Guidance - Waiver of consent/authorization and waiver of documentation of consent

Obtaining the informed consent of research subjects prior to participation is regarded as a cornerstone for the ethical conduct of research, and a fundamental protection for participants' rights. Federal regulations outline general requirements for informed consent at 45 CFR 46.116, including eight "basic" and six "additional" elements to be addressed when obtaining informed consent. An IRB may approve a consent procedure which does not include, or which alters, some or all of the "basic" elements of informed consent or waive the requirements to obtain informed consent; however, the study team must request a waiver or alteration of consent.

The informed consent process involves three key features: (1) disclosing to potential research subjects information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research. Informed consent must contain all required elements and obtained prior to initiation of the research study.

Waiver of Consent/Authorization

It is recognized that there is valuable research that would be difficult, or impossible, to conduct if consent were required; and that subjects can still be adequately protected in the absence of full consent. The waiver allows the interests of subjects to be balanced with societal interests in research, and both will be well served if this regulatory provision is understood and applied appropriately.

Federal regulations(Common Rule (45CFR46) and HIPAA Regulations (45 CFR 164)) allow the IRB to approve a consent/authorization procedure which does not include, or which alters, some or all of the elements of informed consent, or to waive the requirement to obtain any informed consent. Waivers of consent involve studies in which there are minimal risks to subjects. The proposed protocol must meet the following specific criteria found at 45 CFR46.116(d) and 45 CFR164.512(i)(1)(i) :

1. The research involves no more than minimal risk to subjects and their privacy.
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
3. The research could not practicably be conducted without the waiver or alteration and access to and use of identifiable protected health information.
4. Whenever appropriate (generally, when there is a health justification), the subjects will be provided with additional pertinent information after participation.

Additional HIPAA Criteria

The protocol must include, at a minimum, the following elements:

1. An adequate plan to protect identifiers from improper use and disclosure.
2. An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law and
3. Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for the research for which the use or disclosure of protected health information would be permitted.

Example of approval request for waiver of consent:

Review of medical records of all patients who have undergone abdominal surgery in the past two years and correlate the data with blood chemistry values kept by pathology. Researchers are collecting limited data that will be assigned a random code # and the link is known only to the researchers. Results of the research will not affect clinical care of the individuals, since they will already have left the hospital.

Waiver of Documentation of Consent

If the proposed research activity is planned to obtain consent **without** obtaining the subject's signature on a consent form, then the request is waiver of documentation of consent. Waiving the requirement for a written form does not eliminate the requirement for informed consent. Subjects must be informed of the nature of the research, and their consent (or the consent of their legally authorized representatives (LARs) must be obtained whenever appropriate. This type of waiver is useful for some telephone or internet surveys, questionnaires, or when signing the consent document could have a negative consequence for the subject.

According to 45 CFR 46.117(c), an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- Research presents no more than **minimal risk.** (***Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.) **AND**
- Research involves procedures that do not require written consent when performed outside of a research setting **OR**
    - Principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research **AND**
    - Consent document is the only record linking the subject with the research **AND**
    - Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participants wishes will govern.

The IRB may require the use of an information sheet to be given to the potential subject or an oral script to be read to the potential subject. Investigators will use the information sheet or script to guide them through the informed consent discussion/process. The subject's signature on a consent form in not required. The script or information statement must be provided to the IRB at the time of original study submission for review and approval. The PI and/or research staff will document the participant's consent, as well as date, and the name of the person conducting consent in the study files.

In addition to describing the study, the script or information sheet must contain the basic elements of informed consent, as referenced in 45CFR46.116(a) and 21CFR50.25.

The script or information sheet should include the following information:

- State that the study involves research
- Explain the purposes of the research and the expected duration of the subject's participation
- If applicable: describe any foreseeable risk or discomforts to the subject

