Chapter 9
Required Elements of Informed Consent

One overreaching requirement of research involving human subjects is that investigators must obtain the legally effective informed consent of prospective subjects before they can be included in research. Research investigators are responsible for obtaining and documenting informed consent in accordance with Federal regulations (45 CFR 46.116 and 46.117 and 21 CFR 50.25 and 50.27) and HSS policies.

Informed consent presumes two simultaneous concepts: informed decision making and voluntary participation. Prospective subjects must be given sufficient information about the research and its risks and benefits in order to reach an informed decision as to whether they will voluntarily participate.

For an effective informed consent process, DHHS regulations at 45 CFR 46.116(a), the Common Rule, and FDA regulations at 21 CFR 50.25(a) mandate the inclusion of eight basic informed consent elements. Six additional elements may be required, depending on the nature of the research (45 CFR 46.116(b) and 21 CFR 50.25(b)).

The elements of informed consent as outlined in these regulations shall not preempt any other Federal, State, or local regulation which requires additional information to be disclosed for informed consent to be legally effective. Also nothing in the regulations is intended to limit the authority of a physician to provide emergency care to the extent the physician is permitted to do so under applicable Federal, State, or local law. However, such emergency care may not be identified as research, except as required by FDA reporting requirements.

The Informed Consent Templates (included in Appendix II) provide specific guidance on how these should be worded and ordered.

I. Research Statement (Required Element #1). Informed consent information must specifically include each of the following:

A. A statement that the study involves research
B. An explanation of the purposes of the research
C. An explanation of the expected duration of subjects’ participation
D. A description of what procedures will be followed
E. Identification of any procedures that are experimental

II. Reasonably Foreseeable Risks or Discomforts (Required Element #2). Informed consent information must describe any reasonably foreseeable risks or discomforts associated with
the research. All risks listed or described in the research protocol must be referenced in
the informed consent document.

III. Reasonably Expected Benefits (Required Element #3). Informed consent information
must describe any benefits to subjects or to others which may reasonably be expected from
the research. However, benefits must not be overstated as to create an undue influence on
subjects.

IV. Appropriate Alternatives (Required Element #4). Informed consent information must
include a disclosure of any appropriate alternative procedures or courses of treatment that
may be advantageous to the subject. Enough detail must be presented so that the subject
can understand and appreciate the nature of any alternatives. It is not sufficient simply
to state that “the doctor will discuss alternatives to participating.” Where applicable,
informed consent must disclose to subjects when treatments identical to those offered
by the research may be obtained outside the research, i.e., “off protocol.”

V. Extent of Confidentiality (Required Element #5). Informed consent information must
describe the extent to which confidentiality of records identifying the subject will be
maintained (or not maintained). Research often poses the risk of loss of confidentiality to
subjects who participate. Many persons who otherwise would not be privy to identifiable,
private information about the subject may be involved in the research process. Consent
information should describe any procedures that the research team will use to protect
subjects’ private information or records.

Federal officials have the right to inspect research records, including consent forms and
individual medical records, to ascertain compliance with the rules and standards of their
programs. FDA requires that information regarding this authority be included in the consent
information for all research that it regulates. Identifiable information obtained by Federal
officials during such inspections is subject to both the privacy provisions and the disclosure
provisions of the Privacy Act of 1974.

VI. Compensation or Treatment for Injury (Required Element #6). Informed consent
information for research involving more than minimal risk must include explanations
regarding:

A. Whether any compensation is available if injury occurs

B. Whether any medical treatments are available if injury occurs and whether there is a
charge for such medical treatment

C. A description of any such compensation or treatments or where more information
about them is available
VII. Contact Information (Required Element #7). Informed consent information must include details, including telephone numbers, about whom to contact for three specific situations:

A. For answers to questions about the research. The principal investigator and other members of the research team are appropriate contacts for this information.

B. For answers to questions about subjects’ rights. The IRB Office or Legal Counsel are appropriate contacts for information about subjects’ rights.

C. In the event of a research-related injury. Depending upon the nature of the research, the research team, the IRB Office, or Legal Counsel, are appropriate contacts for research-related injury.

II. Voluntary Participation Statement (Required Element #8). Informed consent information must contain clear statements of the following:

A. Participation in the research is “voluntary;”

B. Refusal to participate will involve “no penalty or loss of benefits to which the subject is otherwise entitled;” and

C. The subject may discontinue participation at any time “without penalty or loss of benefits to which the subject is otherwise entitled.”

It is particularly important for subjects and prospective subjects to understand and have complete confidence that declining to participate in research will not jeopardize their care.

III. Additional Elements Where Appropriate. Where appropriate, the regulations require that one or more of the following six additional elements be included in the informed consent information.

A. Unforeseeable Risks to Subjects. Some research involves particular procedures or interventions that may result in unforeseeable risks to subjects, to the embryo, or the fetus (if the subject is or may become pregnant). For research of such a nature, the informed consent information must warn subjects that there may be risks that are not known or not foreseeable.

B. Investigator-Initiated Termination of Participation. There may be instances that would require investigators to terminate the participation of particular subjects (e.g., subject noncompliance with research, subject not benefiting from direct-benefit research). The informed consent information should specify these circumstances.
C. **Additional Costs.** If subjects must bear any additional costs (transportation, time away from work, health costs, etc.), these must be disclosed in the informed consent information.

D. **Early Withdrawal/Procedures for Termination.** Subjects have the right to withdraw from the research. However, some studies involve medications or procedures that would be dangerous for subjects to discontinue abruptly. For studies of this nature, the informed consent information must provide subjects with knowledge of the consequences affecting a decision to withdraw. In addition, if there are procedures regarding how to withdraw safely from the research, these must also be described. It is not appropriate for research staff to administer any additional research-oriented questionnaires or interventions that do not affect the safety of subjects who have decided to withdraw.

