**Broad consent is a type of informed consent provided under the revised Common Rule that is intended for the storage, maintenance, and secondary research use of identifiable private information and/or identifiable biospecimens.**

**The following sample is provided as a TEMPLATE from which a broad consent form can be developed. The elements of broad consent can be found at** [**45 CFR 46.116.**](https://www.ecfr.gov/current/title-45/part-46/section-46.116#p-46.116(d)))

**REMINDERS:**

* **Delete all guided text found in red BEFORE IRB submission.**
* **The consent form should be written in 2nd person language comprehensible to the intended subject (age and mental capacity appropriate).** See OHRP for [Informed Consent Tips](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent-tips/index.html).

**TITLE OF RESEARCH PROJECT**

Enter the project title – it **must** match the title used in your online IRB protocol submission.

 **RESEARCH TEAM**

Enter the name, department, and contact information of the PI. If you are a student, also enter the name, department, and contact information of your faculty advisor. List any other members of the research team that the subjects will interact with and/or may approach to ask questions.

**RESEARCH WITH PRIVATE INFORMATION AND/OR BIOSPECIMENS**

*Instructions: Explain to the subject if you will collect identifiable information and/or biospecimens for future research projects. This broad consent will document if they consent for this type of research. Sample language is provided below. Be sure to tailor the language to your specific need – either identifiable information, identifiable biospecimens, or both*.

Example:

Research using personal information and biospecimens (for example, blood or other body tissues) has led to important advances in medicine, science, and other areas.  As explained in this form, we hope to make it easier for researchers to use your information and biospecimens in the future.

When your information and biospecimens can still be linked to you, we say they are “identified” or “identifiable.”  Research with identifiable information and identifiable biospecimens can be even more helpful to science and medicine, because it allows researchers to put together a lot of information about a person and understand even more about conditions and if and how interventions work.  However, research with identifiable information and identifiable biospecimens bears more risk to people’s privacy, and therefore, there are strict rules for this kind of research. When researchers ask you to say “yes” to allow your identifiable information and identifiable biospecimens to be used in a wide range of different types of research studies in the future, **this is called “broad consent,” and it is what we are asking you to agree to in this form.**

**BROAD CONSENT**
This form asks you to decide if you are willing to give your broad consent now to the future research use of your identifiable information and identifiable biospecimens.

If you say “yes,” researchers in the future may use your identifiable information or identifiable biospecimens in many different research studies, over a long period of time, without asking your permission again for any specific study covered by this form.

If you say “no,” researchers in most cases will have to ask your permission to use your identifiable information or identifiable biospecimens in any future research study.

Remember, this form applies only to research with identifiable information and identifiable specimens.  Researchers can always use de-identified health information and de-identified biospecimens for research, without getting any person’s consent and without asking an ethics committee for permission.

Please ask us about anything in this form that you do not understand, and only make a decision if you have had all your questions answered and have had enough time and opportunity to consider whether to agree to give this broad consent.

**INTRODUCTION**

*Instructions: Let the subjects know they are about to give information or biospecimens about themselves for research purposes.*

Example:

[Name of Lab, PI, and/or Institution] will store and maintain your identifiable information and/or identifiable biospecimens for future use, and may do so for the purpose of medical, scientific, and other research now and into the future, for as long as they are needed for this purpose [or specify a shorter period].  If you say “yes” and give your broad consent in this form, we may share your identifiable information and/or identifiable biospecimens with other research, academic institutions, medical institutions, other researchers, drug and device companies, biotechnology companies and others.

**PURPOSE – GENERAL DESCRIPTION OF RESEARCH**

*Instructions: Provide an explanation of the purposes of the research and potential future uses in non-technical language.*

Example**:**

If you say “yes” in this form, there are no plans to tell you about any of the specific research that will be done with your identifiable information and/or identifiable biospecimens. Possible future research may include, for example:

* Studying the causes and progression of different diseases and conditions
* Developing and testing methods to diagnose and treat different diseases and conditions
* Long-term studies on education
* Whole genome sequencing (meaning that your entire personal genetic code will be identified)
* Specific genetic research looking at diseases and medical conditions that are passed on in families and among populations larger than families
* Research that includes changing the genes in cells or putting human cells into animals
* Research about drug abuse and alcoholism diagnosis and treatment
* Research about mental health diagnosis and treatment
* Research about developmental disabilities

**DURATION**

*Instructions: Provide the expected duration for participation to collect the identifiable information and/or biospecimens from the subject. Explain to the subject the period of time for storage/maintenance of the identifiable information and/or biospecimens.*

**PROCEDURES**

*Instructions: Provide a description of the procedures to be followed by the subjects during the research study.*

Example:

The procedures which will involve you as a research subject include:

1.
2.
3.

