Waiver Request, Consent Documents or Consent Requirements

Part 1 Waiver of Written Documentation of Consent

Section 1: Intend to remind you to explain to the research ethics committee when asking for waiver

PART 1 -SECTION 1	
How you will provide the subjects the information about the research. *Select all that apply*	
[ ]	An oral explanation of the research. *Examples: person-to-person, tape recording, or video recording*
[ ]	A written Information Sheet. *Examples: paper: in-person, faxed, mailed or electronic: email, website or webpage, text message, other*
[ ]	Other, describe to the research ethics committee when asking for waiver

Section 2: Criteria for Approving Waiver

Check the box next to the condition that best fits your study.

NOTE:

- *The IRB cannot waive the requirement for documentation of consent for FDA-regulated research (research that involves giving a drug, device, supplement, botanical, or biologic to subjects)* unless it meets Condition 1 below.
- *The FDA does not accept Condition 2.*

CONDITION 1: Minimal risk

a. Does your research involve greater than *minimal risk* to the subjects?

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.

☐ NO a waiver of consent documentation **can be granted**

☐ YES a waiver of consent documentation **cannot** be granted under this Condition.
Look at the questions for Condition 2.

b. Does your research involve any procedures for which written consent is normally required outside of the research context? *Examples: in everyday life, written consent is needed for surgery but not for many surveys or for non-invasive health measurements by your health care provider.*

☐ NO a waiver of consent documentation **can be granted**

☐ YES a waiver of consent documentation **cannot** be granted under this Condition.
Look at the questions for Condition 2.

CONDITION 2: Signed consent document is the primary risk

c. Is the existence of **a signed consent document the only document or record that would link** the subject to the research? (This means that data and specimens will not be recorded or stored with identifiers or links to identifiers.)

☐ NO a waiver of consent documentation **cannot be granted**

☐ YES a waiver of consent documentation **can be granted**

d. Is the **principal risk** associated with the research the potential harm to subjects that might occur if there was a **breach of confidentiality about their participation**? *Example: a study that involves subjects who use illegal drugs.*

☐ NO a waiver of consent documentation **cannot be granted**

☐ YES a waiver of consent documentation **can be granted**

Part 2 Waiver of Consent Requirement /Alteration of Elements of Consent

Criteria for Approving Waiver

Check the box next to the condition that best fits your study.

CONDITION 1: Minimal risk

a. Does your research involve **greater than minimal risk** to the subjects?

"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.

☐ **NO** a waiver of consent documentation **can be granted**

☐ YES a waiver of consent documentation **cannot** be granted under this Condition. *Look at the questions for Condition 2.*

b. Will a waiver of consent **adversely affect the rights and welfare** of the subjects?

☐ **NO** a waiver of consent documentation **can be granted**

☐ YES a waiver of consent documentation **cannot** be granted under this Condition. *Look at the questions for Condition 2.*

c. Could the research **practicably be carried out without the waiver** of consent?

☐ **NO** a waiver of consent documentation **can be granted**

Select the reasons below:

☐ It is not possible to contact all of the subjects associated with the data or specimens in order to obtain consent.

☐ The design of the study does not allow the possibility of obtaining consent.

☐ The potential study population is so large that it would not be feasible to obtain consent.

☐ The research cannot be conducted with a population for whom consent could practicably be carried out.

☐ Alternative methods for obtaining consent (for example, consent over the phone) are not feasible.

☐ Requiring informed consent may introduce systematic bias into the data.

☐ The risk of contacting the subjects is greater than the risk of the study procedures.

☐ YES a waiver of consent documentation **cannot** be granted

CONDITION 2: Research about local public benefit or service programs.

a. Is the research designed to study, evaluate or otherwise examine any of the following?

Select the reasons below:

☐ Public benefit or service programs. *Examples: unemployment benefits; government-funded health insurance.*

☐ Procedures for obtaining public benefits or services.

☐ Possible changes in or alterations to those programs or procedures.

☐ Possible changes in methods or levels of payment for benefits or services.

☐ **NO** a waiver of consent documentation **cannot** be granted

☐ **YES** a waiver of consent documentation **can be granted**

❖ Definition

- A waiver of the requirement for written documentation of consent
  *This means that consent will be obtained from the subjects, but there will be **no written document signed by subjects or subjects legally-authorized representatives**. Examples:*
  - *Obtaining consent with an **oral process** (for example, face-to-face or over the phone).*
  - *Obtaining consent by an electronic process that does **not involve a verified electronic signature**. Examples: subjects provide consent with a web-based form or by email.*

- A waiver of the requirement for consent
  *This means that you will **not be obtaining consent** of any kind from the subjects. Examples:*
  - *Screening (sometimes called "pre" screening) of records to identify possible subjects*
  - *Doing **a retrospective review of medical records**, many of whom cannot be contacted to obtain consent because they have moved or died.*

- A partial waiver or alteration of consent
  This means that your consent process will alter, or not include, one or more of the required elements of consent. Example:
  - *For a study involving deception, you may wish to exclude the description of some aspects of the purpose and procedures by requesting a waiver.*