

Waiver or Alteration of Informed Consent Checklist

This checklist is to be used when researchers are requesting a waiver of consent to forgo the consent process all together or alter or omit some of the elements of consent (e.g., as with deception).

The research represents minimal risk

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

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

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

Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation (i.e., a debriefing process exists)

If deception is being used, subjects agree to being unaware of or misled regarding the nature and the purpose of the research (i.e., during the consent process)