Example of a Waiver of Informed Consent:
Chart Review Study

A Waiver of Informed Consent is customarily requested for research where:

- There will be no contact with human subjects, and
- It would be impracticable to obtain legally- effective informed consent
- Permitted only for non FDA-regulated research

Regulation at 45 CFR 46.116(d):

The IRB may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent or waive the requirement to obtain informed consent provided the IRB finds and documents specified criteria:

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 wavier or alteration; and*
4. *whenever appropriate, the subjects will be provided with additional pertinent information after participation.*

Scenario for a Waiver of Informed Consent:

An Investigator plans to determine whether some specific blood chemistry values change in individuals undergoing clinically indicated abdominal surgery and if there is a correlation of changes with the increased incidence of complications after surgery. The researcher plans to review the medical records of all individuals who have undergone abdominal surgery in the past 2 years. From a preliminary estimate, there are about 5,000 abdominal surgeries performed per year at the hospital. The researcher will collect limited data for this research. The types of data to be collected include such items as the diagnosis before surgery, the type of abdominal surgery, specific blood chemistry values before the surgery, the same specific blood chemistry values after the surgery, a description of problems after surgery, and the age ranges of the individuals. The researcher will code the data so that only the researcher knows the link in the unlikely event the data must be verified for accuracy. The results of the research will not affect the clinical care of the individuals because the information will not be examined until after subjects leave the hospital.

Applying the regulatory criteria:

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

Do not: State this is a “chart review study,” “retrospective review,” etc. Certain types of chart review studies of sensitive information could involve greater than minimal risk.

Try to: Explain why the research is no more than minimal risk. Describe the nature of information collected and the confidentiality provisions. Specify when information is not sensitive.

Good example: The research involves minimal risk because the review of subjects' medical records is for limited information. The information is not sensitive in nature, and the data are derived from clinically indicated procedures. There is an extremely low probability of harm to subjects' status, employment, or insurability. The precautions taken to limit the record review to specified data and the coding of the data further minimize the primary risk, which is a breach of confidentiality.

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

Do not: Repeat the criteria or state that you will not have contact with subjects.

Try to: Consider the rights to clinical care and privacy. For example, specify that the research will not impact clinical care decisions or access to clinical care.

Good example: The rights and welfare of the individuals would not be adversely affected because the clinically-indicated surgical procedure and the associated blood chemistry values were already completed, regardless of the research. None of the results of the research would affect the clinical decisions about the individual's care because the results are analyzed after the fact. Subjects are not being deprived of clinical care to which they would normally be entitled.

(3) The research could not practicably be carried out without the waiver or alteration
[Consider what "practicably" means: "reasonably capable of being accomplished; feasible."]

Do not: State that it would be "inconvenient" or "time-consuming"

Try to: Focus on practicability with consideration of the following:

- The size of the population being researched;
- The nature (disease state or culture) of the population being researched;
- How recently subjects were last seen and how frequently they might be seen in the future;
- The difficulty of contacting individuals directly when there is no existing or continuing treatment relationship between the researchers and the individuals;
- The proportion of individuals likely to have relocated or died since the time the personal information was originally collected;
- The risk of introducing potential bias into the research thereby affecting the generalizability and validity of results;
- The risk of creating additional threats to privacy by having to link otherwise coded data with nominal identifiers in order to contact individuals to seek their consent;
- The risk of inflicting psychological, social or other harm by contacting individuals or families with particular conditions or in certain circumstances;
- The difficulty of contacting individuals indirectly through public means, such as advertisements and notices; and
- Whether, in any of the above circumstances, the requirement for additional financial, material, human, organizational and other resources needed to obtain such consent will impose an undue hardship on the organization.

Good example: The research could not be practicably carried out without the waiver. Identifying and contacting the thousands of potential subjects, although not impossible, would not be feasible for a review of their medical records for information that would not change the care they would already have received. Further, after two years, many subjects will have changed their telephone numbers or moved without providing forwarding addresses.

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

Do not: State that "there is no contact with subjects." (There are many circumstances where it IS appropriate to contact subjects to give them information.)

Try to: Describe the circumstances of the study and why you think it might be appropriate or inappropriate to provide information. There are no strict rules for deciding when it is "appropriate" to provide additional pertinent information. Some examples of situations where it would be appropriate to provide information include:

- An "opt-out" scenario of research record reviews involving sensitive information where the chart review moves forward under a waiver but all subjects must be contacted to be given the opportunity to refuse participation.

- Subjects are temporarily incapacitated, and should be provided with an information sheet when they regain capacity

Good example: It would not be appropriate to provide these subjects with additional pertinent information about the results of the research as this study is exploratory and would have no effect on the subjects. The surgical procedure and care afterward have both been completed for these subjects. Subjects are not expecting to be contacted and could perceive an invasion of privacy. There is no anticipated benefit to subjects that would change what has already occurred.