Waivers of Informed Consent
January 2020

SOP 1101: Informed Consent
2.9 Waiver of Informed Consent

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements (this includes signature) of informed consent; or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

(a) The research involves no more than minimal risk to the subjects;

(b) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(c) The research could not practicably be carried out without the waiver or alteration; and

(d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Waivers of some or all elements of consent

Not Common

(a) 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:

1. Public benefit or service programs;

2. Procedures for obtaining benefits or services under those programs;

3. Possible changes in or alternatives to those programs or procedures; or

4. Possible changes in methods or levels of payment for benefits or services under those programs; and,

Most Common

(b) The research could not practicably be carried out without the waiver or alteration.

FDA & Waivers of Informed Consent

- Due to the 21st Century Cures Act 12/13/16, the FDA regulations **for the first time permit an exception from informed consent requirements when the study poses no more than minimal risk.** **https://www.fda.gov/media/106587/download**

- Additionally, waivers of consent are not permissible for federally-funded research using Newborn Blood Spots.

Waiver of Documentation of Informed Consent

The IRB can find:

- ICF document poses a risk of potential harm to the subject if there were a breach of confidentiality;
- Research is no more than Minimal Risk & does not involve procedures that normally require written consent outside of research.
  - ***NOTE:*** FDA allows waiver in this situation, i.e., marketing surveys, telemarketing.
- ***NOTE:*** only documentation is waived, **not the consent process itself.**

Deception Practices and Child Findings Reminders

The determinations for child findings and risk findings are required to match the consent process.

1. If a 405/406 is given parental consent cannot be waived.

   *Refer to NC State Law SOP about Minors and Age of Majority around specific research

2. As giving the full purpose and procedures of the study is a required element, deceiving an individual or not disclosing the purpose and procedures is not allowed for a greater than minimal risk study.
   - Studies that have received a 405*/406 can not utilize deception practice as they are greater than minimal risk.*
   - *Studies that were reviewed by a full board and not determined to be expedited can not permit an alteration of elements (waiver).*

Case Study

- A greater than minimal risk (no expedited review/categories given at full board review) study enrolling infants who present to the NICU are randomized to either a cooling blanked with a non-significant risk device determination or no cooling device wants to enroll children through verbal conversations with parents and will have them sign the consent form after they have completed routine monitoring and started the intervention, is this permissible?

Case Study Response

- Not obtaining a signature before conducting research activities is considered an alteration, as the study is greater than minimal risk, and they are conducting the interventional (greater than minimal risk activities) then **signature must be obtained before starting the interventional procedures.**

Case Study Alternatives

Alternatives:

1. Obtain electronic signed consent, or fax/email consent form
2. Alter the signature requirement for minimal risk activities only, obtain signature before greater than minimal risk activities. Requires clear delineation in both minutes and application about activities and risk level.