|  |  |
| --- | --- |
| **ID:** | Click or tap here to enter text formatted as Submission Number – PI Last Name. |
| **Notes:** | Click or tap here to enter text. |

Can non-exempt research be approved?[[1]](#endnote-2)

The following criteria must be met for approval of non-exempt research:

|  |
| --- |
| 1. Criteria for Approval[[2]](#endnote-3) (Check if **“Yes”.** All must be checked.)
 |
| [ ]  | * 1. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for other purposes.[[3]](#endnote-4),[[4]](#endnote-5)
 |
| [ ]  | * 1. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.3,[[5]](#endnote-6)
 |
| [ ]  | * 1. Selection of subjects is equitable.[[6]](#endnote-7)
 |
| [ ]  | * 1. There are adequate provisions for monitoring the data collected to ensure the safety of subjects.[[7]](#endnote-8),[[8]](#endnote-9)
 |
| [ ]  | * 1. There are adequate provisions to maintain the confidentiality of data.
 |
| [ ]  | * 1. There are adequate provisions to protect the privacy of subjects.
 |
| [ ]  | * 1. Additional safeguards are included to protect the rights and welfare of subjects vulnerable to coercion or undue influence.
 |
| [ ]  | * 1. Informed consent will be sought from each subject or LAR, in accordance with, and to the extent required by section 2, or appropriately waived.[[9]](#endnote-10)
 |
| [ ]  | * 1. Informed consent will be appropriately documented, in accordance with, and to the extent required by section 3, or appropriately waived.[[10]](#endnote-11)
 |
| 1. Consent Process[[11]](#endnote-12),[[12]](#endnote-13) (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. Before involving a subject in research, the investigator will obtain the legally effective informed consent of the subject or LAR.
 |
| [ ]  | * 1. The circumstances of consent will provide the subject or LAR sufficient opportunity to discuss and consider whether or not to participate.
 |
| [ ]  | * 1. The circumstances of consent will minimize the possibility of coercion or undue influence.[[13]](#endnote-14)
 |
| [ ]  | * 1. The information given to the subject or LAR will be in language understandable to the subject or LAR.
 |
| [ ]  | * 1. The consent language does NOT include any exculpatory language through which the subject or the representative 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.
 |
| [ ]  | * 1. Research that has to follow the <Revised Rule>[[14]](#endnote-15) (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  | [ ]  | * + 1. The subject or LAR will 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.[[15]](#endnote-16)
 |
|  | [ ]  | * + 1. Consent will begin with a concise and focused presentation of the key information that is most likely to assist a subject or LAR in understanding the reasons why one might or might not want to participate in the research and this part of the consent is organized and presented in a way that facilitates comprehension.[[16]](#endnote-17)
 |
|  | [ ]  | * + 1. The consent as a whole presents information in sufficient detail relating to the research, and is 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.
 |
| 1. Written Documentation of Consent[[17]](#endnote-18) (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. Long Form of Consent Documentation (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  | [ ]  | * + 1. The form is accurate and complete.
 |
|  | [ ]  | * + 1. The form will be signed and dated by the subject or LAR.
 |
|  | [ ]  | * + 1. The form will be signed and dated by the person obtaining consent.
 |
|  | [ ]  | * + 1. If NIH-funded and/or FDA-regulated research: A signed and dated copy will be given to the person signing the form.
 |
|  | [ ]  | * + 1. The investigator will give the subject or LAR adequate opportunity to read the form before it is signed and dated. Alternatively, the form may be read to the subject or LAR.
 |
|  | [ ]  | * + 1. If the subject cannot read, an <Impartial Witness> will witness the consent process and sign and date the form.
 |
|  | [ ]  | * + 1. Signature blanks are appropriate for the protocol and correctly labeled.
 |
|  | [ ]  | * + 1. Addendum consent forms are identified as such.
 |
| [ ]  | * 1. Short Form of Consent Documentation (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  | [ ]  | * + 1. The long form is used as a summary.
 |
|  | [ ]  | * + 1. The short form is written in language understandable to the subject or LAR.
 |
|  | [ ]  | * + 1. The short form states that the required elements of informed consent have been presented orally to the subject or LAR.
 |
|  | [ ]  | * + 1. The short form states that the key information required by 45 CFR §46.116(a)(5)(i) was presented first to the subject, before other information.
 |
|  | [ ]  | * + 1. There will be an <Impartial Witness> to the oral presentation who can converse in the language of the short form and the language of the summary.
