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Informed Consent in Clinical Research- Its Importance, New Changes and Challenges

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Abstract

Recruiting and retaining the participants is the key to a successful clinical trial. Individuals should voluntarily participate in a study and for that, they must receive information about what their involvement would include. This is known as informed consent. It is required by the law and has become the primary standard for protecting the legal rights of patients and guiding the ethical practice of medicine/clinical trials. It may be used for different purposes in different contexts: legal, ethical or administrative. It is a procedure through which a competent subject, after having received and understood all the research-related information, can voluntarily provide his or her willingness to participate in a clinical trial.process. It is a good way to ensure participant's knowledge and start a relationship between researcher and participant based on communication and trust throughout the trial. New guidance primarily eases informed consent requirements for minimal risk trials. The US Food and Drug Administration (FDA) finalized a rule allowing Institutional Review Boards (IRBs) to waive or alter elements of informed consent for certain clinical trials that pose minimal risk to human subjects It is a guidance for IRBs, Clinical Investigators, and Sponsors but ultimately directs towards treatment advances through clinical trials and safeguarding the rights and health of research participants or subjects.

Keywords:

Informed consent;
FDA;
Clinical trials;
IRB;
Legal and ethical.

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1. Introduction

Informed consent in simple terms is a principle in medical ethics, medical law and media studies, that a patient must have sufficient information and understanding before making decisions about their medical care. Pertinent information may include risks and benefits of treatments, alternative treatments, the patient's role in treatment, and their right to refuse treatment [1]. For most research, informed consent is documented using a written document that provides key information regarding the research. The consent form is intended, in part, to

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provide information for the potential subject's current and future reference and to document the interaction between the subject and the investigator. However, even if a signed consent form is required, it alone does not constitute an adequate consent process. The informed consent process is an ongoing exchange of information between the investigator and the subject and could include, for example, use of question and answer sessions, community meetings, and videotape presentations. In all circumstances, however, individuals should be provided with an opportunity to have their questions and concerns addressed on an individual basis. Within the US, definitions of informed consent vary, and the standard required is generally determined by the state [2]. To many, the term informed consent is mistakenly viewed as synonymous with obtaining a subject's signature on the consent form; however, obtaining documentation of a subject's informed consent is only part of the consent process[3].

Informed consent involves providing a prospective subject, or their legally authorized representative (LAR), with adequate information to allow for an informed decision about participation in the clinical investigation prior to enrollment. Informed consent also involves facilitating the prospective subject's understanding of the information, providing adequate opportunity for the prospective subject to ask questions and to consider whether to participate, obtaining the prospective subject's voluntary agreement to participate prior to enrollment, and continuing to provide information as the clinical investigation progresses or as the enrolled subject or situation requires[4]. The informed consent process involves three key features: (i) disclosing to potential research subjects information needed to make an informed decision; (ii) facilitating the understanding of what has been disclosed; and (iii) promoting the voluntariness of the decision about whether or not to participate in the research. Informed consent must be legally effective and prospectively obtained.

The informed consent process is the critical communication link between the prospective human subject and an investigator, beginning with the initial approach of an investigator to the potential subject (e.g., through a flyer, brochure, or any advertisement regarding the research study) and continuing until the completion of the research study. For the purposes of the United States Department of Health and Human Services (HHS) regulations at 45 CFR part 46, "investigators" are individuals who conduct human subjects research projects, including individuals directly involved in seeking the voluntary informed consent of potential subjects. Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others[5].

The informed consent process should be an active process of sharing information between the investigator and the prospective subject. The exchange of information between the investigator and prospective subjects can occur via one or more of the following modes of communication, among others: face-to-face contact; mail; telephone; video; or fax. Prospective subjects should be provided with ample opportunity to ask questions and seek clarification from the investigator. The prospective subjects should be in a position to freely decide whether to initially enroll in the research, or later, to withdraw or continue participating in the research. The informed consent process should ensure that all critical information about a study is completely disclosed, and that prospective subjects or their legally authorized representatives adequately understand the research so that they can make informed choices[6].

