**“Impracticable” Research and Waiving Consent**

According to the federal regulations at 45 CFR 46.116(d), the IRB may waive the requirements to obtain informed consent if the IRB finds that ALL of the following four criteria are met:

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

The third criterion often presents the most trouble for investigators, as it requires the most careful justification. It is important to remember that the criterion states that the *research* could not be practicably carried out with the waiver; therefore, justification must include why the research as a whole could not practicably be carried out if consent was required.

The common definitions of practicable are:

1. capable of being put into practice or of being done or accomplished
2. feasible[[1]](#footnote-1)

Inconvenience, insufficient funds, or time constraints are not allowable as the only justifications for why consent cannot be obtained, though they may play a role in impracticability. Some situations when research could not be practicably carried out without a waiver of consent *do* include:

* Retrospective analysis of completely de-identified data (or other instances when the PI will have no contact with subjects and will not know their identities)
* Research involving deception or when obtaining consent might cause biased/different research responses from subjects (may require debriefing after participation)
* Chart reviews/retrospective data analysis using subjects who have been lost to follow-up for various reasons: no contact information, contact information is out of date, or subjects may be deceased
* Research involving an especially large sample size, ***if*** limiting research to only those subjects whose consent could be obtained would limit or bias data or conclusions, or affect statistics to the point of preventing the drawing of reliable conclusions entirely
* Privacy concerns: When creating or maintaining a link between subject identifiers and de-identified data could create additional risks to privacy (e.g., identifying a sensitive subject population – abuse victims or HIV+ status)
* Increased Risk: When contacting subjects could, by itself, cause harm (physical, psychological, etc.) to subjects

This is not an exhaustive list. The researcher is encouraged to contact the compliance office if there are questions about whether a study qualifies for a waiver of consent.

1. Samuel Tilden, “SACHRP Letter to HHS Secretary,” *Office for Human Research Protections (OHRP), Secretary's Advisory Committee on Human Research Protections (SACHRP)*, January 31, 2008, http://www.hhs.gov/ohrp/sachrp/20080131secretarialadvisoryletter.pdf. [↑](#footnote-ref-1)