V3: July 16, 2014

Requesting Access to Controlled Use Data from the Synapse Commons Repository

Data contributed to the Synapse Commons is made available under a tiered system designed to protect the privacy and confidentiality of study participants. The data you requested is labeled Controlled Use Data by its contributor.

To obtain access to these data on Synapse you must fulfill the following requirements:

(1) Maintain an active account on Synapse: http://www.synapse.org
(2) Provide a brief description of your intended use of the data (1-3 paragraphs).
(3) Provide documented proof that your local IRB or ethics committee has approved your proposed data analysis plan (see Appendix).
(4) Provide the list of your collaborators (including name, Synapse ID, primary email address, and institution) who will be accessing these data to perform the proposed research approved by your ethics board.
(5) If your collaborator is from a different institution than the PI on the request, a separate proof of IRB approval has to be provided by that individual's institution.
(6) Agree to comply with any specific data use terms listed below.
(7) Agree to submit an annual data use report describing the progress of the research performed with these data by the approved users during the access period (1-3 paragraphs).

Data access will be granted for one year. You can apply to extend/renew access to these data to complete the approved research.

Please email the required documents for initial data access request or extension/renewal, to the Synapse Access and Compliance Team (ACT) at act@sagebase.org. Following ACT approval, all investigators listed in your application will receive a confirmation email with instructions to log on to synapse and individually confirm their agreement to the specific data use terms.
The PI is responsible for ensuring that annual reports are filed and that all investigators adhere to these terms. Additional investigators may be added to this application throughout the duration of the study by contacting the ACT.

Controlled Data may not be redistributed. Upon completion of the project or termination of data access permissions, users are required to erase all locally stored copies of the data. Any misuse of data will result in termination of access/use privilege to these data on Synapse. In addition, misuse will be reported to both the researcher and their institution.

By using Synapse you agree to the standard Synapse Terms of Use, including to:

- Protect and respect privacy and confidentiality of data and individuals from whom the data was derived.

- Do not discriminate, identify, or re-contact individuals or groups represented by the data.
- Do not redistribute these data to anyone not authorized to use it.
- Keep data secure.
- Abide by all applicable laws and regulations.

More information describing the data governance process is available though Synapse at: https://www.synapse.org/#!Help:Governance . A tutorial is also available at https://www.synapse.org/#!Help:GettingStarted.

METABRIC

Accessing METABRIC data for use in independent research

The METABRIC dataset contains clinical traits, expression profiles, CNV profiles, and SNP genotypes derived from 1981 breast tumors collected from participants of the METABRIC trial. Secondary use of these data is governed by regulations in the countries from which these data originated: England and Canada.

The expression, CNV, and genotype data from METABRIC is considered to contain information that confers more than minimal risk of re-identification and/or harm to human participants. Therefore, this data is considered 'Controlled Data Under Ethics Board/IRB Review' and must be documented and monitored. As such, Synapse offers access through a **controlled access mechanism**.

TERMS OF DATA USE

In order to use the METABRIC data, you must agree to:

- Only use these data in analyses related to **breast cancer research**.
- Acknowledge the data source by including the following citation in any manuscript derived from analyses of these data: Curtis C, et.al. *The genomic and transcriptomic architecture of 2,000 breast tumours reveals novel subgroups.* Nature. 2012 Apr 18;486(7403):346-52.
- Indicate the Synapse repository as the source of the data by including the following sentence in the methods or acknowledgments section of any manuscript derived from analyses of these data: *These data were accessed through Synapse (synapse.sagebase.org)*.
- Report any misuse or data release, intentional or inadvertent to the ACT within 5 business days by emailing act@synapse.org
- Allow public release of your proposed research protocol through Synapse.

APPENDIX: OBTAINING IRB/ETHICAL BOARD APPROVAL

You must obtain approval to use the specific data within your proposed research plan by an ethical governing body (e.g., IRB or ethics committee). Exemption determination from an accredited IRB can be accepted in lieu of a full protocol approval.

Please provide a copy of the IRB approval letter that indicates approval of your plan *for use of this dataset*. If the specific dataset is not explicitly mentioned in the approval letter, please also submit the full application. The ACT will only grant access to researchers who submitted a copy of their IRB/ethics approval letter that explicitly covers use of the requested data within the scope of the submitted data analysis plan.

Example of language to use in an application for ethical review:

We are pleased to submit the following application for your review. This project focuses on analysis of publically available data from the (insert specific data set name) dataset that are available through the Synapse Commons data repository (synapse.sagebase.org), an IRB-approved data repository. The (insert specific data set name) dataset contains (insert specific data set description). The data has been de-identified through use of a code. These data are considered to contain information that confers more than minimal risk of re-identification and/or harm to human participants. Therefore, secondary use of these data must be documented and monitored.

In order to access these data, Synapse requires that (1) users comply with data-specific conditions of use, (2) provide a detailed data analysis plan and (3) that the proposed data analysis plan be reviewed by an independent ethics committee or IRB to ensure that the data will be used in an ethically appropriate manner and that the proposed research protocol is designed to minimize risk of re-identification or harm to the individuals from whom the data is derived

Use of the requested data are restricted to analyses related to (data set specific area of focus e.g. breast cancer or Rheumatoid Arthritis).

I am seeking the opinion of this committee in the form of a formal approval or exemption determination, regarding the appropriateness of using these data within the scope of the data analysis plan described below.

[INSERT BRIEF DATA ANALYSIS PLAN]