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2. Research Method

The present report is primarily based on a study, involving compilation and analyses of information and data from official documents, research papers/reports, media reports and articles. The following topics are explored:

a) Informed consent- components and regulatory requirements

b) Importance

c) New changes and challenges

d) Conclusion and a suggestive way forward.

3. Results and Analysis

3.1) What is the Consent Form?

The consent form can be defined as a written summary of the communication taking place between the investigator and the study participant and serves as documentation that consent was requested. It does not take the place of personal interaction between the participant and the researcher, but it may serve as a catalyst for discussion about the research and participating in it. It is used as a written presentation of information. It provides a base for the consent process and allows the subjects a reference point to go back to when questions arise regarding procedures, follow-up appointments to be scheduled or if a subject experiences a side effect. The document must be signed by the subject or subject's Legally Authorized Representative (LAR) and a copy must be given to the subject. The elements required in the informed consent document are listed in 45 CFR 46.116 and 21 CFR 50.25 [4],[5].

3.2) Informed consent- components and regulatory requirements

Informed consent is mandatory for all clinical trials involving human beings. The U.S. Department of Health and Human Services (HHS) regulations require that an investigator obtain legally effective informed consent from subjects or a legally authorized representative before the subjects may be involved in research [5],[7]. The consent process must respect the patient's ability to make decisions and adhere to the individual hospital rules for clinical studies. Adherence to ethical standards in study design and execution is usually monitored by an Institutional Review Board (IRB). The IRB was established in the United States in 1974 by the National Research Act which called for regulation in human research that was prompted by questionable research tactics used in the Tuskegee syphilis experiments and others. Ethical and safe research standards have been an area of federal and presidential interest since then, with the development of many organizations and task forces since 1974 dedicated to this topic alone[8].

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In fact, The origin of the modern regulations for informed consent in the U.S. date back to the 1930s, when Nazi physicians conducted horrific experiments on human subjects without their consent before and during WWII. After the war, from the Nuremberg Trials came the Nuremberg Code, a set of 10 ethical principles for physicians and researchers to follow when conducting experimentation on humans, one of which was informed consent. As mentioned above , the egregious actions taken by the U.S. Government during the Tuskegee Syphilis Study from 1932-1972 without the consent of the men involved in the study led to the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974. Four years later, this commission published the Belmont Report [9] , which laid out the essential need for informed consent in human research. In the 1980s, the U.S. Department of Health and Human Services (HHS) operationalized the findings of Belmont Report into a set of guidelines and principles for research and specific requirements for informed consent that is referred to collectively as the "Common Rule" [10].

As mentioned earlier , a valid informed consent for research must include three major elements: a) disclosure of information like the diagnosis, the proposed treatment, the attendant risks and benefits of the treatment, b) competency of the patient (or surrogate) to make a decision, by giving them all information like alternative treatments and their risks and benefits, and the risks and benefits of declining treatment. and c) voluntary nature of the decision. US federal regulations require a full, detailed explanation of the study and its potential risks [11].

Guidance on Creating a Consent Process and Documentation briefs that an Informed consent must be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 or 21 CFR 50.27. Informed consent is documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy of the signed and dated consent form must be given to the person signing the form. It is important to note that the consent form may be either a written consent document that embodies the elements of informed consent may be read to the subject or the subject's legally authorized representative, but the subject or representative must be given adequate opportunity to read it before it is signed or a short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative[4],[5]. When this method is used:

- there must be a witness to the oral presentation; and
- the IRB must approve a written summary of what is to be signed by the subject or representative; and
- the witness must sign both the short form and a copy of the summary; and
- the person actually obtaining consent must sign a copy of the summary; and
- a copy of the summary must be given to the subject or representative, in addition to a copy of the short form[4],[5].

There are a few exceptions to this in the new guidance that will be discussed under separate sections later on.

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3.3) Basic Elements of Informed Consent

Basic elements of informed consent must be included in the information provided to participants unless elements are waived or/and alteration is approved by the IRB under specific conditions(to be discussed later). The basic elements of informed consent include all of the following[12].