**POSSIBLE BENEFITS**

*Instructions: Describe any benefits to the subject that may be reasonably expected. If the research is not of direct benefit, explain possible benefits to others or contribution of knowledge to society. Compensation in any form is not to be listed as a benefit (including classroom credit).*

Example:

You will not personally benefit from saying “yes” in this form. Research with your identifiable information and/or identifiable biospecimens may help others by improving our understanding of health and disease, improving health care and making safer or more effective medical therapies, and developing new scientific knowledge.

**COMMERCIAL PROFIT**

If you say “yes,” your identifiable information and/or identifiable biospecimens may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are [no plans] [or insert plans] to tell you, or to pay you, or to give any compensation to you or your family.  Most uses of biospecimens or information do not lead to commercial products or to profit for anyone.

**ALTERNATIVES TO BROAD CONSENT**You are free to say “no” to the use of your identifiable information and identifiable biospecimens.  Saying “yes” to this broad consent is voluntary.

If you say “yes” now, you can later change your mind, but there are some limits. If you change your mind, contact [Name or office] at [Phone Number].

If you later withdraw your broad consent, [Name of Lab, PI, and/or Institution] will not begin new research uses of your identifiable information or identifiable biospecimens, but those specimens will continue to be used in studies that started before you changed your mind. If your identifiable information and/or identifiable biospecimens have already been given to another researcher, person, institution, or company, it may not be possible to limit their continued and new uses.

If you change your mind, [Repository/Biobank/Institution/Institutional Department or Division] [may de-identify your information and biospecimens and use them in the future] OR [will not use your identified or de-identified information and biospecimens for future research].

**POSSIBLE RISKS/DISCOMFORTS**

*Instructions: Describe any foreseeable risks and/or discomforts to be expected as a result of participating in this research study. Specify safeguards in place to minimize potential risks and add a statement explaining that the subject has the right to discontinue any or all procedures at any time at no consequence should they experience any discomfort. If there are no perceived risks and/or discomforts, state as such. The language provided below is an example for broad consent, but be sure to describe other potential risks (physical or psychological) as applicable to your study.*

Example:

A risk in saying “yes” to broad consent is that your privacy could be violated. We will do our best to protect your information from going to people who should not have it, including removing information that could be used to easily identify you. The risk that your identifiable information and/or identifiable biospecimen will go to someone who should not get it is very small.

Another risk is that if you say “yes,” your identifiable information or identifiable biospecimens could be used in a research project to which you might not agree, if you were asked specifically about it.  The examples listed above should give you a good idea of the kinds of research projects that might be done.

**COMPENSATION**

*Instructions: Specify the type and amount of compensation offered for participation, if any (such as money, gift, or extra credit), and when subjects can expect to receive it. If no compensation will be offered for participation in this study, state as such. Also, please add the statement below to all consent forms with financial compensation:*

“The Internal Revenue Service (IRS) considers all payments made to research subjects to be taxable income. Your personal information, including your name, address, and social security number, may be acquired from you and provided to UT Arlington’s accounting office for the purpose of payment.  If your total payments for the year exceed $600.00, UT Arlington will report this information to the IRS as income and you will receive a Form 1099 at the end of the year. If you receive less than $600.00 total for payments in a year, you are personally responsible for reporting the payments to the IRS.”

For studies that involve **physical risks,** such as biomedical research studies, include the following statement about compensation for research injuries:

It is important that you report any illness or injury to the research team listed in this form immediately. Compensation for an injury resulting from your participation in this research is NOT available from The University of Texas at Arlington. In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you retain your legal rights during your participation in this research.

**VOLUNTARY PARTICIPATION**

*Instructions: Specify that participation in this research study is voluntary and subjects are free to withdraw consent and to discontinue participation at any time without penalty. If compensation is affected by withdrawal from the study, specify as such.*

Example:

Participation in this research study is voluntary. You have the right to decline participation in any or all study procedures or quit at any time at no consequence. Should you choose not to complete all study procedures, you will still receive (compensation type/amount).

**RETURN OF RESULTS**

*Instructions: Unless the subject or legally authorized representative will be provided details about specific research studies, insert a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information and/or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies. Also, unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, please insert a statement that such results may not be disclosed to the subject*

Example:

Because this is a broad consent, there are no plans to tell you about any specific research studies that might be done with your identifiable information or identifiable biospecimens, and there are no plans to give you any results from these studies.

Most tests done on biospecimens in research studies are only for research and have no clear meaning for health care.  If future research with your identifiable information and/or identifiable biospecimens gives results that do have meaning for your health, the researchers may – but are not required to – contact you to let you know what they have found.  If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results.   If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

**CONFIDENTIALITY**

*Instructions: Describe the extent to which confidentiality of records identifying the subject will be maintained. Include information regarding video/audio recordings as well. The following template language in the example below should be used and completed as applicable to this research study.*

Example:

If you say “yes” in this form, we may share your identifiable information and/or identifiable biospecimens with researchers in the future, as described above.  We may also share your identifiable information with regulatory authorities that oversee research, including the Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP), and with committees and people here at [institution/entity] and in other places whose job is to review and oversee research.

