

**Massachusetts Institute of Technology**
Committee on the Use of
Humans as Experimental Subjects

COUHES

**COUHES Protocol #**

**Genomic Data Sharing Submission Certification Request Form**

*Complete this form when data from NIH-funded research is being submitted to an NIH Designated Repository.*

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| I. GENERAL INFORMATION |
| 1. Title of Study*Title must match any existing protocols.*  |
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| 2. Principal Investigator |
| Name:       | Email:       |
| Title:       | Department:       |
| 3. Contact Person: |
| Name:       | Email:       |

**II. Request Type**

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| **1. Indicate the type of data that will be submitted to an NIH Designated Repository**Check all that apply: |
| [ ]  **Prospective Dataset** Dataset that will be submitted comes from participants that have not yet been consented[ ]  **Retrospective Dataset** Dataset that will be submitted comes from participants that have already been consented.*Please submit all consent forms that were used to collect data from participants and IRB approval letter (if applicable)*[ ]  **Not Human Subject Research Dataset** Data was/will be obtained from sources determined to not meet the [definition of a human subject[[1]](#footnote-1)](#Footnote1) |
| **2.** **Data Use Limitations***Indicate if data will be submitted to an unrestricted or controlled access database. Consult with COUHES on what, if any, data use limitations are needed.* |
| [ ]  **Unrestricted access** Data made publicly available to anyone[ ]  **Controlled access\*** Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project |
| *\*If controlled access is selected, select the following uses that should be allowed according to the intent of the study and the consent form. Select all that apply.*[ ]  **General Research Use** Data can be used for any research purpose but would not be made available for non-research purposes[ ]  **Health/Medical/Biomedical** Use of these data is limited to a focus on health/medical/biomedical research objectives, excluding the study of population origins or ancestry[ ]  **Genetic Studies Only** Data can be used only for genetic studies. [ ]  Research on the role of genetics in any disease, condition or non-disease trait[ ]  Statistical methods development research that may have general applications to studying the genetics of different diseases)[ ]  Research relating to population structure, including research that may have applications or implications for the understanding of ancestral history because of the information it may provide about allele frequencies in different populations. [ ]  **Disease-specific** Data can be used only for research on a specific disease or related condition.*Note: When the informed consent documents that allowed the data to be used for future studies related only to a particular disease (e.g., diabetes and related conditions), a disease-specific Data Use Limitation (DUL) would be appropriate.* [ ]  **Methods** Data can be used for statistical methods research and development (e.g., development of statistical software or algorithms). [ ]  **Not-for-profit Use Only** Data can be used only by not-for-profit organizations. *Note: If the data should not be made available to commercial entities, this restriction should be stated specifically in the DUL.* [ ]  **Publication Required** The informed consent of the study participants requires that the investigator requesting the data and his/her institution disseminate the findings of studies using the data to the larger scientific community. [ ]  **IRB Approval Required** If required by the submitting institution’s IRB, approval of secondary research by the requesting institution’s local IRB can be stipulated as part of the DUL.*Note: Documentation of local IRB approval, including a description of the type of review, e.g., full or expedited, would be submitted as part of the data access request which is reviewed by the Data Access Committees (DACs).*  |

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| **3. Data Elements, Risk, and Study Population** |
| 1. Briefly describe the study population that is represented by the dataset (e.g. age of participants, race/ethnicity, disease type and disease prevalence).

Click or tap here to enter text.1. Describe all data fields (genotype and phenotype) that will be submitted to the NIH-designated repository.

Click or tap here to enter text. 1. Will whole genome or whole exome sequencing data be submitted?

[ ]  Whole genome sequencing[ ]  Whole exome sequencing[ ]  N/A1. Describe the method(s) to be used to code data for transmission to the NIH.

Click or tap here to enter text. 1. Describe how the code key(s) will be maintained by the PI.

Click or tap here to enter text.1. Does the data contain information that may be sensitive related to individual privacy or potential for group harm? For example, study populations are isolated geographical regions, small and easily identifiable populations, tribal populations, Native Americans/Alaska Natives, indigenous populations, rare disease communities, potentially stigmatizing traits.

 Click or tap here to enter text. |

**II. SCOPE OF INFORMED CONSENT**

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| **1. Required Elements***Confirm the consent form meets the following criteria. Include the wording from the consent form as well as the page number where it can be found. If the consent form does not meet one or more criterion, explain in the comments section below.* |
| Participation may generate genetic information and/or analysis. | [ ]  Yes | [ ]  Consent form is silent | Click or tap here to enter text. |
| Coded genomic and phenotypic data may be used for future research. | [ ]  Yes | [ ]  Consent form is silent | Click or tap here to enter text. |
| Individual level Genotype and phenotype data will be submitted to a government research database that is broadly accessible to qualified investigators. Safeguards to protect the data will be implemented. | [ ]  Yes | [ ]  Consent form is silent | Click or tap here to enter text. |
| Access to individual level de-identified data will be unrestricted and shared broadly for the use for any research purpose. *OR*The consent form place limitations or other controls on use (e.g. data may only be used for research on a specific disease). | [ ]  Yes | [ ]  Consent form is silent | Click or tap here to enter text. |
| Even if access is controlled and data security standards are met, confidentiality cannot be guaranteed. Re-identified data could potentially discriminate against or stigmatize participants, their families, or others. | [ ]  Yes | [ ]  Consent form is silent | Click or tap here to enter text. |
| There may be unknown risks. | [ ]  Yes | [ ]  Consent form is silent | Click or tap here to enter text. |
| *Please provide any clarification to responses if needed:*Click or tap here to enter text. |
| **2. Re-Consent***If the consent form was silent on any of the elements above, indicate below if there is a plan to seek re-consent.* |
| [ ]  There is a plan to contact participants and request consent of past participants to share data.[ ]  There is NO plan to contact past participants. |

#### III. INSTITUTIONAL CERTIFICATION REQUIREMENTS

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| **INTERNAL USE****For completion by COUHES office***This section is to evaluate whether an investigator’s genomic data sharing plan meets the criteria for submission to an NIH-designated repository.* |
| [ ]  Data submission and subsequent data sharing for research purposes are consistent (or not inconsistent for specimens/cell lines collected/created before 2015) with the informed consent of study participants from whom the data were obtained;[ ]  The protocol for the collection of genomic and phenotypic data is consistent with 45 CFR Part 46;[ ]  Consideration was given to risks to individual participants and their families associated with data submitted to NIH-designated data repositories and subsequent sharing; [ ]  To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing; *and* [ ] The investigator’s plan for de-identifying datasets is consistent with the standards outlined in Section IV.C.1. of the NIH Genomic Data Sharing Policy |

#### IV. CERTIFICATION

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| **I certify the information provided in this application is complete and correct.****I confirm that the code keys will not be shared with the NIH.****As the Principal Investigator, I certify that I will de-identify the data prior to submission:*** **To ensure that the identities of participants cannot be readily ascertained according to 45 CFR 46.102(f);**
* **To strip the data of identifiers according to the HIPAA rule (45 CFR 164.514(b)(2), if applicable.**
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**Signature of Principal Investigator Date**

**Print Full Name and Title**

**Please submit this form and additional documentation by email to COUHES at** **COUHES@mit.edu**

1. According to [45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) , a human subject is "a living individual about whom an investigator conducting research:

	* Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
	* Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." [↑](#footnote-ref-1)