- 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 and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For FDA regulated research, a statement that notes the possibility that the Food and Drug Administration may inspect the records;
    - 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 bio-specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies[12] .
    - 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 pertinent questions about the research (researcher's name and phone/address, and that of faculty advisor if investigator is a student);
        - Regarding research subjects' rights (Research Compliance Services);and
        - In the event of a research-related injury to the subject (Research Compliance Services)[12] .

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- A statement that:
  - Participation is voluntary;
  - Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; and
  - The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- An indication that the subject may keep a copy of the consent form [12].

3.4) Importance of Informed Consent

There are several reasons why informed consent is necessary for clinical trials. Here are at least 5 reasons:

a) Protecting Participant Rights: Informed consent ensures that participants fully understand the nature of their involvement, potential risks, and benefits.
b) Ethical Conduct: Obtaining informed consent aligns with ethical principles by promoting transparency, honesty, and respect for participants' decisions. It ensures that the welfare of the participants is prioritized over societal interests.
c) Decision-Making Empowerment: Informed consent allows individuals to be involved in their own healthcare decisions. By providing them with full information about the trial, participants can make informed choices that align with their values and preferences.
d) Risk and Benefit Assessment: Informed consent allows participants to weigh the potential risks and benefits of participating in a clinical trial. It helps them assess whether the research aligns with their circumstances and expectations.
e) Legal Compliance: Regulatory bodies, such as the FDA, require researchers to obtain informed consent to ensure compliance with ethical and legal standards. Non-compliance can lead to serious consequences, including invalidation of the study results or legal ramifications [13].

Informed consent demonstrates respect for personal autonomy which is referred to as *"Respect for Persons"* in the Belmont Report and is an important ethical requirement in research. The consent process clarifies to participants that research is distinct from clinical care, as the purpose is to benefit society rather than solely the individual. Even if consent is not legally required in a specific circumstance, researchers should consider what information is important to convey to ensure respect for participant autonomy[10]. This process is both an ethical and legal requirement for healthcare providers and in clinical research. Informed consent obtained effectively promotes patient autonomy, builds trust and confidence in medical professionals, and reduces the risk of unnecessary legal claims based on incorrect assumptions about appropriate medical care.The consent process makes it clear to participants that research differs from clinical care in that the goal is to benefit society rather than just the individual. Researchers should consider what information should be provided to ensure participant autonomy, even if consent is not legally required in certain situations [14].

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3.5) New Changes and Challenges

A new guidelines on Informed Consent Guidance for IRBs, Clinical Investigators (the "Final Guidance"), and Sponsors by the U.S. Food and Drug Administration ("FDA") had been issued on 15 August 2023[15].This guidance finalizes the draft "Informed Consent Information Sheet" from 2014 (the "Draft Guidance") and supersedes FDA's guidance from 1998, "A Guide to Informed Consent."(FDA, Informed Consent Information Sheet: Guidance for IRBs, Clinical Investigators, and Sponsors (Draft Guidance: July 2014). FDA's issuance of the Final Guidance follows FDA's continuing efforts in recent years to modernize and streamline the clinical trial enterprise [16].

The document provides general guidance for informed consent, covering:
- exceptions to informed consent,
- avoiding coercion and exerting undue influence on subjects,
- how to make language understandable to the subject and/or their legally authorized representative, and
- avoiding the use of exculpatory language on consent forms [17].

Detailing on the Some of the more substantial changes that FDA has proposed in the new final guidance are as follows:

- ***Streamlining IRB Review of Informed Consent Forms*:** The Final Guidance highlights certain changes to informed consent forms in ongoing studies that do not require IRB review. These include corrections of typographical and spelling errors, changes in contact information, and translations of consent forms into languages other than English.
- ***Communicating New Information to Subjects***: The Final Guidance highlights several examples of new information concerning a clinical investigation that do not need to be communicated to previously enrolled subjects. These include most instances in which a subject has completed active participation in the study and instances in which the information is unlikely to affect the subject's willingness to continue in the study.
- ***Investigator Conflicts of Interest*:** Like the Draft Guidance, the Final Guidance advises investigators to consider the effects of potential conflicts of interest on clinical investigations. The Final Guidance adds that IRBs have final responsibility for determining whether the informed consent process should include disclosure of investigators' financial conflicts of interest. This suggests that IRBs should maintain processes to require disclosures of financial interests to the IRB.
- ***Template/Model Informed Consent Forms*:** The Final Guidance addresses the reality that template informed consent forms are often provided to study sites by the sponsor. FDA provides recommendations for how changes to the template forms suggested by FDA during the IND or IDE review process should be communicated to investigators and how site-specific, substantive changes to the template informed consent form should be communicated to other study sites in a multisite study.

