FORM: Request for Waiver/Alteration of Informed Consent

Directions: Complete this form and attach it to your application if you desire a waiver or alteration of informed consent (includes studies seeking no consent, studies involving deception/concealment, and studies using a short form informed consent document.) ALL conditions must be met for a waiver/alteration to be granted. Also state in your application that you are requesting a waiver of informed consent and describe what you will do in the procedure section of your application. The IRB often requires investigators to provide participants with a written information statement about the research when informed consent is waived; you may wish to include one in your initial application. NOTE that the IRB does not allow passive consent and that waivers may not be granted for FDA-regulated research. You are welcome to call Research Compliance staff at 205-348-8461 to discuss your need for a waiver in advance of application submission.

1. Describe exactly what you wish to waive: How do you wish to depart from the usual written informed consent procedure? (For example, you wish to waive consent from parents of UA students less than 18 years of age.)

2. Describe why the research involves no more than minimal risk to the subjects: “Minimal risk” means that the likelihood or magnitude of harm/discomfort is not greater than what subjects would ordinarily encounter in daily life or during routine clinical care.

3. Describe why the waiver or alteration will not adversely affect the rights and welfare of the subjects: The IRB will assess whether subjects’ rights, such as the “right to privacy”, would be violated if the consent were waived, and the potential benefits of participation.

4. Describe why the research could not practicably be carried out without the waiver or alteration of informed consent. For example, research using deception/concealment, cases where obtaining informed consent would not be practicable if the investigator will have no direct contact with subjects and will not know their identities. (Investigator convenience may not be a compelling argument here.)

5. Will subjects be provided with additional pertinent information after or during the research? If yes, describe how information will be provided to participants: In social science research involving deception/concealment, subjects should be debriefed at the conclusion of the study. This may not be needed in other studies or, if data were collected without identifiers, it may not be possible, since the identity of subjects would be unknown.