuals or populations in insurance, employment or other uses, as well as the assurance that the user will not identify or attempt to identify human participants. When re-distribution is permitted, Users must assure all subsequent recipients comply with identical Terms and Conditions.</p> <p>Access to Data that may confer more than minimal additional risk of harm to human subjects, such as de-identified human genotype data, requires a further institutional certification of User conduct, training and compliance with all laws and regulations governing use of such Data. Access to such Data will be contingent on successful review by the Access Compliance Team. Users and Institutions will be solely and fully responsible for Data use and the consequences of unlawful or prohibited use of the Data.</p> <p>Users can elect to perform Data analysis either within or outside the Synapse Commons computational environment. Analysis conducted within Synapse Commons will be made public. Content posted on the Commons is the responsibility of its contributor. Sage Bionetworks does not guarantee the accuracy, integrity or quality of Synapse content and is not liable for the content posted by non-Sage Bionetworks Staff.</p>
Privacy of Human Study Participants	<p>In order to ensure confidentiality of human study participants, Contributors of Data will only submit de-identified genomic and clinical Data to the Commons as permitted by HIPAA Data Set Regulations. The Data Contributor will remove all identifiable information from the aggregate Data as per HIPAA privacy rule standards for de-identification set forth in 45 CFR 164.514(b) (http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/index.html). Identifiable information must be removed from Data prior to submission in such way that identity of study participants cannot be readily ascertained or otherwise associated with the Data by Sage Bionetworks staff or secondary Data Users. The Data Contributor is responsible for ensuring the ability to link different types of Data pertaining to the same de-identified donor.</p> <p>Synapse Users, including Sage Bionetworks staff, must agree to not use the Data received, alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities or to make contact with any of the</p>

	<p>study participants or their relatives.</p> <p>If requested by the Data Contributor, Sage Bionetworks will further limit risks of identification by generating a dual coding schema and destroying all keys linking the Sage Bionetwork identifiers to the original Contributor's identifier.</p> <p>Access to restricted Data such as human genome-wide DNA variation will only be provided after approval from an Access Compliance Team and the User's agreement with the conditions and Terms of Use determined for each dataset.</p> <p>When human Data is only available through a third party Data repository (e.g. dbGaP, ICGC, etc.), Synapse Users will need to request access directly from the third party. Sage Bionetworks will not redistribute such Data without permission from the Data Contributor or third-party Data repository.</p>
Use of Data by Sage Bionetworks	<p>Sage Bionetworks will abide by the same rules as any other Synapse users. Sage Bionetworks will use Data for research and training purposes in compliance with all applicable regulations and policies including use restrictions, if any, established at time of Data generation via IRB-approved consent forms or terms of use documents provided by the Data Contributor. Sage Bionetworks research may include collaborations with third parties. Such collaborators will be bound by the same restrictions as Sage Bionetworks.</p> <p>It is Sage Bionetworks' policy to make high quality research Data available to the public promptly. When Sage Bionetworks is a co-investigator or a collaborator in a private project, the Data Contributor must agree to deposit the Data into the Synapse Commons within twelve (12) months of project completion. During the Embargo Period, as defined below, Sage Bionetworks and other project collaborators may use the Data for internal research and training purposes but Sage Bionetworks will not post the Data in the public Commons. The "Embargo Period" will extend to the shorter of twelve (12) months from project completion or upon acceptance of a manuscript describing the Data for publication. Following the Embargo Period, Sage Bionetworks will post part or all of the Data in the Commons to the extent permitted by regulations, participant consent and Terms of Use.</p> <p>Sage Bionetworks collaborates on private projects only with assurance that Data will be deposited to the Synapse Commons at the conclusion of the customary Embargo Period.</p> <p>There is no Embargo Period for Data available through publications, public databases, or public disclosure.</p>
Attribution of Data	<p>All users will agree to proper Institution and personal attribution as specified by the Data Contributor as a requirement for continued use of the Synapse Commons.</p>

Intellectual Property	Sage Bionetworks does not claim and will not hold intellectual property rights in the Data, tools, workflows or training materials available through the Synapse Commons
Sage Bionetworks Adaptive Policies	Sage Bionetworks will encourage dialogue and feedback from Users through a web interface where concerns, issues and suggestions can be publicly posted, reviewed and assessed. Sage Bionetworks will perform periodic audits of the Synapse Commons to assess the practices within the analytical environment and to confirm compliance with Data sharing policies where applicable. Results of such audits will be reviewed by the SB-EAT. Sage Bionetworks policies may be modified, supplemented or replaced to address emerging issues based on Users' input, audit results, evolving social and regulatory contexts, or other concerns. Policy changes will be done in coordination with the SB-EAT. New policies and/or amendments will be submitted to Users and Institutions and must be agreed to in order for such Users' and Institutions' continued use of Synapse.
Data Stewardship	Sage Bionetworks maintains strict information technology procedures to safeguard information and data within Sage Bionetworks and to prevent improper access. Data access occurs via a set of web services and client tools that manage authentication, authorization, and log all Data access. This Data ultimately resides on a distributed 'cloud' providing users the option to deploy compute resources without moving the Data to a new location. These services have been developed and reviewed by our cloud provider partners to ensure reasonable security measures are applied to Data access control. Details of the data-hosting architecture are described in the Sage Bionetworks IT policy which is available upon request.
Community Expectation	Underlying the willingness of patients to provide data and of researchers to engage in scientific collaborations is the expectation that all results from data sharing and co-analysis will be published for the benefit of everyone.
Sustainability	In the event that Sage Bionetworks goes through a management or business transition such as merger or closure, the data may be transferred. In such case the data use will remain subject to these Policies and Terms of Use.
Violation Consequences	Intentional or unintentional violation of these Policies and Terms of Use will result in termination of current and future access to the Commons. Any breach of obligations under the Terms of Use will be reported to the User's Institutional official. Sage Bionetworks has no responsibility to Users, Institutions or any third party for the breach or violation by Users. Users and their Institutions will be fully and solely responsible for all breaches, violations and their consequences.

