**CERTIFICATE OF CONFIDENTIALITY**

**INFORMATION SHEET**

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality related to participation in this study. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below:

Include any of the following as applicable to the research study:

* If we learn about current or ongoing child [or vulnerable adult] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

Or

* An exception to our promise of confidentiality is when we in good faith are required or permitted by law or policy to report evidence of child [or vulnerable adult] abuse or neglect.

Or

* We will not ask you about child [or vulnerable adult] abuse, but if you tell us about child [or vulnerable adult] abuse or neglect, we may be required or permitted by law or policy to report to authorities.
* [Describe any other limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover drug use or other sensitive information (refer to Reportable Disease Rule for information about Minnesota’s communicable disease reporting rule), explain that this information may be disclosed to appropriate authorities.]

If you have questions about the Certificate of Confidentiality, contact the study team:

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| Investigator Name:Phone Number:Email Address: | Study Staff (if applicable):Phone Number:Email Address:  |