Every attempt will be made to see that your study results are kept confidential. A copy of this signed consent form and all data collected [including transcriptions/tapes if applicable] from this study will be stored at UTA for at least three (3) years after the end of this research. The results of this study may be published and/or presented at meetings without naming you as a subject. Additional research studies could evolve from the information you have provided. Your records will be kept completely confidential according to current legal requirements. They will not be revealed unless required by law, or as noted above. The IRB at UTA has reviewed and approved this study and the information within this consent form. If in the unlikely event it becomes necessary for the Institutional Review Board to review your research records, the University of Texas at Arlington will protect the confidentiality of those records to the extent permitted by law.

**FOR ALL NIH FUNDED STUDIES:** Please include the following additional text regarding the new NIH policy on Certificates of Confidentiality:

“To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, we can’t be forced by a court order or subpoena to disclose information that could identify you in any civil, criminal, administrative, legislative or other proceeding. However, there are circumstances where the Certificate does not protect against disclosure of your personally identifiable information:

- when the US government is inspecting or evaluating federally-funded studies;

- when information must be disclosed to meet FDA requirements;

- if you give someone written permission to receive research information, or if you voluntarily disclose your study information;

- if the researcher reports that you threatened to harm yourself or others;

- in cases of child abuse or elder abuse reported by the researcher;

- if the investigator reports cases of contagious disease (such as HIV) to the state.”

**CONTACT FOR QUESTIONS**.

Questions about this research study may be directed to [Researcher/Faculty Advisor name and contact information]. Any questions you may have about your rights as a research subject or a research-related injury may be directed to the Office of Research Administration; Regulatory Services at 817-272-3723 or regulatoryservices@uta.edu.

**CONSENT**

*Instructions: If the subject is 18 years of age or older and capable of consenting on their own behalf, this paragraph should be used.*

As explained above, the law allows de-identified information and/or de-identified biospecimens to be used without permission.  Therefore, this form is asking only about the future use of your identifiable information and/or identifiable biospecimens.

If you give a definite and clear “Yes” or “No” to this broad consent, then researchers now and in the future will have a clear idea about what they are allowed and not allowed to do with your identifiable information and identifiable biospecimens.  Not giving any answer will also have implications, as described below.

**IF YOU SAY “YES”**

* Your identifiable information and identifiable biospecimens will be stored, used, and shared for the kinds of future research described in this broad consent form without anyone asking your permission for each new study.
* Identifying information may also be removed from your information and biospecimens, allowing them to be used for any future research or other purpose.

**IF YOU SAY “NO”**

* The researchers and institutions identified above will not store, use, or share your identifiable information and/or identifiable biospecimens for the research described in this broad consent form.
* [However, identifiers may be removed from your information and biospecimens, allowing them to be used for any future research or other purpose.] OR [The researchers and institutions identified above will not use your de-identified information and biospecimens for future research.]
* Researchers could come to you again in the future and ask to store, use, and share your identifiable information or biospecimens for research.

**IF YOU DO NOT SAY “YES” OR “NO”**

* If you do not mark “yes” or “no” on this form (if you do not return it, or leave it blank), then it will be the same as if you were never asked to make a choice.
* This means that your identifiable information and/or identifiable biospecimens may be used for future research if:
	+ The researchers ask you to say yes to a specific research study, and you agree.
	+ An IRB allows your identifiable information and/or identifiable biospecimens to be used in a study that is low risk to you without asking for your consent.
	+ Another legal exception applies.
* Identifiers may be removed from your information and biospecimens, allowing them to be used for any purpose.
* Researchers could come to you in the future and ask for your broad consent again.

**Please check either “YES” or “NO” by the box below and sign your name after the check boxes.**

[ ]  I say **YES**. The broad consent has been explained to me, and I agree to give my broad consent to the future research uses of my identifiable information and/or identifiable biospecimens. My participation is voluntary, and I may withdraw at any time without penalty or loss of benefits to which I am entitled.

[ ]  I say **NO**. The broad consent has been explained to me, and I **do not agree** to this broad consent.

**As a representative of this study, I have explained the purpose, the procedures, the benefits, and the risks that are involved in this research study:**

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**Signature & Name of Research Team Member Conducting Consent Process DATE**

**CONSENT**

By signing this form, you are confirming that you understand the study’s purpose, procedures, potential risks, and your rights as a research subject. By agreeing to participate, you are not waiving any of your legal rights. You can refuse to participate or discontinue participation at any time, with no penalty or loss of benefits that you would ordinarily have. Please sign below if you are at least 18 years of age and voluntarily agree to participate in this study.

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**SIGNATURE OF VOLUNTEER                                                               DATE**

*\*If you agree to participate, please provide the signed copy of this consent form to the research team. They will provide you with a copy to keep for your records.*