**Additional Standard Language for Informed Consent**

Below is standard or canned language investigators can add when appropriate to their research. Each section includes a brief description of when the language would be appropriate. Please complete the italicized or empty sections with the necessary information.

A Word document of this page is available on the [Forms & Templates](https://couhes.mit.edu/forms-templates) page.

**Participation and Withdrawal Section**

Include the following when participants will be **recruited from MIT**:

*If you are a student or lab member of \_\_\_\_\_\_(PI name), your decision to participate or not to participate will not in anyway influence your grade, funding, or other relationship with \_\_\_\_\_\_(PI name).*

**Procedures Section**

Include the following when your research is **self-experimentation**:

*I am an investigator or key personnel on the above-referenced research study and intend to conduct the procedures as described in the approved protocol and consent form on myself: I am aware that the procedures are considered to constitute research on human subjects. I am performing these procedures on myself voluntarily.*

Include if research procedures involve **randomization**:

*Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group. (OR If the randomization is not equal; then state the odds).*

Include if **focus groups** will occur:

*Although we ask everyone in the group to respect the privacy and confidentiality of participants, and to keep the discussion in the group confidential, we cannot guarantee this. Please keep this in mind when choosing what to share in the group setting.*

**Potential Risks and Discomforts Section**

Include the following when your research involves **MRI procedures:**

*The known risks or side effects associated with conventional MRI procedures are minimal, except for those people who have electrically, magnetically or mechanically activated implants (such as cardiac pacemakers) or those who have intracerebral vascular clips. The greatest risk is of a metallic object flying through the air toward the magnet and hitting you. To reduce this risk we require that all people involved with the study remove all ferrous metal from their clothing and pockets before entering the magnet room. No metal objects are allowed to be brought into the magnet room at any time, unless they are permanently installed. There are no other known risks associated with high-speed MRI. Both the conventional and the high-speed MRI systems have been approved by the FDA and will be operated within the operating parameters reviewed and accepted by the FDA.*

*A magnetic resonance scan is not uncomfortable but if you are prone to claustrophobia (fear of enclosed spaces) you should notify the researcher in charge of the scan. You can expect to hear a knocking sound during the imaging. For loud scanning sequences, ear plugs or headphones will be provided so the sound should not be bothersome. In some cases, it may be necessary to use earphones that provide less sound attenuation, in which case, a quieter scanning sequence will be used.*

*It is important in these studies that you remain motionless. The head holder is reasonably comfortable, and is designed to keep your head immobilized and in a relaxed position. If the head holder is uncomfortable, you should notify the researcher in charge of the scan. You are free to stop the study at any point if for any reason you do not wish to continue.*

Include the following when **simulators** will be used:

*There is a small risk that people who take part will develop what is ordinarily referred to as simulator sickness. It occurs once in a while to people who are exposed to prolonged continuous testing in simulated environments. Symptoms consist of nausea and a feeling of being light- headed. The risk is minimized as a result of the short duration of each session in the simulator. If you experience any of the symptoms mentioned, please tell the researcher and remain seated until the symptoms disappear. You are free to stop the study at any point if for any reason you do not wish to continue.*

Include the following when **virtual reality** will be used:

*Side effects of VE (virtual environment) use may include stomach discomfort, headaches, sleepiness, dizziness and decreased balance. However, these risks are no greater than the sickness risks participants may be exposed to if they were to visit an amusement parks and ride attractions such as roller coasters. You will be given [n]-minute breaks during the exercise to lessen the chance that you will feel sick. If you experience any of the symptoms mentioned, please tell the researcher and remain seated until the symptoms disappear. You are free to stop the study at any point if for any reason you do not wish to continue.*

**Incidental Findings Section**

Include the following when your research includes **MRI procedures**:

*The MRI scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project are not clinicians trained to perform medical diagnoses, and are not responsible for failure to find existing abnormalities.*

*This MRI scan is not a substitute for one a doctor would order. It may not show problems that would be picked up by a medical MRI scan. However, if we believe that we have found a medical problem in your MRI scan, we will ask a doctor who is trained in their reading of MRI scans, a radiologist, to help us review the scan. If the radiologist thinks that there may be an abnormality in your MRI scan, we will contact you and will help you get medical follow-up for the problem. If you have a primary care doctor, we can contact your doctor, with your permission, and help him or her get the right follow-up for you. No information generated in this study will become part of a hospital record routinely. It is possible that you could be unnecessarily worried if a problem were suspected, but not actually found.*

*If your study does not have access to a radiologist, include the following:*

The MRI scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project are not clinicians trained to perform medical diagnoses, and are not responsible for failure to find existing abnormalities. If we find results that could potentially be clinically relevant, we will share with you and advise you to follow up with your primary care doctor. It is your responsibility to follow up with your doctor for further discussion. We {will OR not will} provide you with a copy of the scan.

**Genomic Information Section**

If **whole exome or whole genome sequencing studies** (i.e. sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) will be done, include the following:

*We (may/will) perform a whole genome or whole exome analysis on your sample. Some research involves just studying a few genes that are linked to a disease or condition. In whole genome or whole exome analysis, all or most of your genes are studied and used by researchers to find causes of [signify here whether the sequencing data will be limited to the disease under study and related disorders or "many diseases or conditions"]. [Explain the associated risks such as the risk of re-identification based on a subject’s unique genetic code.]*

***Note if your research is subject to the NIH Genomic Data Sharing policy and submission to dbGaP, please see “Future Data Use” section below for additional language specific to dbGaP.***

If participants can **opt-in/opt-out of genome sequencing** in the research include the following:

*My blood/tissue sample may be used for genetic research in this study.*

 *\_\_\_\_Yes \_\_\_\_ No*

*My blood/tissue sample may be stored/shared for future genetic research in \_\_\_\_\_\_[specify health problems (such as cancer, heart disease, etc.)].*

 *\_\_\_\_ Yes \_\_\_\_ No*

*My blood/tissue sample may be stored/shared for future genetic research without limitations. This means my samples and genetic information will be available for any research question,* such as research aimed at understanding the development and causes of many diseases and conditions or the development of new scientific methods.