 |
|  | [ ]  | * + 1. The subject or LAR, person obtaining consent, and witness will sign and date the short form and the summary.
 |
|  | [ ]  | * + 1. The subject or LAR will be given signed and dated copies of the short form and the summary.
 |
|  | [ ]  | * + 1. Signature blanks are appropriate for the protocol and correctly labeled.
 |
| 1. Consent Disclosures (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
| [ ]  | * 1. Required Disclosures11 (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  | [ ]  | * + 1. Study involves research.
 |
|  | [ ]  | * + 1. Purposes of the research.
 |
|  | [ ]  | * + 1. Expected duration of the subject’s participation.
 |
|  | [ ]  | * + 1. Procedures to be followed
 |
|  | [ ]  | * + 1. Any procedures that are experimental.
 |
|  | [ ]  | * + 1. Any reasonably foreseeable risks or discomforts to the subject.
 |
|  | [ ]  | * + 1. Any benefits to the subject or others that may reasonably be expected from the research.
 |
|  | [ ]  | * + 1. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
 |
|  | [ ]  | * + 1. The extent, if any, to which confidentiality of records identifying the subject will be maintained.
 |
|  | [ ]  | * + 1. How to contact the investigator for questions, concerns, and complaints.
 |
|  | [ ]  | * + 1. How to contact someone independent of the investigator for questions, concerns, complaints, and subjects' rights.
 |
|  | [ ]  | * + 1. Whom to contact in the event of a research-related injury to the subject.
 |
|  | [ ]  | * + 1. Participation is voluntary.
 |
|  | [ ]  | * + 1. Refusal to participate will involve no penalty or loss of benefits which the subject is otherwise entitled.
 |
|  | [ ]  | * + 1. Discontinuing participation at any time will involve no penalty or loss of benefits which the subject is otherwise entitled.
 |
|  | [ ]  | * + 1. If there is a likelihood of child abuse coming up in the study, make sure the consent mentions the mandated reporting requirement. If equivalent language is not already in the consent, have them add the following, “Although this is not the purpose of this research, we are required to report instances of child abuse and/or neglect to the relevant university and law enforcement agencies.”
 |
|  | [ ]  | * + 1. Research involving more than <Minimal Risk> to subjects (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  |  | [ ]  | * + - 1. Whether any compensation is available if injury occurs and, if so, what it consists of.
 |
|  |  | [ ]  | * + - 1. Whether any medical treatments are available if injury occurs and, if so, what they consist of.
 |
|  | [ ]  | * + 1. FDA-regulated research[[18]](#endnote-19) (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  |  | [ ]  | * + - 1. A statement that notes the possibility that the Food and Drug Administration may inspect the records.
 |
|  |  | [ ]  | * + - 1. For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: "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."
 |
|  |  | [ ]  | * + - 1. A statement that already collected data cannot be destroyed.
 |
|  | [ ]  | * + 1. Research that has to follow (International clinical trials or results being sent to the FDA or other regulatory body) ICH-GCP[[19]](#endnote-20),[[20]](#endnote-21) (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  |  | [ ] [ ] [ ] [ ]  | * + - 1. Clinical trials should be scientifically sound and reflect the state of knowledge and experience with the investigational product(s), including, if applicable,
		- The condition to be treated, diagnosed or prevented.
		- The current understanding of the underlying biological mechanism (of both the condition and the investigational product).
		- The population for which the investigational product is intended.
			1. There should be periodic review of current scientific knowledge and approaches to determine whether modifications to the trial are needed, since new or unanticipated information may arise once the trial has begun.
			2. The scientific goal and purpose should be carefully considered so as not to unnecessarily exclude particular participant populations.
			3. Probability for random assignment, if any.
 |
|  |  | [ ]  | * + - 1. Any subject responsibilities.
 |
|  |  | [ ]  | * + - 1. Monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent document, the subject or the subject's legally acceptable representative is authorizing such access.
 |
|  |  | [ ]  | * + - 1. Reasonably foreseeable risks to an embryo, fetus, or nursing infant, if any.
 |
|  |  | [ ]  | * + - 1. If no intended clinical benefit to the subject, a statement to that effect.
 |
|  |  | [ ]  [ ]  | * + - 1. If the results of the trial are published, the subject's identity will remain confidential.
			2. The amount and method of payment to participants to assure that neither presents problems of coercion or undue influence on the trial participants.
		- Payments to a participant should be timely, prorated and not wholly contingent on completion of the trial by the participant.