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- ***Sponsor-Subject Interactions*:** In the Final Guidance, FDA addresses a scenario in which sponsor personnel may be present to observe certain study procedures. FDA states that the presence of sponsor personnel should be disclosed to subjects during the informed consent process.
- ***Enrollment in Multiple Investigations*:** As in the Draft Guidance, FDA discourages concurrent enrollment of a subject in more than one clinical investigation. However, in the Final Guidance, FDA recognizes that a subject's enrollment in more than one study at a time could be appropriate in certain circumstances. These include rare disease trials that evaluate different aspects of a condition or a clinical investigation of a novel drug and a companion in vitro diagnostic device.

Other important topics are:

- **On communicating and educating research subjects-** FDA encourages researchers to use innovative methods and technologies in informed consent to aid in communicating and educating research subjects. In accordance with 21 CFR Parts 50 and 56 , the IRB is responsible for reviewing informed consent materials and ensuring the adequacy and appropriateness of the wording of the consent materials [4],[18]. Acknowledging that a lengthy informed consent form may not always communicate information to subjects effectively, FDA stated in the Draft Guidance that pictures and diagrams "may be used to improve understanding of medical terms or how an investigational product functions."The Final Guidance adds to this point, noting that there might be "other visual aids" that can be used for this purpose, suggesting that video or three-dimensional objects may be used to facilitate communication during the informed consent process. For subjects with physical or sensory disabilities, FDA recommends that investigators provide "reasonable modifications and auxiliary aids and services when necessary to meet the specific needs of the study population," for example, audio recordings of the contents of the consent form or consent forms with enlarged text font[16].

- **Alternative to the traditional paper consent forms**- In the Final Guidance it is stated that new technologies can be used to obtain consent through mechanisms other than paper consent forms, citing to its guidance from 2016 on Electronic Informed Consent [19]. FDA clarifies that despite the flexibility of investigators to use methods other than paper consent forms, a purely oral discussion of informed consent is not sufficient. When written documentation of informed consent is required, informed consent cannot be obtained and documented by oral communication through the telephone alone [20]. Although FDA regulations do not require the subject's copy to be a signed copy, FDA recommends that a copy of the signed consent form be provided (section III.E.3, "Requirement for Dating Consent Form")[21]. In situations in which the signed document cannot be retrieved for filing in the study records (e.g., because the subject is in strict isolation due to a highly transmissible infectious disease), and electronic consent is

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not available, it is acceptable to retain for the study records a photographic image of the signed consent form along with an attestation by the person entering the photograph into the study records that states how the photograph was obtained and that it is a photograph of the informed consent form signed by the subject [20].

- **IRB review of consent forms-** It is sometimes required that the IRB review and approve all changes made to an informed consent form. FDA clarifies in the Final Guidance that the IRB does not need to review and approve certain administrative changes to consent forms or the translated versions of an informed consent form.With respect to translated versions of informed consent forms, the Final Guidance provides that IRBs can approve "reasonable procedures for ensuring that translations will be prepared by a qualified individual or entity, and that interpretation assistance is available." This differs from the approach articulated in the Draft Guidance, which recommended that IRBs review and approve "all English and non-English language versions of any consent documents." FDA's Final Guidance appears to acknowledge that IRBs in the United States often have limited capabilities to review consent forms in languages other than English and thus frequently ask investigators to submit documentation indicating that the consent forms are accurately translated[22].

