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Consensus

Consensus on informed consent for participants in cancer clinical studies (2021 edition)

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ABSTRACT

To fully protect the rights of participants in cancer clinical studies and clarify the key points for the ethics review of the content of informed consent forms and the process of collecting informed consent, the Medical Ethics Professional Committee of the China Anti-Cancer Association engaged in joint discussions with the ethics committees of well-known cancer hospitals in China to formulate this consensus, along with the attached general template for informed consent forms for cancer clinical studies. This work is expected to provide guidance and suggestions for the practice of the sponsors, researchers, and ethics committees.

1. General

1.1. Purpose

In cancer clinical studies, beyond the sponsors' and investigators' compliance with good clinical practice (GCP) and other regulations, fulfillment of relevant duties, and standardized implementation of clinical studies, the effective protection of participants' health, maintenance of their dignity and personal integrity, and guarantee of their rights to full autonomy in decision-making largely depend on the quality of the ethics review of the informed consent forms (ICFs) and processes. It was clarified in the Good Clinical Practice for Drugs framework issued by the National Medical Products Administration and National Health Commission of China in 2020 that "ethics review and informed consent are important measures to protect the rights of subjects."[1,2] The specification for informed consent is described in great detail, and its importance is self-evident. High-quality ICFs and standardized informed consent processes are important measures to ensure the rights and safety of participants and are also necessary measures to avoid physician-patient disputes (Table 1).

During the implementation of multicenter clinical studies, the review requirements and opinions of the ethics committees of various institutions regarding the specific contents of ICFs and the process of informed consent are often inconsistent or even differ greatly from each other, which gives rise to some problems regarding the quality and efficiency of implementation, especially in cancer clinical studies with

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Table 1
Basic content and review points of the informed consent form for cancer clinical studies.

No.	Basic contents	Review points
1	General information	Title, version number and date, and information about the study site.
2	Nature of study	Clinical studies are exploratory in nature.
3	Background and objectives	① Background and current situation. ② Objectives.
4	Procedures	① The estimated duration of the study and total number of participants planned to be enrolled. ② Study process, including stage (screening period, treatment period and follow-up period), experimental intervention measures/procedures, possibility of random allocation to each group, and description of all traumatic operations, with a focus on describing the experimental content that differ from conventional medical practice, including the process of experimental intervention, sample collection, and exploratory content. For clinical studies of multidisciplinary treatments in particular, explanation of experimental (such as adjuvant or concurrent targeted/immune new drugs) and standard (such as surgery, radiotherapy, and interventional therapy) treatments should be given, and then specifically describe the treatment process. ③ Notification for obtaining biological samples, including collection purpose, method, and quantity; testing and storage site; whether the test results are returned; and approximate time needed for testing. If necessary, a sub-informed consent form for the testing of biological samples can be designed separately (details in Module 18 "Notification of obtaining biological samples"). ④ For the possibility of continuation of study interventions after disease progression or crossing over to other treatment groups, if a relevant process exists, writing a separate sub-informed consent form is recommended (details in Module 19 "Continuing treatment after disease progression" and Module 20 "Crossover after disease progression"). ⑤ Frequency and approximate duration of on-site visits and telephone follow-ups for participants after the end of the study treatment. ⑥ The expected situation and reasons why the participation in the trial may be terminated, and the specific grouping will be provided after unblinding at the end of the study. * The description of study intervention in a non-interventional study is not applicable. A statement should indicate that the study process will not affect the routine diagnosis or treatment.
5	Matters requiring participants' cooperation	Participants should be compliant with the study's procedures, including making on-time visits, adhering to diet/concomitant medication requirements, and informing physicians of any problems or discomfort during the study.
6	Alternative treatments	In interventional clinical studies, participants should be clearly informed about alternative therapies in the event that they do not participate in or withdraw from the study. The existing standard treatment should be fully described, especially for patients with treatment-naïve advanced tumors or resectable tumors.
7	Risks and discomforts of participation	① Safety information, including expected adverse reactions. For special treatments such as immune checkpoint inhibitors, CAR-T cell therapy, and oncolytic virus therapy, immune-related adverse events should be described clearly. For surgery, radiotherapy, and interventional therapy, the possible risks should be described in detail according to the specific treatment site and style. For multidisciplinary clinical studies, adverse reactions that may be additionally increased by experimental content compared with standard treatment should be addressed. ② Expected risks of invasive examination in the protocol and possible inconvenience to the participants. ③ Some specific interventions or treatments (such as innovative therapies and combined therapies) may have risks that are currently unanticipated. ④ A statement should indicate that the intervention measures or treatments may cause unanticipated risks to the embryo or fetus if the participant is pregnant or becomes pregnant during the trial. * The anticipated risks of the study interventions in non-interventional studies are not applicable, and participants are informed that participation in the study does not add any additional risk to routine medical activities.
8	Possible benefits of participation	① Reasonably expected benefits (for individuals and the whole social group). If there is no expected benefit to the participants, it is necessary to inform them. ② Persuasive language should not be used, and compensation should not be described as a benefit.
9	Relevant expenses of participation	① Relevant expenses for participating in the study. ② All study medications/devices and study-related tests will be provided by the sponsor at no cost. The investigational drugs/devices and examination items specified in the study's protocol of registration will be provided free of charge. For combined medications, surgery, radiotherapy, interventional therapy, and other basic treatments, participants will be informed about the items provided free of charge or the reasons for not providing them, and if they exceed the routine clinical practice of the study site, they will be provided freely (eg., if the surgical style or radiotherapy plan specified in the protocol is different from the guideline or standard treatment).
10	Compensation	① All compensation will be paid to participants as scheduled and based on the actual number of visits (generally a fixed amount). ② Compensation should not be withheld until the end of the study.
11	Indemnities	In the event of any injuries related to the trial, the participants shall receive free medical treatment and/or indemnity.
12	Right to voluntarily participate in or withdraw from the study	Participation in the study is voluntary, and the participants may refuse to participate in or withdraw from the study at any time without penalty or loss of any benefits to which the participant is otherwise entitled.
13	Privacy and confidentiality	① The monitor, auditor, ethics committee, and government administrative department may consult the participant's original medical records directly to verify the procedures and/or data of the clinical study to the extent permitted by the current laws and regulations. ② To the extent permitted by the current laws and regulations, the participants' personal identity information will be kept confidential, and these records will not be disclosed. ③ In real-world studies and clinical studies involving big data, protective measures for personal information should be described.
14	Treatments upon completion of the study	Regarding treatment measures for participants after the discontinuation or completion of the study, especially for those with clinical benefits, participants should be informed of the need to discuss subsequent alternative treatments with the study physician or to enter the extended dosing phase (please refer to the Consensus on extended dosing after clinical trials of registered anti-cancer drugs issued by the Chinese Anti-Cancer Association). * Not applicable for non-interventional studies
15	Provision of new information and contact information	① Participants should be informed of any significant new information about the study in a timely manner, including the latest progress and new adverse reactions, and they should have an opportunity to voluntarily decide whether to continue the study and re-sign the informed consent form after receiving the information.