		- Reasonable reimbursement of expenses incurred by participants, such as for travel and lodging, is not coercive.
 |
|  | [ ]  | * + 1. Research that has to follow the <Revised Rule> (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  |  | [ ]  | * + - 1. One of the following is true **(Check box that is true)**:
 |
|  |  |  | [ ]  | * + - * 1. 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.
 |
|  |  |  | [ ]  | * + - * 1. 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.
 |
|  |  |  | [ ]  | * + - * 1. Neither of the above (because the research does NOT involve the collection of <Identifiable Private Information> or <Identifiable Biospecimens>).
 |
|  |  | [ ]  | * + - 1. If the consent form body is longer than 4 pages. (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  |  |  | [ ]  | * + - * 1. The forms starts with a concise presentation that summarizes the most important aspects of the following disclosures:15 (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  |  |  |  | [ ]  | The fact that consent is being sought for research. |
|  |  |  |  | [ ]  | The expected duration of the prospective subject’s participation. |
|  |  |  |  | [ ]  | Purposes of the research. |
|  |  |  |  | [ ]  | 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. |
|  |  |  |  | [ ]  | Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. |
|  |  |  |  | [ ]  | Participation is voluntary. |
|  |  |  | [ ]  | * + - * 1. The concise and focused presentation does not exceed 3 pages or 1/3 of the length of the remaining document (exclusive of face page and signature blocks), whichever is shorter.16
 |
|  | [ ]  | * + 1. NIH-funded research (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  |  | [ ]  | * + - 1. The protections afforded by the Certificate of Confidentiality and any exceptions to that protection.
 |
|  |  | [ ]  | * + - 1. For studies classified as a clinical trial per the NIH definition[[21]](#endnote-22): "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."
 |
|  |  | [ ]  | * + - 1. A statement that the data will be de-identified and shared for future research studies without additional informed consent from the subject or the legally authorized representative (NIH typically requires investigators to share their data).
 |
|  |  | [ ]  | * + - 1. For studies that include the prospective collection of and potentially sharing biological specimens, it is recommended (not required) to have the consent permit genetic analyses.
 |
|  | * 1. Additional Disclosures to be Included When Appropriate11 (Check if **“Yes”.**)
 |
|  | [ ]  | * + 1. Treatment or procedure may involve unforeseeable risks to the subject that are currently unforeseeable.
 |
|  | [ ]  | * + 1. Treatment or procedure may involve unforeseeable risks to the embryo or fetus, if the subject is or becomes pregnant.
 |
|  | [ ]  | * + 1. Any additional costs to the subject that may result from participation in the research.
 |
|  | [ ]  | * + 1. Anticipated circumstances under which participation may be terminated without regard to the subject’s/LAR's consent.
 |
|  | [ ]  | * + 1. The consequences of a subject’s decision to withdraw from the research.
 |
|  | [ ]  | * + 1. Procedures for orderly termination of participation by the subject.
 |
|  | [ ]  | * + 1. Significant new findings that may relate to the subject’s willingness to continue will be provided to the subject.
 |
|  | [ ]  | * + 1. Approximate number of subjects involved in the study.
 |
|  | [ ]  | * + 1. Amount and timing of payments.
 |
|  | [ ]  | * + 1. For research with a Certificate of Confidentiality, the protections afforded by the Certificate and any exceptions to that protection.[[22]](#endnote-23)
 |
|  |  | * + 1. Research that has to follow the <Revised Rule> (Check if **“Yes”.**)
 |
|  |  | [ ]  | * + - 1. 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.
 |
|  |  | [ ]  | * + - 1. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
 |
|  |  | [ ]  | * + - 1. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.[[23]](#endnote-24)
 |
| [ ]  | * 1. HIPAA Authorization[[24]](#endnote-25) (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  | [ ]  | * + 1. Core Elements (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  |  | [ ]  | * + - 1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
 |
|  |  | [ ]  | * + - 1. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.
 |
|  |  | [ ]  | * + - 1. The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.
 |
|  |  | [ ]  | * + - 1. A description of each purpose of the requested use or disclosure.[[25]](#endnote-26)
 |
|  |  | [ ]  | * + - 1. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure.[[26]](#endnote-27)
 |
|  |  | [ ]  | * + - 1. Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual is provided.
 |
|  | [ ]  | * + 1. Required Statements (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  |  | [ ]  | * + - 1. The individual's right to revoke the authorization in writing, and either (A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or (B) To the extent that the individual's right to revoke the authorization in writing is included in the covered entity's Notice of Privacy Practices, a reference to that Notice.