- **Regarding communication of new information** -In the Final Guidance, FDA provides an in-depth discussion regarding communicating to subjects with significant new information (e.g., protocol changes, new findings related to safety) that could affect a subject's willingness to continue their participation in the clinical trial. In such situations, the IRB is responsible for determining (1) "whether currently enrolled subjects should be provided with the new information and given an opportunity to affirm their willingness to continue in the research"; and (2) "whether the investigator should provide currently enrolled subjects with the new information either with the revised informed consent document or an alternative method ." It provides certain clarifications about the means of communicating new information to subjects and accounting for subject withdrawal. Alternative methods of communication "such as a consent addendum or information sheet" can be used to communicate significant new information to subjects. In such cases "the enrolled subject should be asked to sign and date the consent addendum or information sheet" and "a copy of the signed and dated consent addendum or information sheet [should] be provided to the subject."[3]. Researchers do not need to share significant new information with (1) "subjects who have completed their active participation in the study . . . unless the new information relates to risks that may manifest after such participation" and (2) "subjects who are still actively participating . . . when the change will not likely affect their decision to continue in the study (e.g., an increase in the number of study subjects)." Reconsent of subjects is not required upon a change of contact information for the individual(s) whom the subject may contact for questions about research subject rights or to report a research-related injury. New contact

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information "may be given to the subject during a visit or mailed to the subject in an envelope to protect the subject's privacy." [3].

- **Subjects Withdrawal -** Under FDA regulations, data collected on subjects up to the time of withdrawal from clinical investigations of drugs and devices conducted under an IND or IDE must remain in the study database (see, e.g.,21 CFR 312.62(b) and 812.140(a)(3)) because If a subject withdraws from a study, removal of data that were already collected would undermine the scientific validity, and therefore the ethical integrity, of the research. Such removal of data could also put enrolled subjects, future subjects, and eventual users of marketed products at an unreasonable risk and could compromise FDA's ability to perform its mission to protect public health and safety by assuring the safety and effectiveness of regulated medical products[23]. FDA's position here is consistent with that taken in guidance issued by HHS under HIPAA, which provides that upon a research subject's revocation of their authorization for use and disclosure of PHI, a covered entity may continue to use and disclose PHI obtained prior to the time of revocation "as necessary to maintain the integrity of the research study," including to account for the subject's withdrawal from a research study, as necessary to incorporate the information as part of a marketing application submitted to FDA, or as necessary to conduct investigations of scientific misconduct or report adverse events[24]. FDA further clarifies that if subjects withdraw from a clinical investigation, they should be asked if they wish to withdraw only from investigational interventions while continuing to provide follow-up clinical information. If the withdrawal is limited to study interventions, the subject should be asked to provide informed consent for any follow-up not addressed in the original consent document using a new IRB-approved consent document [3].

- **Regarding Legal and Regulatory Environment around informed consent**

a. In the Final Guidance, FDA continues to emphasize that sponsors and investigators will need to comply with all applicable requirements under HIPAA and other applicable laws even if in scenarios that do not require informed consent under FDA's regulations. FDA regulations require that informed consent forms include statements describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records[25].

b. Researchers often need access to subject protected health information ("PHI") throughout the course of the clinical trial, which generally requires authorization from subjects as set forth in the HIPAA Privacy Rule[26]. For researchers and institutions, it is crucial that the consent forms and HIPAA authorization forms comprehensively specify the parties that might later have access to the records. In the Final Guidance, FDA emphasizes that there might be several parties who require access to the patient records, such as "the study sponsor, the research team, regulatory agencies, and/or ethics committee members," and that this information should be communicated to subjects during the informed consent process[3].

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c. Regarding financial conflicts of interest - FDA maintains regulations and guidance pertaining to disclosure to FDA of investigator financial interests. It advises that investigators should consider including information in the informed consent form regarding any investigator financial interests that could affect the research as well as details of any associated conflict management plan. It further states that IRBs have the final responsibility of determining whether subjects should be provided with information regarding the source of funding, funding arrangements, or financial interests of parties involved in the clinical investigation as part of the informed consent process[27].

