**Study Title:** ***Click here to enter text.***

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|  | Institutional Review Board  **WAIVER OF ASSENT**  Return to the Office of Research Integrity  1055 N. Curtis Road  Boise, ID 83706  Phone: (208) 367-8897  Phone: (208) 367-2233  [Nancy.Heaton@saintalphonsus.org](mailto:Kimberly.garst@saintalphonsus.org) |
| Confidential pursuant to Idaho Code |

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| Date of Application: Click here to enter a date. | IRB Number if known: Click here to enter text. |

Study Title:Click here to enter text.

*PRINCIPAL INVESTIGATOR (PI) INFORMATION: Please provide information about the person legally responsible for the conduct of the research. The Office of Medical Affairs must be assured that the investigator can personally oversee the conduct of the research and the protection of human subjects. {21 CFR 56.102(h)}*

**Principal Investigator Contact Information:**

Name: Click here to enter text.

Mailing Address:Click here to enter text.

|  |  |  |
| --- | --- | --- |
| Phone:Click here to enter text. | Fax:Click here to enter text. | Email:Click here to enter text. |

* Assent may be waived for part or all of a study.
* Assent from a child participant should be gained for non-exempt research, unless there are reasons for not doing this such as the child's age or psychological state is such that he or she would not comprehend verbal or written assent; the criteria for a waiver of assent is met; and other reasons.
* This form is the method to request that assent not be required or be waived.
* Note that HIPAA authorization (permission) is always required by federal regulations when a researcher wishes to access a participant's medical record or in the use and disclosure of protected health information (PHI) to conduct research, unless an IRB/Privacy Board grants a waiver of this required authorization. See the Waiver of HIPAA Authorization form to request this.
* Need help? Call (208) 367-8897 or (208) 367-2233

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| **Waiver of Informed Assent**  **for Child\* Participants** | ***No assent will be obtained for part or all of the research*** |

**\*Child: less than 18 years of age**

Indicate the study components that you are requesting that assent not be required for:

Screening for eligibility criteria in the medical record for an OHRP (non FDA) regulated study

(Screening is considered research; 45 CFR 46.116 applies. HIPAA regulations may also apply)

A part of the study: Click here to enter text.

The entire study

Planned emergency research (under 21 CFR 50.24) – contact the Research Integrity Office for a different form

A waiver of assent cannot be granted for research that includes child participants who meet the regulatory definition of a prisoner (juvenile). Will your research involve the participation of prisoners?

Prisoner status will not be known

No prisoners will participate (prisoner status known)

Yes – ***STOP***, a waiver can only be granted for those participants in the study that are not prisoners.

If yes, describe how you will differentiate between child participants that are prisoners and those that are not, so that juvenile prisoners may be assented:

Click here to enter text.

Are you requesting a waiver of assent to look at mental health records or to look at HIV status?

No

Yes – ***STOP*** –HIV status and mental health records may not be accessed or used for research purposes without the individual's written permission for a specific research use. You must assent each participant.

If yes, describe how you will differentiate between child participants that are prisoners and those that are not, so that juvenile prisoners may be assented:

Click here to enter text.

Indicate if any of the following apply:

Some or all of the children are not capable of understanding the proposed study or the assent (either written or verbal). This could include age, maturity, psychological state, limited capacity:

All of the children – this completes this form. The IRB will review this request.

Some of the children – continue to the waiver section, below, if you wish to request a waiver for the remaining child participants.

Research or study procedure or monitoring procedure holds prospect of direct benefit that is important to the child's health or well-being and is only available in the context of research (requesting that assent not be required; no need to request a waiver of assent below) – this completes this form. The IRB will review this request.

***All questions must be answered in order for a waiver to be granted***

1. Explain why the research involves no more than minimal risk\* to the child participants:

Retrospective chart review where all of the data already exists at this time

Other – please describe: Click here to enter text.

* *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.*

1. Explain why the waiver will not adversely affect the rights and welfare of the child participants:

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

Click here to enter text.

1. Why is it not possible or practical to obtain the required assent:

Click here to enter text.

1. If appropriate, will the child 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: Click here to enter text.

***NOTE: Studies that involve children require parental permission to be obtained from one or both parents, unless a***

***waiver is requested by the Investigator conducting OHRP-regulated research and an IRB grants the request.***

Click here to enter text.

**Principal Investigator (Typed/Printed Name)**

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** Click here to enter a date.

***Principal Investigator's Signature Signature Date***

***Please visit the IRB website for all of your resources and forms at*** <http://www.saintalphonsus.org/forms-and-resources>