 |
|  |  | [ ]  | * + - 1. The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either (A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations applies; or (B) the consequences to the individual of a refusal to sign the authorization when the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.
 |
|  |  | [ ]  | * + - 1. The potential for information disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and no longer be protected.
 |
|  | [ ]  | * + 1. Additional Requirements (Check if **“Yes”.** All must be checked.) **N/A** [ ]
 |
|  |  | [ ]  | * + - 1. The authorization is written in plain language.
 |
|  |  | [ ]  | * + - 1. If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.
 |
|  |  | [ ]  | * + - 1. No material information in the authorization is known to be false.
 |
|  |  | [ ]  | * + - 1. The authorization follows additional state law for CA, DE, IN, IL, MT, WA, WI.
 |
| 1. Additional Considerations
 |
| ● | * 1. Does the IRB have sufficient expertise to review this research?
 |
| ● | * 1. Are other criteria applicable, and if so met?
 |
|  |  | * CHECKLIST: Waiver of Consent (HRP-300)
* CHECKLIST: Waiver of Documentation of Consent (HRP-303)
* CHECKLIST: Pregnant Women (HRP-305)
* CHECKLIST: Neonates of Uncertain Viability (HRP-306)
* CHECKLIST: Nonviable Neonates (HRP-307)
* CHECKLIST: Prisoners (HRP-308)
* CHECKLIST: Unexpected Incarceration (HRP-309)
* CHECKLIST: Children (HRP-310)
* WORKSHEET: Adults Lacking Capacity (HRP-414)
 |
| ● | * 1. Does the research involve more than minimal risk to subjects?
 |
| ● | * 1. Is continuing review NOT required because:
 |
|  |  | * + The research is NOT FDA regulated and/or DOJ funded
	+ The research does NOT have to follow the <Original Rule>, and
	+ One of the following is true:
	+ The research is eligible for exemption in accordance with "WORKSHEET: Exemptions (HRP-423)
	+ The research is eligible for expedited review under categories (1)-(7), (8)(a), (8)(c) of "WORKSHEET: Expedited Review (HRP-424)," or
	+ The research has progressed to the point that it solely involves data analysis and/or accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care, including analysis of <Identifiable Private Information> or <Identifiable Biospecimens>, which are part of the IRB-approved study.
 |
| ● | * 1. Based on risk, should continuing review be conducted more often than annually?
 |
| ● | * 1. Is there limited reliability of submitted information such that verification is needed from sources other than the investigator?[[27]](#endnote-28)
 |
| ● | * 1. Are there new findings that may relate to the subject’s willingness to continue participation which should be provided to the subject?
 |
| ● | * 1. If the research involves human gene transfer, would the protocol significantly benefit from RAC review and does it meet one or more of the following criteria?
 |
|  |  | * + The protocol uses a new vector, genetic material, or delivery methodology that represents a first-inhuman experience, thus presenting an unknown risk.
	+ The protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value.
* The proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies involved to evaluate the protocol rigorously.
 |
| 1. Primary Presenter Considerations
 |
| ● | * 1. Are the submitted materials consistent?
 |
| ● | * 1. If the investigator is the lead of a multi-site study, is the management of information relevant to the subject protection adequate?
 |

**Footnotes**

1. . In this worksheet, "research" means <Human Research> and "subject" means <Human Subject as Defined by HHS> or <Human Subject as Defined by FDA> [↑](#endnote-ref-2)
2. . 21 CFR §56.111, 45 CFR §46.111 [↑](#endnote-ref-3)
3. . Consider physical, psychological, social, legal, and economic harms. [↑](#endnote-ref-4)
4. . Evaluate whether these resources are sufficient to protect participants: Time to conduct and complete the research, number and qualifications and training of investigators and staff, facilities, access to a population that will allow recruitment of the necessary number of subjects, and availability of medical or psychosocial resources that subjects may need as a consequence of the research. Consider whether there is a safer way to perform the research that might still accomplish the scientific aims. [↑](#endnote-ref-5)
5. . Evaluate whether the materials accurately describe the subject risks, subject benefits, and knowledge to result. For clinical trials, consider whether the available non-clinical and clinical information on an investigational product is adequate to support the research. [↑](#endnote-ref-6)
6. . Take into account: the purposes of the research; the setting in which the research will be conducted; whether prospective subjects will be vulnerable to coercion or undue influence; the selection (inclusion/exclusion) criteria; subject recruitment and enrollment procedures; the influence of payments to subjects. [↑](#endnote-ref-7)
7. . For research involving no more than <Minimal Risk> the absence of a plan is sufficient. [↑](#endnote-ref-8)
8. . Consider what safety information will be collected; how it will be collected; the frequency of collection, when collection starts; the frequency or periodicity of review; whether a data monitoring committee is needed; statistical tests for analyzing the data to detect harm; provisions for the oversight of safety data; stopping conditions. [↑](#endnote-ref-9)
9. . See "CHECKLIST: Waiver of Consent (HRP-300)." [↑](#endnote-ref-10)
10. . See "CHECKLIST: Waiver of Documentation of Consent (HRP-303)." [↑](#endnote-ref-11)
11. . 21 CFR §50.20 and 45 CFR §46.116 [↑](#endnote-ref-12)
12. . An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. [↑](#endnote-ref-13)
13. . Advertisements and Payments:

Advertisements: Review advertisements for the mode of communication and review the final copy. Advertisements should not state or imply a certainty of favorable outcome or other benefits beyond what is in the consent document and protocol, not include exculpatory language, not emphasize the payment or the amount to be paid, by such means as larger or bold type, and not promise “free treatment” when the intent is only to say subjects will not be charged for taking part in the research. Advertisement should be limited to the information prospective subjects need to determine their eligibility and interest.