Instances in which consent is not required

The rule, published on 21 December 2023, finalizes a proposal the agency issued in 2018 and implements provisions of the *21st Century Cures Act* that gave FDA the authority to allow an informed consent exception for minimal risk clinical testing that includes human subjects safeguards and directed FDA and the US Department of Health and Human Services to harmonize their human subjects regulations [28]. Under FDA's current regulations, informed consent exceptions are only allowed in certain cases, such as life-threatening situations, when certain emergency research requirements are met, and with a Presidential waiver for specific military operations. In 2017, the agency issued guidance advising informing and research sponsors that it would not object to waiving or altering informed consent requirements for certain minimal risk clinical trials. The FDA plans to withdraw the 2017 guidance as the final rule in effect since January 2024[29].

a. In the Final Guidance, FDA discusses situations in which informed consent is not required beyond the circumstances of life-threatening situations and emergency research that are contemplated expressly in FDA regulations [30]. The Final Guidance notes that FDA continues to exercise enforcement discretion regarding informed consent when human specimens that were previously collected and are not individually identifiable are used for FDA-regulated in vitro diagnostic device investigations. FDA also reiterates that it does not intend to object to IRBs approving consent procedures that do not include some, or that alter, some or all of the elements of informed consent set forth in 21 CFR Section 50.25 for certain minimal risk clinical investigations under the circumstances described in FDA's 2017 guidance on waiver or alteration of informed consent[3].

b. In the Final Guidance, FDA restates its position that "FDA generally discourages enrollment in multiple investigations" but adds that "there are some circumstances in which co-enrollment may be appropriate." These situations include studies involving "rare disease studies that are evaluating different aspects of the condition and involvement in one study does not affect the other study" or "certain appropriately designed studies, such as a clinical investigation of a novel drug and a companion in vitro diagnostic device that is essential for the safe and effective use of the drug." FDA also clarifies that "the risks of participating simultaneously in more than one clinical

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investigation should be discussed with subjects during the consent process but do not necessarily need to be included in the informed consent form."[3]

To summarize , the final draft finalizes five criteria for IRBs to waive or alter informed consent [29]:

- The clinical investigation involves "no more than minimal risk" to research subjects.
- Waiving or altering informed consent will not adversely impact the rights and welfare of participants.
- The investigation could not be practicably carried out without the waiver or alteration of informed consent.
- When appropriate, participants are provided with additional relevant information after participation in the investigation.
- For research involving identifiable private information or identifiable biospecimens, the research could not be practicably carried out without using the information or biospecimens in an identifiable format.

4. Conclusion

Informed consent is the recognition of the moral right of research subjects to make their own choice or to self-determine or decide on the research participation and has been one of the most important developments in the field of ethics related to biomedical research involving human subjects. It is the foundation of ethics in clinical research and is an important legal and ethical requirement for clinical trial researchers. The waivers for informed consent is only permitted in circumstances where the risks posed to subjects by the research are minimal and where an IRB has reviewed the research and determined, among other things, that the waiver or alteration will not adversely affect the rights and welfare of subjects.

There was criticism regarding waiving or altering informed consent where the concern was that the "minimal risk" threshold was too vague and could be misused, and it was also argued that IRBs should not be the ones to make minimal risk determinations. FDA noted in the final rule that it was not revising the definition of minimal risk since doing so would risk confusion in the research community. According to the FDA, there is a longstanding consistency in the definitions of minimal risk provided in both FDA regulations and the Common Rule, IRBs have experience in applying the term 'minimal risk' to research involving human subjects, including determining when a clinical investigation involves no more than minimal risk. It also declined to impose a new process on IRBs to document waiver or alteration decisions for a clinical investigation since FDA already inspects IRBs to ensure they are following FDA regulations when approving and reviewing research.

New guidelines by FDA provide increased guidance for IRBs, Clinical Investigators, and Sponsors on how new technologies can be incorporated into the informed consent process and the interaction between FDA regulations and other bodies of law, including HIPAA. It is a guidance regarding informed consent process for IRBs, Clinical Investigators, and Sponsors but ultimately directed towards treatment advances through clinical trials and at the same time not jeopardizing the rights and health of research participants or subjects.

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