E. **Significant New Findings.** Subjects will be informed of any new knowledge or findings about the medication or test article and/or the condition under study that may affect the risks or benefits to subjects or subjects’ willingness to continue in the research.

F. **Approximate Number of Subjects.** For certain types of research, the informed consent information should disclose the approximate number of subjects to be enrolled.

G. **ClinicalTrials.Gov.** If a study is to be posted at ClinicalTrials.gov, a Federal Government website listing studies, please include Federally mandated language about the listing.

**IV. Requirement for Authorized Personnel to Obtain Consent.** Informed consent may only be obtained by personnel authorized to do so by the IRB. The person who conducts the informed consent interview must be knowledgeable about the study and be able to answer questions. Informed consent information can be presented by any qualified person involved in conducting the study and is not limited to persons with MD’s or PhD’s. Every effort should be made to list on the informed consent document those personnel who may actually give the informed consent information to the potential subject. Thus, only a principal investigator, co-investigator, or study coordinator who is listed on the informed consent document can obtain informed consent.

**V. Waiver or Alteration of Informed Consent Requirements.**

A. **State or Local Public Benefit Programs.** DHHS regulations at 45 CFR 46.116(c) and the Common Rule permit an IRB to approve a consent procedure that eliminates or alters the required elements of informed consent, or to waive the requirement to obtain informed consent altogether. In order to approve such a waiver or alteration, the IRB must find and document that:
1. The activity constitutes a research or demonstration project that 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: (i.) public benefit or service programs; (ii.) procedures for obtaining benefits or services under those programs; (iii.) possible changes in or alternatives to those programs or procedures; or (iv.) possible changes in methods or levels of payment for benefits or services under those programs; and

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

These findings and their justifications will be clearly documented in IRB minutes when the IRB exercises this waiver provision. This waiver provision is not applicable to research governed by FDA regulations, and the IRB will not approve such alterations or waivers for FDA-regulated research.

VI. Waiver or Alteration of Informed Consent Requirements.

A. Minimal Risk Research. DHHS regulations at 45 CFR 46.116(d) and the Common Rule permit an IRB to approve a consent procedure that eliminates or alters the required elements of informed consent, or to waive the requirement to obtain informed consent altogether. In order to approve such a waiver or alteration, the IRB must find and document 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 practically be carried out without the waiver or alteration; and

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

These findings and their justifications will be clearly documented in IRB minutes when the IRB exercises this waiver provision. This waiver provision is not applicable to research governed by FDA regulations, and the IRB will not approve such alterations or waivers for FDA-regulated research.

B. Research Involving Deception. Deception research involves social science research in which the subject is not told, or is misled, about the true purpose of the research, such as in certain studies of group processes, contextual influences on cognition, etc. The IRB reviewing research involving incomplete disclosure or outright deception must apply both common sense and sensitivity to the review.
Where deception is involved, the IRB needs to be satisfied that the deception is necessary and that, when appropriate, the subjects will be debriefed. (Debriefing may be inappropriate, for example, when the debriefing itself would present an unreasonable risk of harm without a countervailing benefit.) The IRB should also make sure that the proposed subject population is suitable.

Deception can only be permitted where the IRB documents that waiver of the usual informed consent requirements is justified under the criteria present at 45 CFR 46.116(d).

In making the determination to approve the use of deception under a waiver of informed consent, the IRB will consider each criterion in turn, and document specifically (in the minutes of its meeting and/or in the IRB protocol file) how the proposed research satisfies that criterion. Note that the regulations make no provision for the use of deception in research that poses greater than minimal risks to subjects.

### VII. Waiver of Documentation of Consent

DHHS regulations at 45 CFR 46.117(c) and the Common Rule permit an IRB to waive the requirement to obtain written documentation of informed consent. In order to approve such a waiver, the IRB must find and document either of the following conditions:

- **A.** The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In this case, each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

- **B.** The research presents no more than minimal risk of harm to subjects and involves procedures or activities for which written consent is not normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the Principal Investigator to provide subjects with a written statement regarding the research.

These findings and their justifications will be clearly documented in IRB minutes when the IRB exercises this waiver provision. This waiver provision is not applicable to research governed by FDA regulations, and the IRB will not approve such alterations or waivers for FDA-regulated research.

### VIII. Informed Consent from Non-English Speakers

Federal regulations at 45 CFR 46.116 and 21 CFR 50.20 require that informed consent be obtained in language that is understandable to the subject (or the subject’s legally authorized representative).
In accordance with these regulations, informed consent discussions must include a reliable translator when the prospective subject does not understand the language of the person who is obtaining consent.

As indicated previously, investigators may document informed consent in either of two ways:

A. A full-length informed consent document written in language understandable to the subject; or

B. A “short-form” consent document in the language of the subject that states the general elements of informed consent.

HSS will provide generic “short form” consent documents to investigators in languages typically encountered among subject populations. Investigators will be responsible for providing documents in languages not typically encountered.

If investigators use the “short form” to document informed consent, they must also provide subjects with (i) the full-length informed consent document in English, and (ii) a translator who can take part in the oral informed consent discussion to ensure subject’s understanding and who may serve as the witness. The “short form” consent document written in the subject’s language must be signed by the subject (or the subject’s legally authorized representative) and the witness. The full-length English consent document must be signed by the witness and the person obtaining consent. The subject must be given copies of both the “short form” consent document and the English consent document.

Whether a full-length or a “short form” consent document is utilized, the IRB will require that appropriately translated documents be submitted to the IRB for review and approval prior to their use in enrolling subjects.