Advertisements for clinical trials should not make claims, either explicitly or implicitly, about the drug, biologic, or device under investigation that are inconsistent with FDA labeling, not use terms, such as “new treatment,” “new medication,” or “new drug,” without explaining that the test article is investigational, and not include compensation for participation to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

Payments: FDA does not consider reimbursement for travel expenses to and from the clinical trial site and associated costs such as airfare, parking, and lodging to raise issues regarding undue influence. For other payments, review the amount, method, and schedule of all payments. The amount, method, and timing of disbursement cannot be coercive or present undue influence. Credit for payment should accrue as the study progresses and is not be contingent upon completing the entire study. Any amount paid as a bonus for completion should be reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. Payment should not include a discount on the purchase price of the product once it has been approved for marketing. [↑](#endnote-ref-14)
14. . 45 CFR §46.116(a) [↑](#endnote-ref-15)
15. . For example, with regard to risks in a cancer trial, instead of needing to mention every reasonably foreseeable risk, this beginning section of the consent form should identify the most important risks, similar to the information that a doctor might deliver in the clinical context in telling a patient how sick the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study. [↑](#endnote-ref-16)
16. . If the body of the consent form is four pages or shorter, the body serves as the concise and focused presentation. [↑](#endnote-ref-17)
17. . 21 CFR §50.27 and 45 CFR §46.117 [↑](#endnote-ref-18)
18. . For FDA-reglated research, when a subject withdraws from a study, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed. The subject cannot be informed otherwise. [Guidance for Sponsors, Clinical Investigators, and IRBs: Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials](https://www.fda.gov/media/75138/download) [↑](#endnote-ref-19)
19. . International Conference on Harmonisation: Guideline For Good Clinical Practice E6(R1) [↑](#endnote-ref-20)
20. . The requirement to disclose the approval of the IRB is accomplished through the approval stamp. [↑](#endnote-ref-21)
21. . The [NIH has a broad definition of clinical trial](https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition#:~:text=Clinical%20Trial%20Stewardship.-,NIH%20Definition%20of%20a%20Clinical%20Trial,related%20biomedical%20or%20behavioral%20outcomes.) (i.e., if there is an intervention involved, it is likely a clinical trial). [↑](#endnote-ref-22)
22. . NIH Policy [Suggested Consent Language Describing the CoC Protections](https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects) [↑](#endnote-ref-23)
23. . Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen/ [↑](#endnote-ref-24)
24. . 45 CFR §164.508(c) [↑](#endnote-ref-25)
25. . The statement "at the request of the individual" is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose. [↑](#endnote-ref-26)
26. . The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository. [↑](#endnote-ref-27)
27. When determining if verification from sources who are not the investigator are needed, the IRB should consider all (but not limited to) the following: (i) The nature of and any risks posed by the clinical investigation. (ii) The degree of uncertainty regarding the risks involved. (iii) The vulnerability of the participants. (iv) The experience of the clinical investigator in conducting clinical research. (v) The IRB’s or EC’s previous experience with that researcher or sponsor (e.g., compliance history, previous problems with the researcher obtaining informed (vi) consent, prior complaints from participants about the researcher). (vii) The projected rate of enrollment. (viii) Whether the study involves novel therapies. [↑](#endnote-ref-28)