**Supplement Form W\***

**Request for Waiver, Alteration and/or Documentation of Consent**

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| **PI Name:**  | **Date**  |
| IRB#/Title:  |

Complete the applicable sections of this form if you are requesting a waiver or alteration of consent/parental permission or a waiver of documentation of consent/parental permission for research subject to the 2018 Common Rule requirements. Assent for children is addressed in Supplement A. Planned Emergency Research is not addressed in this supplement, contact the IRB office for Planned Emergency Research.

1. **Request for Waiver of Informed Consent or Parental Permission** [ ]  **NA**

The IRB may waive the requirement to obtain consent from research subjects if the investigator justifies, and the IRB agrees, that specific criteria have been met.

* 1. **Is the request for a full or partial waiver?**

[ ]  Full Waiver – Consent will not be sought from any subjects

[ ]  Partial Waiver – Consent will not be sought for some subjects (e.g., historical cohort) or for some activities. **Note:** *The FDA does not permit a partial waiver of consent for a subset of activities (e.g., for a single blood draw/test prior to obtaining informed consent) unless the clinical investigation as a whole is minimal risk (i.e., all four of the waiver criteria must be satisfied for the research as a whole).  However, a* [*waiver of documentation of consent*](https://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm) *may be permissible*.

 If request is for a partial waiver, explain what you are requesting:

* 1. **Select the appropriate consent waiver category for this request and then fill out the applicable section.** Please note that FDA does not generally consider review of [patient records](https://www.fda.gov/RegulatoryInformation/Guidances/ucm404975.htm#patientrecords) to assess potential subjects’ eligibility to be a research activity that requires prior consent.

[ ]  General (46.116(f)(1), [FDA Guidance](https://www.fda.gov/RegulatoryInformation/Guidances/ucm566474.htm)), complete Section C

[ ]  Parental Permission is not in the best interests of children ([46.408(c)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.408)), complete Section D

* 1. **General Waiver Criteria** [ ]  **NA**
1. In order to waive the requirement for informed consent or parental permission under this category, ALL of the following criteria must be met:

 [ ]  The research involves no more than minimal risk\*.

 Please explain:

\**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.*

 [ ]  The waiver will not adversely affect the rights and welfare of the subjects.

 Please explain:

 [ ]  The research could not be carried out without the waiver.

 Please explain:

 [ ]  If the research involves using identifiable private information or identifiable biospecimens,

the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

**Note:** *This is a new waiver criterion in the revised Common Rule, which applies to research with identifiable private information or identifiable biospecimens. The purpose of this additional criterion is that if the research could be done using non-identifiable information, then that is what should be done. In these cases, researchers shouldn’t be using identifiable information because it increases the risk of breaches of privacy or confidentiality. [Refer to 45 CFR 46.116(e) and 45 CFR 46.116(f) of the revised Common Rule.]*

*If your research only falls under FDA or Department of Justice Regulations, this criterion does not apply, and you should enter 'NA'.*

 Please explain:

 [ ]  Whenever appropriate, the subjects will be provided with additional pertinent information

 after participation.

 Please explain:

* 1. **Parental Permission is not in the best interests of children** [ ]  **NA**

In order to waive the requirement for parental permission under this category, **ALL** of the following criteria must be met:

[ ]  The research is not FDA-regulated.

[ ]  The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children).

Please explain:

[ ]  A mechanism is substituted for parental permission to ensure the protection of children. The choice of an appropriate mechanism (e.g., child advocate, witness, etc.) should be in keeping with the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Please explain:

1. **Request for a General Alteration of Consent (alteration or exclusion of one or more of the required elements of consent)** [ ]  **NA**

The IRB may alter the required elements of consent if the investigator justifies, and the IRB agrees, that specific criteria have been met. (46.116(f), [FDA Guidance](https://www.fda.gov/RegulatoryInformation/Guidances/ucm566474.htm))

* 1. **Explain which element(s) of consent you wish to alter or exclude and why? Note:** None of the Common Rule *General Requirements for Informed Consent* can be omitted or altered. A listing of the FDA and Common Rule Elements of Consent is at the end of this form for reference.

* 1. **General Alteration Criteria**

In order to alter the requirement for informed consent or parental permission under this category, ALL of the following criteria must be met:

[ ]  The research involves no more than minimal risk\*.

Please explain:

\**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.*

[ ]  The alteration will not adversely affect the rights and welfare of the subjects.

Please explain:

[ ]  The research could not be carried out without the alteration.

Please explain:

[ ]  If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

 **Note:** *This is a new criterion in the revised Common Rule, which applies to research with identifiable private information or identifiable biospecimens. If your research only falls under FDA or Department of Justice Regulations, this criterion does not apply and you should enter 'NA'.*

Please explain:

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

Please explain:

* 1. **Is the alteration for the purposes of deception (withholding the true purpose or certain aspects of the research)?**

[ ]  Yes [ ]  No

If yes, answer the following:

* + 1. Explain why deception is necessary in this research:

* + 1. Describe any provisions for debriefing of subjects after participation, and if not, explain why subjects won’t be debriefed. Include any written debriefing materials or scripts with your submission.

