**Waiver of Informed Consent**

* Consent may be waived for *part or all* of a study.
* Non-exempt research: Informed consent from each participant is always required by federal regulations, UNLESS an IRB grants a waiver of the required consent.
* Exempt research: consent or its waiver are NOT required for research that meets an exempt category.
* Federal regulations stipulate criteria that must be met in order for an IRB to grant a waiver.
* Use the *Waiver of Assent* form for children who are participants (and this form for the parents, if applicable).
* Need help? Call (559)450-7790

**Waiver of Informed Consent** *No consent will be obtained for*

*part or all of the research*

**Adult Participants**

**Title of Research Project:**

1. Indicate ALL the study components that you are requesting a **waiver of informed consent** for:

**[ ]** A part of the study:

**[ ]** The entire study

**[ ]** Parental permission for an OHRP-regulated study

**[ ]** Planned emergency research**\*** (under 21 CFR 50.24)- contact the Research Compliance Dept for a different form.

**[ ]**  Screening, recruiting or determining eligibility for an **OHRP** regulated study *(HIPAA regs may also apply)*, provided that either of the following conditions are met: ***Choose one***

**[ ]**  The investigator will obtain information through oral or written communication with the prospective participant or legally authorized representative – *you are finished with the form; complete the separate Waiver of HIPAA form.*

**[ ]**  The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens – *you are finished with the form; complete the separate Waiver of HIPAA form.*

**[ ]** None of the above are true- *Please continue to the next question.*

**[ ]** Screening for eligibility criteria or contact info in the medical record for an **FDA**-regulated\* study (safety and effectiveness of FDA regulated products; drug, device or biologic)**—STOP**, *the FDA does not consider this to be research, so you do not need to request a waiver for this step of your research; however, the HIPAA regulations may still apply. Note: Screening in the medical record for other reasons and screening tests/procedures that are performed solely to determine eligibility are considered research and informed consent from each participant is required.*

**\*Note: *For FDA-regulated drugs, devices, or biologics,*** *consent may only be waived**in limited circumstances-- for**emergency use of a**test article (21 CFR 50.23) or for planned emergency research (21 CFR 50.24). In planned emergency research, a waiver cannot be granted for pregnant women or those people meeting the regulatory definition of a prisoner.*

1. Are you requesting a waiver of consent to look at mental health, substance use disorder, or social services information/records or to look at HIV or AIDs or AIDS-Related Complex status?

**[ ]** No

**[ ]** Yes - please be aware of the following:

* *Under California law (and some other states’ laws),* ***HIV status*** *may not be accessed or used for research purposes without the individual's written permission for a specific research use. You must consent each participant, therefore you may not use this form to request a waiver of consent or HIPAA.*
* ***Substance abuse*** *Federal laws allow you to waive consent if the identifiable information will not be released to anyone outside of Trinity Health or re-disclosed to anyone. Researchers must maintain and destroy patient identifying information in accordance with Federal substance abuse laws.*
* *Information in the California record of a recipient, and other information acquired in the course of providing* ***mental health*** *services to a recipient:* *The individual who is the subject of the information shall not be identified in the disclosed information unless the identification is essential in order to achieve the purpose for which the information is sought or if preventing the identification would clearly be impractical, but not if the subject of the information is likely to be harmed by the identification.* ***Psychotherapy notes*** *may not be accessed in California unless prior consent is provided by the subject.*

**Choose one of the following two options in order to request a waiver of informed consent**

**for OHRP-regulated research (see 45 CFR 46.116):**

**1st Option:** *(a-e must be answered in order for a waiver to be granted)*

a) Why is it not possible or practical to obtain the required informed consent for each participant?

b) Explain why the research involves no more than minimal risk\* to the participants:

 **[ ]** Retrospective chart review portion of the study where all of the data already exists at this time

**[ ]**  Other- please describe:

*\*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

c) Explain why the waiver will not adversely affect the rights and welfare of the participants:

*(i.e., describe the plan to protect the confidentiality of the information to be collected; explain why the info being sought is important enough to justify invasion of privacy without the participants' consent to do so; etc.)*

d) State why the research could not practicably be carried out without identifiable private information or identifiable biospecimens in an identifiable format:

e) ***If appropriate,*** will the participants be provided with additional pertinent information after participation?

**[ ]** No, the research team will not interact with the participants (i.e., retrospective chart)

**[ ]**  Other- please describe:

***OR***

**2nd Option:**

a) A demonstration project or research that is designed to study, evaluate, or otherwise examine (*identified as a demonstration project meeting 45 CFR 46.116(e) by the sponsoring federal department or agency)*:

 **[ ]** Public benefit or service programs;

 **[ ]**  Procedures for obtaining benefits or services under those programs;

 **[ ]**  Possible changes in or alternatives to those programs or procedures; ***OR***

 **[ ]** Possible changes in methods or levels of payment for benefits or services under those programs;

b) The demonstration project or research will be conducted by or subject to the approval of state or local government officials [see 45 CFR 46.116(e)]. Please describe how your study meets this definition and provide evidence:

c) Describe why the research or demonstration project could not practically be carried out without the waiver or alteration of consent:

*NOTE: If you intend on accessing the medical record, you will need to also request a waiver of HIPAA Authorization. The PI's signature is not required for a waiver of informed consent.*

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| **Please return this completed form via e-mail to:** irb.irb@samc.com |