HIPAA drop-in language for consent

Will health information about you be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing [*add name of investigator or student/faculty*] and his/her research team to create, get, use, store, and share protected health information that identifies you for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your medical record that is needed for the research and that specifically includes:
[Modify the list below to specify all elements of health information that may be accessed, used or disclosed for research purposes. Add to the list below any additional elements, as applicable. Delete from the list any elements that do not apply.]

- Personal identifiers (your name, address, phone number, date of birth, social security number, medical record number), dates of service, and demographic information (race, gender, ethnicity, age)
- Results of physical examinations
- Medical history
- blood tests, x-rays and other diagnostic and medical procedures (being as specific and detailed as is necessary)
- certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices
- Billing information
- HIV testing results
- Substance Use Disorder information: [Specify.]
- Mental Health information: [Specify.]
- Genetic Testing information: [Specify.]
- Genetic Counseling information
- Sexual Assault/Abuse
- Domestic Abuse of an Adult with a Disability
- Child Abuse and Neglect
- Sexually Transmitted Illnesses (Minors)
- Pregnancy (Minors)
- Birth Control (Minors)

During the conduct of the research, the researchers may use or share your health information:
[*delete any bullets that do not apply to your research*]

- With each other and with other researchers involved with the study.
- With law enforcement or other agencies, when required by law.
- With the sponsor/funding agency of the research, *[sponsor's/funding agency's name]* [*if applicable add, "and its agents or contractors", listing specific names, if known (i.e. CRO)*], as required to conduct the research and/or confirm the results of the research.
- With non-UIC collaborators of the research study: [*insert the name(s) and affiliation (institution) and/or location of the collaborators*].
- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- United States Government Regulatory Agencies, including but not limited to the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA).
- [*List any other groups with whom the information may be shared*].

If all information that identifies you is removed from the research data, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

During your participation in this research, you will not have access to the research records or information that is not usually kept in your medical record. However, this information is available to your doctor in the case of an emergency. The researcher may provide you with access to the research records or information related to this research once the study is done.

How will your health information be protected?

The researchers [*and (sponsor's name)*] agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, unless permitted by laws that they have to follow.

Your Authorization for release of health information for this research study [*insert either: "does not have an expiration date" OR "expires at the end of the study"*], but can be canceled sooner if you decide to withdraw your permission.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to: [*Principal Investigator name and address*].

If you cancel this Authorization, you may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

Right to Refuse to Sign this Authorization

You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

[The following is to be incorporated into the "Signature of Subject or Legally Authorized Representative" section]

If you have not already received a copy of the Notice of Privacy Practices, you should ask for one.

Your signature below indicates that you are providing both consent to participate in the research study and authorization for the researcher to use and share your health information for the research.

_____ _____

Signature of Subject Date

[*If someone other than the subject will be providing authorization for the subject, the following signatures/information must be added to the signature area of the combined consent/authorization form instead of the parent guardian signature lines used for the consent template in order to meet both the consent and HIPAA regulations.]*

_____ _____

Signature of Parent / Guardian or Legally Authorized Representative of Subject

Date (must be same as Subject's)

Printed name of Parent / Guardian or
Legally Authorized Representative of
Subject

Describe relationship to subject including the legal authority this individual has to act on behalf of the subject. (Check one below)

☐ Parent
☐ Medical Power of attorney/representative
☐ Legal guardian
☐ Health care surrogate
☐ Other; specify

_____

_____

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[*OPTIONAL --- If all subjects will be physically able to provide consent/authorization, the witness signature section is not needed for authorization. A witness' signature is only required under HIPAA when the research subject is physically unable, for any reason, to sign the authorization document. The witness is attesting that the research subject is providing authorization in some manner other than signing the document. If you do not anticipate any subjects in this condition, then delete the witness lines*. *However, if a witness signature is required for the consent process for a different reason (i.e. witness to subject signing consent document, witness to consent process), there should be a statement above the signature line indicating what the witness is attesting to with their signature.]*

Signature of Witness Date (must be same as Subject's)

Printed name of Witness

Describe why a witness signature is required and the relationship to the Subject.

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