



HRP-314a | 12/1/2025

WORKSHEET: Criteria for Consent

The purpose of this worksheet is to provide support for IRB members reviewing research consent process(es) and documentation. It does not need to be completed or retained. (LAR = “subject’s Legally Authorized Representative”).ⁱ

1. Consent Process (Check if “Yes”. All must be checked)

- The investigator will obtain the legally effective informed consent of the subject or LARⁱⁱ.
- The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether to participate.
- The circumstances of consent minimize the possibility of coercion or undue influence.
- Information to be given to the subject or LAR will be in language understandableⁱⁱⁱ to the subject or LAR.
- 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. **(NA if research is subject to Pre-2018 Requirements) NA:**
- 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. **(NA if research is subject to Pre-2018 Requirements) NA:**
- There is no exculpatory language^{iv} through which the subject or LAR is made to waive or appear to waive the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.
- Consent will disclose the elements in **Section 3: Elements of Consent Disclosure**

2. Long Form of Consent Documentation (Check if “Yes” or “NA”. All must be checked.)

- The written consent document is accurate, complete, and consistent with the protocol.
- The written consent document embodies the elements in **Section 3: Elements of Consent Disclosure**
- The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.
- The subject or LAR will sign and date the consent document.
- The person obtaining consent will sign and date the consent document.
- A copy of the signed and dated consent document will be given to the person signing the document.

- If there is a LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. (“NA” if no signature line) NA:
- When a subject or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. (“NA” if all subjects are able to read) NA:

3. Elements of Consent Disclosure^v (Check if “Yes” or “NA”. All must be checked)

Required Elements

(*Can be omitted if there are none.)

- The study involves research.
- The purposes of the research.
- The expected duration of the subject’s participation.
- The procedures to be followed.
- Identification of any procedures, which are experimental.*
- Any reasonably foreseeable risks or discomforts to the subject.*
- Any benefits to the subject or to others, which may reasonably be expected from the research. ^{*vi}
- Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*
- The extent, if any, to which confidentiality of records identifying the subject will be maintained.*
- How to contact the research team for questions, concerns, or complaints about the research.
- How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects’ rights; to obtain information; or to offer input.
- Whom to contact in the event of a research-related injury to the subject.
- Participation is voluntary.
- Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- 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 LAR, 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.

(NA if research is subject to Pre-2018 Requirements) NA:

Required for More than Minimal Risk Research

- Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.
- Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

Required for Clinical Trials that Follow ICH-GCP

- The trial's investigational product(s) and probability for random assignment to each treatment, if applicable.
- What is expected of the participants.
- When applicable, the reasonably foreseeable risks or inconveniences and benefits to the participant's partner, to an embryo, fetus, or nursing infant.
- The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.
- When there is no intended clinical benefit to the participant, the participant should be made aware of this.
- The process by which the participant's data will be handled, including in the event of withdrawal or discontinuation of participation in accordance with regulatory requirements.
- That by agreeing to participate in the trial, the participant or their legally acceptable representative allows direct access to source records, based on the understanding that the confidentiality of the participant's medical record will be safeguarded. This access is limited for the purpose of viewing trial activities and/or revising or verifying data and records by the regulatory authority(ies) and the sponsor's representatives, for example, monitor(s) or auditor(s), and in accordance with applicable regulatory requirements, the IRB.
- If the results of the trial are published, the participant's identity will remain confidential. The trial may be registered on publicly accessible and recognized databases, per applicable regulatory requirements.
 - Trial results and information on the participant's actual treatment, if appropriate, will be made available to them should they desire it.

Required for FDA-Regulated Research^{vii}

- The possibility that the Food and Drug Administration may inspect the records and should not state or imply that FDA needs permission from the subject for access to the records^{viii}.

- The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
- The investigator should ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.
 - 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.”

Additional

- The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.
- If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
- Anticipated circumstances under which the 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.
- Procedures for orderly termination of participation by the subject.
- 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.
- Approximate number of subjects involved in the study.
- Amount and schedule of all payments.
- 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. **(NA if research is subject to Pre-2018 Requirements)**
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. **(NA if research is subject to Pre-2018 Requirements)**
- 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). **(NA if research is subject to Pre-2018 Requirements)**
- Any additional information which should be given to subjects when in the IRB’s judgement the information would meaningfully add to the protection of the rights and welfare of subjects.
 - When the study involves genetic testing, a statement that outlines the protections afforded to the subject under the Genetic Information Nondiscrimination Act (GINA).

4. Additional Considerations for Electronic Consent (Check if “Yes” or “NA”. All must be checked)

Electronic consent document includes all elements in **Section 3-Elements of Consent Disclosure**

The date of the electronic signature will be captured.

(NA if waiver of documentation of consent is requested and justified) NA:

Questions or methods to gauge subject comprehension of key study elements are clearly defined in the informed consent procedures.

Electronic consent process includes age-appropriate materials to facilitate comprehension.

