

Lourdes University Institutional Review Board
REQUEST TO WAIVE INFORMED CONSENT REQUIREMENTS

Explanation: In certain circumstances an IRB may approve a consent procedure that does not include, or that alters, some or all of the required elements of informed consent. If you feel that a waiver may apply to your study, please check the appropriate box(es) and provide details.
 Source: 45 CFR46.116(d)

IRB # _____ Research Title _____

Investigator _____ Faculty Advisor _____

1. Which consent process would be affected by the waiver or alteration?

I am requesting a waiver of some or all consent elements for the following participants (check all that apply)

	Adult informed consent
	Adults who lack consent capacity
	Parental permission
	Child/minor assent
	Partial Consent/Assent: This study involves deception

2. In order to grant a waiver or alteration of informed consent, the IRB must review your answers to the following 4 questions. Please answer each question by checking the appropriate box.

1. The research in its entirety involves no greater than minimal risk.		Yes		No
2. The waiver of informed consent will not adversely affect the rights and welfare of the participants.		Yes		No
3. It is not practicable to conduct the research without the waiver/alteration		Yes		No
4. Subjects will be provided with additional pertinent information after their participation.		Yes		No

3. If you have checked “Yes” to each of the four previous statements, in order to receive the waiver, you must (a) 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.