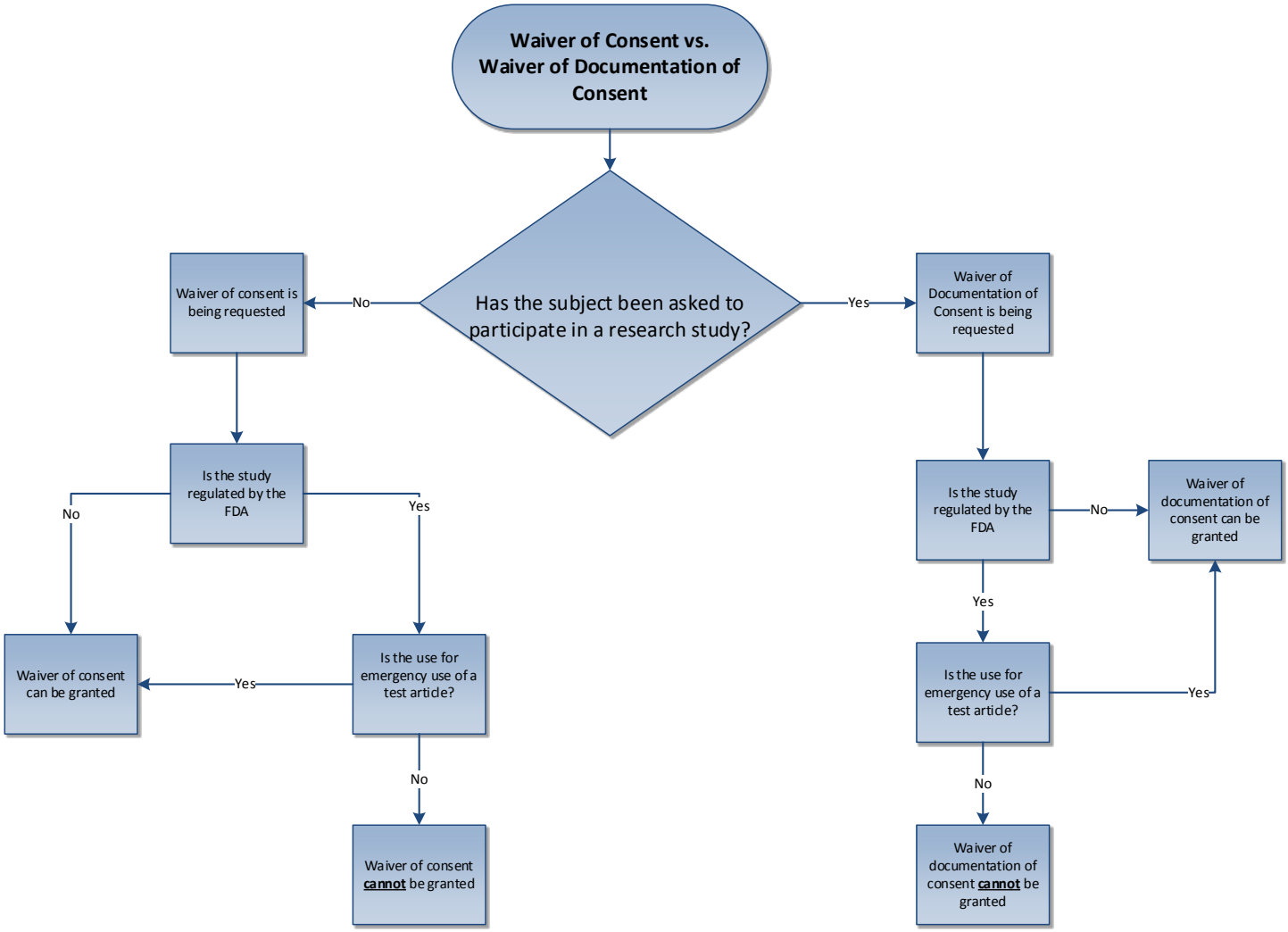
- If applicable: describe any benefits to subjects or to others that may reasonably be expected from the research.
- If applicable: disclose alternatives
- Describe the extent to which confidentiality of records identifying subjects will be maintained, where the records will be stored and who will have access to them.
- Provide contact information for answers to pertinent questions about the research, and participants' rights.
- Include that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which participants are otherwise entitled, and also that participants may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.

Some examples of approvable waiver of documentation of consent:

- When the identities of subjects will be completely anonymous and there is minimal risk involved in the study. The signed informed consent would be the only record linking the subject to the study therefore it would be the only identifier in the study.
- When obtaining signed consent is not appropriate or feasible according to the cultural standards of the population being studied, and there is minimal risk involved in the study.
- When there is a possible legal, social or economic risk to the subject entailed in signing the consent form, e.g., for immigrants who might be identified as being illegal aliens, or for HIV antibody-positive individuals who might be identified as such by signing the consent form.
- When the study involves only a telephone interview.

PLEASE NOTE: **T**he IRB **cannot** **grant a waiver of consent or documentation of consent** if the research study involves the use of an investigational drug (IND) or device (IDE) that is regulated by the Food and Drug Administration (FDA) and is more than minimal risk,. **The only exception is for emergency use of a test article FDA 21 CFR 50.23, or planned emergency research FDA 21 CFR 50.24.**

See Flow Chart Guidance – Waiver of Consent vs Waiver of Documentation of Consent


Waiver of Consent vs. Waiver of Documentation of Consent
Has the subject been asked to participate in a research study?
No
Yes
Waiver of consent is being requested
Waiver of Documentation of Consent is being requested
Is the study regulated by the FDA
No
Yes
Waiver of consent can be granted
Is the use for emergency use of a test article?
Yes
No
Waiver of consent cannot be granted
Is the study regulated by the FDA
No
Waiver of documentation of consent can be granted
Yes
Is the use for emergency use of a test article?
Yes
No
Waiver of documentation of consent cannot be granted