When can my study receive a waiver of informed consent process?

45 CFR 46.116(d) states, “An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
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.”

It’s easy to slip into the following short-hand for when a waiver can be granted:

- **When It’s Only a Minimal Risk Study:** The IRB found the research presented no more than minimal risk but OHRP found no documentation that the IRB made the three additional requirements at 45 CFR 46.116(d). OHRP, Letter to Dr. Norman Altman from Sandford Leikin, MD (1/19/2001).

- **When it’s Only a Retrospective Study:** UM IRB approved a waiver of the requirement for informed consent for all research involving retrospective review of medical records. OHRP finds that the UM IRB failed to document the specific criteria for waiver of informed consent for the research. OHRP, Letter to Patrick J. McNeilly, Ph.D. from Fawwaz T. Ulaby (2/21/2003).

The above determination letters warns us there are no short-cuts. The regulations require the documentation and finding of every element to satisfy a waiver of informed consent.

Just because a study is minimal risk only or simply a retrospective study does not automatically mean a waiver of informed consent is justifiable.

When is it “not practicable” to obtain informed consent?

HHS regulations 45 CFR 46.116(d) require the IRB when evaluating whether a waiver of informed consent process is approvable to find that it is not practicable to conduct the research without a waiver of informed consent. This is often the most difficult element to prove to obtain a waiver.

However, the regulations do not specify or define when it might not be “practicable” to obtain informed consent. Here are some excerpts from OHRP determination letters on the topic:

- **When there is a Potential for Low Enrollment:** Study team claimed subject enrollment is too low when informed consent is solicited with a procedure that requires all required elements of informed consent. “OHRP is concerned that the justification proposed by the investigator for finding that the research could not practicably be carried out without the waiver is not ethically justifiable.” OHRP, Letter to Eugene P. Trani, PhD from Micheale Carome, MD (9/22/2000).

- **When it is Inconvenient to Contact Potential Subjects:** “HHS regulations at 45 CFR 46.116(d)(3) … require that the IRB find and document that the research could not practicably be carried out without a waiver. Please note that mere inconvenience in contacting individuals is not
a justification for concluding that obtaining informed consent is impracticable.” OHRP, Letter to Dr. Gerald Litwack from Carol J. Weil, JD (6/10/2002).

- **When contact with the subjects occur at some point in the study:** “[I]t appears that it would have been practicable to obtain parental permission for at least the conduct of the follow-up research interviews and probably for the prospective collection of routine clinical data related to the emergency room evaluation. If so, the research would have not have satisfied the requirements for waiver of informed consent.” OHRP, Letter to William New from Patrick J. McNeilly, PhD (2/8/2001).

The above determination letters do not come out and define when it is “not practicable,” giving institutions some flexibility.

However, they do remind us that the goal is to get informed consent from participants and this responsibility should be shirked lightly based on mere inconvenience or because getting informed consent may affect enrollment numbers.