* + 1. Explain whether subjects will be able to disallow use of their data for research after debriefing, and if not, provide justification:

1. **Request for Waiver of Documentation of Consent** (waiver of the requirement to document consent using a signed written consent form)[ ]  **NA**
	1. **Is the request for a full or partial waiver?**

[ ]  Full Waiver – Signed written consent will not be obtained from any subjects (e.g., a verbal consent process will be used)

[ ]  Partial Waiver – Signed written consent will not be obtained from some subjects or for some activities (e.g., a verbal consent process will be used for some activities)

If request is for a partial waiver, explain what you are requesting:

* 1. **There are three categories of waivers of documentation of consent, select the appropriate category for this request and then fill out the applicable section.**

[ ]  General (46.117(c)(1)(ii)/[56.109(c)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.109)) - Permissible under Common Rule and FDA

[ ]  Consent as only identifying record (45 CFR 46.117(c)(1)(i)) - Permissible under Common Rule only [ ]  Signing forms is not a cultural norm (45 CFR 46.117(c)(1)(iii)) - Permissible under Common Rule only

* + 1. General:

The research involves no more than minimal risk; and involves only procedures that do not require written consent outside of research. Please explain:

* + 1. Consent as only identifying record:

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. Please explain:

* + 1. Signing forms is not a cultural norm:

The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained**.** Please explain:

* 1. **Please explain how the elements of consent will be presented to potential subjects absent a signed consent form.**

[ ]  Script

[ ]  Information sheet to be distributed to subject

[ ]  Survey introductions, videos, and other materials or aides

[ ]  Other, Explain:

**Note:** *This material should be included with this submission. If your script, survey introduction, information sheet or other mechanism will not include all required elements of consent (see checklist at the end of this form), you also will need to request an alteration of consent (see Section II above).*

* 1. **Please explain if and how, in the absence of signed written consent forms, consent will be documented (e.g. tape recordings, videos, chart notes, completion of a survey, etc.)**

**Federal Consent Elements**

| **General Requirements for Consent** (45 CFR 46.116(a), [21 CFR 50.20](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.20)) |
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| Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject’s legally authorized representative (LAR) |
| Informed consent will be sought only under circumstances that provide the prospective subject or LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence |
| The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR. |
| [Common Rule only] The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. |
| [Common Rule only] Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.* *Generally, the consent should begin with a concise explanation of the following:*
	+ *The fact that consent is being sought for research and that participation is voluntary;*
	+ *The purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research;*
	+ *The reasonably foreseeable risks or discomforts to the prospective subject;*
	+ *The benefits to the prospective subject or to others that may reasonably be expected from the research; and*
	+ *Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.*
 |
| [Common Rule only] Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or LAR’s understanding of the reasons why one might or might not want to participate. |
| No informed consent may include any [exculpatory language](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/exculpatory-language-in-informed-consent-documents/index.html) through which the subject or the LAR is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. |

| **Basic Elements** (45 CFR 46.116(b), [21 CFR 50.25(a)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25)) |
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| Each of the following:* A statement that the study involves research
* An explanation of the purposes of the research
* The expected duration of the subject’s participation
* A description of the procedures to be followed
* Identification of any procedures which are experimental
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| A description of reasonably foreseeable risks or discomforts |
| A description of any benefits to subjects or others which may reasonably be expected from the research |
| A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to subjects |
| A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained |
| For research involving more than minimal risk, an explanation as to whether any compensation **and** an explanation as to whether any medical treatments are available if injury occurs **and, if so**, what they consist of, or where further information may be obtained |
| An explanation of whom to contact:* For answers to questions about the research
* For answers about research subject’s rights
* In the event of a research-related injury
 |
| A statement that:* Participation is voluntary
* That refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled
* That the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
 |
| [Common Rule only] One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: * A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
* A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
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| **Additional Elements** (45 CFR 46.116(c), [21 CFR 50.25(b)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25)) – required when applicable |
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| A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable |
| Anticipated circumstances under which a subject’s participation may be terminated by the investigator without regard to the subject’s consent |
| Any additional costs to the subject that may result from participation in the research |
| The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject |
| A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject |
| The approximate number of subjects involved in the study |
| [Common Rule only] A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit |
| [Common Rule only] A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions |
| [Common Rule only] For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) |

| **Additional FDA Requirements** ([21 CFR 50.25(a)(5), 21 CFR 50.25(c)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25) |
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| The statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained must also note the possibility that the FDA may inspect records. |
| If the trial must be registered on clinicaltrials.gov under [FDAAA801](https://clinicaltrials.gov/ct2/manage-recs/fdaaa), the following statement verbatim: A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. |