Pittsburg State University
Application for Informed Consent
Waiver or Alteration

Research Project Title: _____

Principal Investigator: _____

To obtain approval for a waiver or alteration of informed consent, the research project must meet one of the criteria listed below. Please check which criteria apply and describe how your study meets these criteria. Submit this form as an attachment to your application.

Waiver or alteration of the requirements for obtaining informed consent from ***adult subjects*** can occur under any of the following provisions [1]:

☐ Public benefit or service programs. Some or all of the elements of informed consent may be altered or waived provided that both of the following conditions are met:
1. the research could not practicably be carried out without the waiver or alteration; **AND**
2. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
   a) public benefit or service programs; **OR**
   b) procedures for obtaining benefits or services under those programs; **OR**
   c) possible changes in or alternatives to those programs or procedures; **OR**
   d) possible changes in methods or levels of payment for benefits or services under those programs.

☐ Research in general. Some or all of the elements of informed consent may be altered or waived provided that all of the following conditions are met:
1. the research involves no more than minimal risk to the subjects; **AND**
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects; **AND**
3. the research could not practicably be carried out without the waiver or alteration; **AND**
4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

☐ Research in emergency settings. Some or all of the elements of informed consent may be altered or waived provided that the research meets the requirements of the HHS Secretarial waiver (*45 CFR 46.101(i)*) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings.

For research involving ***children***, the requirements for obtaining parental or guardian permission may be waived under any of the following four provisions [1]:

☐ Public benefit or service programs. Some or all of the elements of informed consent may be altered or waived provided that both of the following conditions are met:
1. the research could not practicably be carried out without the waiver or alteration; **AND**
2. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

a) public benefit or service programs; **OR**
b) procedures for obtaining benefits or services under those programs; **OR**
c) possible changes in or alternatives to those programs or procedures; **OR**
d) possible changes in methods or levels of payment for benefits or services under those programs.

☐ Research in general. Some or all of the elements of informed consent may be altered or waived provided that all of the following conditions are met:

1. the research involves no more than minimal risk to the subjects; **AND**
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects; **AND**
3. the research could not practicably be carried out without the waiver or alteration; **AND**
4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

☐ Subject Protection. Some or all of the elements of informed consent may be altered or waived provided that parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), and the following 2 criteria are also met:

1. an appropriate mechanism is in place to protect the children, **AND**
2. the waiver is consistent with federal, state, or local law. The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child's age, maturity, status, and condition.

☐ Research in emergency settings. Some or all of the elements of informed consent may be altered or waived provided that the research meets the requirements of the HHS Secretarial waiver (*45 CFR 46.101(i)*) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings.

_____	_____	_____
Signature of Principal Investigator	Name (please print)	Date

[1] HHS.gov "Informed Consent FAQs" (2021) *HHS.gov*, Retrieved 02/11/21 https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html.