Valparaiso University
Institutional Review Board (IRB)

Waiver of Informed Consent

For research that is no more than minimal risk, the IRB may approve a request to waive some or all of the required elements of informed consent under specific circumstances. Waivers of informed consent are primarily requested for projects involving the secondary analysis of existing data or in projects involving deception. To waive in total or to alter informed consent elements, the IRB must determine that:

- The research involves no more than minimal risk to subjects;
- The research could not be carried out practicably without the waiver;
- The waiver will not adversely affect the rights and welfare of the subjects;
- Where appropriate, the subjects will be provided with additional information about their participation (i.e., a debriefing will be conducted for participants involved in research that uses deception); and,
- If the research involves identifiable private information or identifiable biospecimens, this research could not be carried out practicably without using the information/specimen in an identifiable form.

PI Name: _____

Date: _____

Protocol/Project Name: _____

This protocol meets the requirements listed above regarding a waiver of informed consent because [check all boxes that apply]:

- ❑ Research poses minimal risk
- ❑ Research could not be conducted without a waiver
- ❑ The waiver will not adversely impact the human subjects
- ❑ A debriefing will be conducted because the protocol involves deception
- ❑ Private information must be used in its identifying form

Explanation: _____
_____
_____
_____

IRB Determination (Date:_____)

❑ A Waiver of Consent is Granted ❑ A Waiver of Consent is Not Granted and Consent Must be Obtained

Explanation: _____
_____
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_____

Valparaiso University
Institutional Review Board (IRB)
Waiver of *Documentation* of Informed Consent

For some research projects, the IRB may approve a request to waive the *documentation* of informed consent. The PI/research team must provide subjects with the required consent information, but are not required to obtain the subject's signature on the informed consent document. Subjects should be offered a copy of the consent information for their records. A waiver of *documentation* is permissible when:

- The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of confidentiality; o**r**
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online.
- Where the participants are members of a cultural group in which signing forms is not a normal/acceptable practice.

PI Name: _____

Date: _____

Protocol/Project Name: _____

This protocol meets the requirements listed above regarding a waiver of informed consent because [check all boxes that apply]:

- ❑ Signature links the subject to the research and poses a breach of confidentiality
- ❑ Written consent is not normally required
- ❑ Signing forms is not a cultural norm

Explanation: _____
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_____
_____

IRB Determination (Date: _____)

☐ A Waiver of Documentation is Granted

☐ A Waiver of Documentation is Not Granted and Signed Consent Must be Obtained

Explanation: _____
_____
_____
_____