 *\_\_\_\_ Yes \_\_\_\_ No*

*Please add your initial and date. Initial \_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_*

Include the following when human DNA is sequenced but not analyzed, such as during **microbial sequencing** of human biospecimens:

*When your samples are sequenced, both microbial sequences and human genetic sequences will be generated. Please be informed that we will not analyze or release any human genetic information. Any human sequences generated as a result of the sequencing technique will be removed before analysis.*

*There is some possibility that someone might be able to use bacterial sequence information to identify close contacts with other people. This is a minor risk, as it is only possible if they have also whole-genome sequenced information about the bacteria from the other individuals that are close contacts. Additionally, certain health and lifestyle information might be theoretically predictable from bacterial composition at various body sites.*

**Future Data Use Section**

Include the following when **genetic information** may be shared or stored in **NIH-supported repositories**:

*In order to allow researchers to share results, the National Institutes of Health (NIH) and other repositories have developed special data databases. Information, including your demographic, phenotypic and genetic information, may be placed into these databases to be used for future research [include if applicable: and to be shared broadly]. No traditionally used identifying information about you, such as your name, address, telephone number, or social security number, will be placed into the database. However, we cannot predict how genetic information will be used in the future. It may be possibly to identify you based on the information in these databases and/or other public information. The risk of this happening is currently very low. In addition, there are many safeguards in place to protect your privacy. Your de-identified, individual-level data may be shared through [unrestricted or controlled] access repositories. [There should be data use limitations considering risks to individual participants, their families, groups or populations associated with data submitted to the databases and subsequent sharing. Access should be limited if data are considered to have particular sensitivities related to individual privacy or potential for group harm. Examples include but are not limited to: study populations from isolated geographical regions, small and easily identifiable populations, tribal populations, Native Americans/Alaska Natives, indigenous populations, rare disease communities, or potentially stigmatizing traits.]*

If the research is **NIH funded and subject to the NIH Genomic Data Sharing Policy**, please include the following information:

*Portions of your de-identified, individual level data and health information will be stored for an unlimited period of time in a database [include database name: such as in the database of Genotypes and Phenotypes (dbGaP )]to be used for future research and to be shared broadly. The data may include:*

1. *Your genomic data: Genomic data is information about a person’s complete DNA. DNA stores messages or codes, which are passed on to future generations.*
2. *Your phenotypic data: Phenotypic data are the observable characteristics about DNA, such as hair color or height.*
3. *Your demographic data such as your age, gender, [include other demographic variables if applicable: ethnicity]*
4. *Your health information such as [your disease diagnosis.]*

When appropriate, include the following passage:

*Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, geographic region, age range, and sex [specify demographic variables]. This information may help researchers study whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.*

Investigator must include one of the following paragraphs regarding data access when the research is NIH funded and subject to the NIH Genomic Data Sharing Policy, either for Unrestricted Access or Restricted Access.

Unrestricted access

*[For data sharing to unrestricted access databases:]Your de-identified, individual level demographic, genomic and phenotypic data and health information will be shared in a database [database name: such as in dbGaP] with unrestricted access. This means that anyone from the public can access and use the data. [For example], the public database will include information on hundreds of thousands of genetic variations in your DNA code, as well as your ethnic group and sex. The only health information included will be whether you had [disease X] or not. This public information will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information from your genome, when combined with information from other public sources could be used to identify you. We believe it is unlikely that this will happen, but we cannot make guarantees.*

Controlled-Access

*[For data sharing to controlled-access databases:]Your de-identified, individual level demographic, genomic and phenotypic data and health information will be shared in a database [ database name: such as in dbGaP] with controlled-access. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to directly identify you. Although the NIH takes measures to protect privacy, we do not know how likely it is that your identity could become re-connected with your genetic and health information. We believe the chance that this will happen is very small, but we cannot make guarantees. Researchers approved to access information in the database will agree not to attempt to identify you.*

In addition, include one of the two following paragraphs regarding access to Genomic Summary Results (GSR):

Genomic Summary Results (GSR) under Unrestricted access

*The genomic summary results from this study will be made available through unrestricted-access. It will be possible for outside researchers to access some summary-level information about all the participants included in a dataset (including you), or across multiple datasets, without applying for permission. This information may be shared through the scientific literature or through other public scientific resources, such as data repositories that provide unrestricted access to the information. Some examples of information that may be shared includes how different genes are associated with different traits or diseases across the many participants in a dataset, or how often certain gene changes are seen across participants from many studies. The risk of anyone identifying you with this information is very low.*

Genomic Summary Results (GSR) under Controlled-Access

*The genomic summary results from this study will be made available through controlled-access. Although researchers will not be able to access information specific to you without permission, some summary-level information about all the participants included in a dataset (including you) may be shared through the scientific literature. Some examples of information that may be shared includes how different genes are associated with different traits or diseases across the many participants in a dataset, or how often certain gene changes are seen across participants. The risk of anyone identifying you with this information is very low.*

Research funded by the NIH that include a **Certificate of Confidentiality,** must include the following passage:

*The privacy protections, and limitations of those protections, afforded by a Certificate of Confidentiality to individual-level data do not apply to summary results.*