Lourdes University Institutional Review Board

REQUEST TO WAIVE DOCUMENTATION OF INFORMED CONSENT

Explanation: In certain circumstances an IRB may approve a consent procedure that waives the requirement to obtain the participant's signature on a consent form. If you feel that a waiver of the requirement to document informed consent may apply to your study, please check the appropriate box(es) and provide details. Source: 45 CFR 46.117(c)

IRB #_____ Research Title_____

Investigator_____Faculty Advisor _____

1. **Which consent process would be affected by the waiver of informed consent documentation?**

I am requesting a waiver of the requirement to obtain a signed consent/permission/assent form for the following participants (check all that apply)

☐	Adult informed consent
☐	Adults who lack consent capacity
☐	Parental permission
☐	Child/minor assent

2. **In order to grant a waiver or alteration of informed consent, the IRB must review your answers to the following 3 questions. Please answer each question by checking the appropriate box.**

1. The entire consent (or elements thereof) was waived under 45 CFR 46.116(d). I have completed a *Request to Waive Informed Consent Requirements Form*		**Yes** ☐		**No** ☐
2. The only record linking the subject and the research is the consent document, and the principal risk is potential harm resulting from a breach of confidentiality. Subjects are asked whether they want documentation linking them to the research, and their wishes will govern. .		**Yes** ☐		**No** ☐
3. The research involves no more than minimal risk of harm and involves no procedure for which written consent is normally required outside of the research context.		**Yes** ☐		**No** ☐

3. **If you have checked "Yes" to at least one of the 3 previous statements, in order to receive the waiver, you must describe the reason(s) why the waiver is necessary. Provide details: provide reasons for the waiver and alteration and (b) explain whether the entire informed consent is being waived or only certain elements are being waived. Provide details:**

Submission instructions: Include the completed form in the Application document

If a waiver is granted under the previously mentioned conditions, documentation of informed consent (i.e. signed consent form) is also waived. Even if the waiver is granted, the IRB may require other conditions. The IRB may require the researcher to provide subjects with an information sheet (written summary) about the research.

Form is adapted from the University of Chicago Office for Protection of Research Subjects and Bankert, E.A. and Amdur, R. J., *Institutional Review Board: Management and Function, 2nd Edition.* Boston: Jones and Bartlett Publishers, 2006.