Electronic consent process is suitable to the study population or procedures are outlined to accommodate subject’s needs.

Electronic consent document/process allows subjects to proceed forward or backward or pause for review later.

Measures are present to ensure that subjects have access to all of the consent related materials, including hyperlinks or other external documents.

Plans are adequate to maintain external hyperlinks or documents and subject access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures.

The informed consent process outlines in detail how any included documents will be utilized.

Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team.

For FDA-Regulated Clinical Trials including children as research subjects, if the parent or guardian initially documents the child’s assent, procedures are in place to verify the child’s identify and assent when the child initially presents to the investigator.

(NA if the research is not a FDA-Regulated Clinical Trial) NA:

5. Consent Form Considerations for NIH-Funded Research with Digital Health Technologies^x (Check if “Yes” or “NA”. All must be checked)

Indicate if use of the digital health technology is mandatory for participation in the study. Indicate the technological capability(ies) needed for successful participation, including but not limited to WiFi, Bluetooth, smartphone model, data plans, or access to other devices and if these technological capabilities will be provided by the study

Specify which digital health technology will be used and whether it is proprietary to the research team or an outside entity, such as a commercial company (e.g., manufacturers and/or software developers). The software model used can have significant implications for privacy and security, may determine who owns, has access, or rights to distribute the data, and potentially affects the integrity of and confidence in the data associated with the technology.

- If appropriate, disclosure of any relationship (e.g. financial, board position, advisor) between investigators and the company that owns the digital health technology used in the study
- Clear description of how the digital health technology will be used including the types of data collected and the frequency it will be shared with the study team. This should include a statement that describes under what conditions and how frequently participants will be asked to use or interact with the digital health technology for study purposes (e.g., turn on, use, enter data), whether data will be collected without purposeful participation (i.e., passive data types such as location data, steps, heart rate), and how the technology may impact their daily activities. Expectations about what participants should not do (e.g., move a device, turn it off) should also be clearly communicated
- A statement explaining if the interactions with the digital health technology will involve notifications or communications from computer generated sources and at what frequency.
- A statement explaining the device(s) being used in the study and that they will need to agree to the standard terms and conditions for the use of the device(s) and instructed use. Clear instructions should be provided on how to install, configure, and use the study-related digital health technology.
- A statement explaining if the study team will provide the digital health technology, if the participant will be asked to connect hardware or install software on a personal digital device, the expected duration of the use of the digital health technology, and when and if the participant must return study-provided devices or discontinue any subscription services (e.g., if the participant withdraws from the study, or at the study's conclusion). Indicate what happens if a device is not returned per instructions.
- When participants are familiar with the technology outside the study context, state any key differences between use of the technology for the purposes of the study compared to use in the general population.
- Indicate the names of all third parties that may have access to participant data, including the frequency of their access and level of detail they may have.
- A statement informing participants if their personal health care providers will receive information collected by the digital health technology (including atypical readings or alarms from the digital health technology), whether providers will receive this information (e.g., real-time, specific intervals), and if data will be integrated with a participant's electronic health record (EHR). Also indicating under what circumstances clinically actionable data will be shared and with whom it will be shared. Participants should be informed if they will have direct access to their collected digital health technology data, how often they will be able to directly access this data, and how this can be done.
- Participants should be alerted to the steps to stop the collection and/or sharing of their data with the study team, which may include discontinuing use of wearables, removing sharing permissions, and/or uninstalling software application(s).
- A statement clarifying whether any portion of a study incentive is dependent on participant use of the device or application
- A statement indicating whether the data collected by the digital health technology is owned by the company and whether the data may be sold or shared to third parties without explicit participant consent. Provide awareness of end user agreements, terms and conditions, and terms of service that participants will need to accept, including hyperlinks to these documents. Educate participants about the implications on the use of their data as part of these agreements.

