**Attachment D—IRB Waiver of Informed Consent Application**

Complete for to request a waiver of physical informed consent documentation for your human subjects research project.

# **I. Principal Investigator / Project Director**

**Name**: Click or tap here to enter text. **Email**: Click or tap here to enter text.

**Date Form Completed**: Click or tap to enter a date.

# **II. Project Information**

1. **Project Title** (250 character maximum)

Click or tap here to enter text.

1. **Is this waiver application for a study that has previously been approved by UWL’s IRB?**

 [ ]  No [ ]  Yes\*

*\*If ‘Yes,’ what was the date of your approval letter?* Click or tap to enter a date.

# **III. Waiver Type**

Select which type of waiver you are requesting:

[ ]  Waiver of informed consent for participants 18+ years of age.

[ ]  Waiver of informed consent for parents or legal guardians of minor participants (persons younger than 18 years of age). **See section V**.

[ ]  Waiver of informed consent for legal guardians of persons 18+ years of age with legally appointed decision-makers. **See section V**.

# **IV. Justification of Waiver**

Complete this section to determine if your protocol is eligible to receive a waiver of consent.

## **A.** **Does your research meet all of the federal requirements for a waiver of consent as outlined by** **45 CFR 46.116(f)(3) of the Common Rule?** If you would answer no to any of the following, you may have to revise your protocol in order to request a waiver.

1. The research involves no more than minimal risk to the subjects.

 [ ]  Yes [ ]  No

1. The research could not practicably be carried out without the requested waiver or alteration.

 [ ]  Yes [ ]  No

1. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format (if not applicable to your research, put N/A for #3).

[ ]  Yes [ ]  No

1. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

 [ ]  Yes [ ]  No

1. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

 [ ]  Yes [ ]  No

## **B. Please provide justifications for each of the above, and number them accordingly:**

1. Click or tap here to enter text.
2. Click or tap here to enter text.
3. Click or tap here to enter text.
4. Click or tap here to enter text.
5. Click or tap here to enter text.

# **V. Additional Justification for Waivers of Informed Parental or Legal Guardian Consent**

Fill out this section if you are requesting a waiver of informed parental or legal guardian consent (if applicable). This applies to both minors and persons 18+ years of age with legally appointed decision-makers.

## **A. Is your research being conducted in or are you recruiting participants via any of the following service providers?**

[ ]  K-12 school, school district, or school program

[ ]  Childcare or other child service facility/provider

[ ]  Nursing home, senior/assisted living, or other assisted care facility/provider

[ ]  Other (e.g., care providers for vulnerable populations): Click or tap here to enter text.

**B. Provide the name of the school and district, facility, or provider:** Click or tap here to enter text.

 [ ]  Yes [ ]  NoHave you received prior approval or support from the school, district, or facility/provider to conduct this research?

[ ]  Yes [ ]  No Was the use of opt-out, passive, or implied parental/legal guardian consent forms specifically requested by the facility/provider listed above?

**C. Please provide additional justification(s) as to why you feel that your research must be conducted using opt-out, passive, or implied informed parental/legal guardian consent. Increased participation for researcher benefit is not an appropriate justification for research involving minors or other vulnerable populations.**

Click or tap here to enter text.

**D.** Attach any **letters of support and/or commitment** from school, district, or facility/provider officials at the end of this document.

# **VI. SIGNATURE**

By typing my name below, I agree that I have notified my university’s Institutional Review Board to the best of my knowledge and ability about why my human subjects research would benefit from a waiver of informed consent.

**Name**: Click or tap here to enter text. **Date**: Click or tap to enter a date.