- If applicable, a statement explaining the potential risk (including mitigation steps and how to notify participants) of reidentification as capabilities evolve to enable linkages between digital health data and disparate data sources, consider the risk of re-identification and its implications on participant's privacy and confidentiality.
- If applicable, a statement of where and how the study team or others involved in the research store and manage participant data and how to contact the digital health technology company (e.g., their website) for questions about how it stores data. Explain what security protections will be put in place by the study team, who has access to the data, and the controls to prevent unauthorized data access, noting that data held by a digital health technology company may not be protected in the same way.
- A statement informing participants about the length of time their data will be retained for the study, purposes for which data could be used during and after the study (i.e., repositories or future studies) and if additional consent will be required for any further activities
- A statement explaining if the digital health technology may store, collect, and/or display additional information as part of the technology's normal functioning that is beyond the scope of the research study
- A statement outlining the reasonably foreseeable risks and/or discomforts that may be associated with digital health technologies being used in the study. This includes possible privacy and security risks (e.g., location data), along with physical or psychosocial discomforts (e.g., skin irritation, allergic reaction, broken skin, anxiety). Investigators will need to be aware of any changes that might alter the risks of the study and consider these with the IRB for the purposes of notification to participants. Study teams should prioritize selecting technologies capable of the study measures needed while presenting the least amount of risk to participants.
- A statement addressing the potential risk of continued data collection after the study ends should the digital health technology remain on a participant's device or continue to be used by the participant.
- A statement informing participants if there could be updates to software, privacy policies, or terms of service agreements during the study period and the potential risks these updates may pose. This includes informing participants that companies deploying a commercial digital health technology may not be required to follow the same study privacy rules as the research team and the company's rules can change at any time without notice. The study team should include language explaining whether the privacy policies for the digital health technology used in the study can or cannot be changed by the research team
- A statement informing participants how linking or using multiple technologies might impact who has access to the participant's data and how much data they might have access to. If the participant has a digital health technology that can be accessed by others (e.g., shared devices or accounts with family members, relatives, neighbors), they need to be informed that this might result in less privacy and an inability to maintain confidentiality
- A statement providing participants with a clear understanding of how their study data is being protected, who might have access to it, and the steps being taken to minimize possible privacy risks that could arise
- A statement explaining if the interactions with the digital health technology will involve notifications or communications from computer generated sources and at what frequency.
- A statement helping participants understand the role they can play in protecting their confidentiality and private information when using digital health technologies (e.g., creating a secure password).

- A statement addressing the potential risks for breaches of participant study data.
- When the digital health technology used in the study could collect information on other individuals, especially when those individuals may not know their data is being collected (e.g., participant's social networks, or home and other surroundings), language should be added to inform participants of the possible risks (e.g., security risks) for non-participants and whether/how these risks can be mitigated by the study team and/or participant
- A statement addressing the potential risks for breaches of participant study data.
- A statement addressing any potential risks that arise from adding the digital health component to a participant's existing technology, including the potential for interference with another technology the participant currently uses.
- A statement outlining any anticipated direct benefits related to their use of digital health technologies during the research study.
- If the participant will be using their own device and/or needs a cellular service/ internet connection to transmit data, clearly outline who is expected to cover the cost of the required cellular service/internet connection (i.e., any reimbursement provided to cover or offset the costs).
- If the study provides paid access/subscription to a digital technology, clearly specify how long the participant will have access to the application and whether they will have to pay for the service after the study ends should they wish to continue use.
- When applicable, if there could be situations where the device breaks, is lost or stolen, is faulty, or needs maintenance (e.g., replacement parts including batteries). Specify what to do in such situations and under what circumstances the participant or the study will be responsible for paying for the maintenance or replacement of the device
- If considering commercial technologies that may offer in-app paid features, describe who is responsible for those costs and explicitly state what will be provided as part of the study
- A statement informing participants whether the study team and/or the digital health technology company may be able to keep and use participant data after the study ends or a participant withdraws from the study.
- A statement informing participants if their study data cannot be removed even upon withdrawing from the study.
- A statement informing participants if the digital health technology will continue to collect data until the device and/or the software application have been removed, uninstalled, or the associated account is deactivated or closed.
- A statement informing participants if the digital health technology will continue to collect data until the device and/or the software application have been removed, uninstalled, or the associated account is deactivated or closed.
- A statement that establishes and clearly communicates a protocol for addressing participant use of the technology as outlined in the study, defining specific criteria and time frames for non-adherence (e.g., 30 days of no interaction), using multiple methods (emails, calls, letters) for attempts to re-establish contact, and ensuring ethical considerations are met before formally withdrawing participants who do not explicitly request to drop out but show complete lack of adherence to required study activities.

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- ⁱ This document satisfies AAHRPP elements I.1.E, I.1.F, I.7.C, I-9, II.1.E, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, III.1.F
- ⁱⁱ LAR = “subject’s Legally Authorized Representative”
- ⁱⁱⁱ “Understandable” means the information presented to prospective subject is in a language and at a level the subjects can comprehend (including an explanation of scientific and medical terms) *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download>
- ^{iv} FDA considers exculpatory language to be language that has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download>
- ^v For additional guidance for FDA-regulated research on the elements of consent (including examples and recommendations on language), please see *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download>
- ^{vi} If payments, including reimbursement for research-related expenses incurred by subjects due to participation, are provided, the consent process should not identify them as benefits *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download>
- ^{vii} The FDA generally recommends against including statements such as “FDA has given permission for the clinical investigation to proceed” or “FDA has approved the clinical investigation” in the informed consent process, because such statements may suggest to subjects that the investigation has FDA’s endorsement. *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download>
- ^{viii} *FDA’s Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* <https://www.fda.gov/media/88915/download>
- ^{ix} 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
- ^x NIH Guidance is located here: [Blue and White Professional Modern Business Report Cover Page \(nih.gov\)](#). According to this guidance, digital health technology refers to wearable devices, sensor technologies, and mobile software applications (“apps”) most often used with tablets, watches, or phones.