(*continued on next page*)

Table 1 (*continued*)

No.	Basic contents	Review points
		② The study physician's name and phone number should be provided (out-of-hours phone numbers are required for high-risk studies). ③ A contact person on the ethics committee and their phone number should be provided.
16	Language description	① The language should be easy to understand, conform to the general public's level of understanding, and not be too lengthy. ② The meanings of the terms "patient" and "participants" should be clearly defined.
17	Notification of biopsy procedures (if applicable)	① The biopsy procedures and related risks should be specified in the "study process" and "study risks." ② The bearer of biopsy expenses, the location of biopsy tests, whether the participants are informed about the results, and whether the participants are compensated shall be described in the corresponding module.
18	Notification of obtaining biological samples (if applicable)	(A separate sub-consent form should be prepared if necessary) ① Whether the purpose of collecting biological samples is routine medical treatment or entirely for research purposes, and whether it belongs to the pre-screening or the screening phase of the study should be specified. ② The method of collection and the volume of collection should be indicated. The collection volume of biological samples will meet the requirements of the Human Genetic Resources Management Department. The number of tissue sections collected will not affect the subsequent pathological diagnosis of participants; when the sections cannot be provided or a biopsy is required for other reasonable reasons specified in the protocol, the participants should be fully informed. ③ The name and location of laboratories and whether there are additional risks and economic burdens, especially for centralized tests performed outside medical institutions (for details, please refer to the Consensus on central laboratory usage in anti-cancer drug clinical trials issued by the Chinese Anti-Cancer Association). ④ Approximate time for feedback of test results: the central evaluation results necessary for judging the participant's eligibility and/or the follow-up diagnosis and treatment should be reported in a timely manner. ⑤ The storage place, storage period, and when the biological samples will be destroyed should be specified. ⑥ If the samples will be used for genetic studies, this should be clearly specified.
19	Continuation of treatment after disease progression (if applicable)	(A separate sub-consent form should be prepared if necessary) ① The purpose of treatment continuation after disease progression. ② Conditions for treatment continuation after disease progression, follow-up methods, and other treatments. ③ Relevant risks, including the risk of treatment failure. * Not applicable for non-interventional studies
20	Crossover treatment after disease progression (if applicable)	(A separate sub-consent form should be prepared if necessary) ① Purpose and background of crossover treatment after disease progression. ② Conditions for crossover treatment and eligibility screening procedure; relevant procedures if disease progression must be confirmed by central imaging. ③ Follow-up methods and other optional treatments. ④ Possible risks and benefits of the new treatment group. * Not applicable for non-interventional studies

rapidly progressing disease or complex treatment methods. The development of a relatively unified template for writing ICFs and a consensus on the ethics review to address the characteristics and needs of cancer clinical studies may improve the efficiency of the ethics review of multicenter studies and help with collaborative reviews.

With the continual development of cancer clinical studies, the meaning of 'informed consent' itself is also expanding. In the daily ethics review, in addition to overseeing traditional clinical studies with specific objectives and subjects, the ethics committees of various institutions also encounter special informed consent conditions,[3] such as the secondary use of biological samples, big data research for group health,[4] and electronic informed consent.[5] With these non-traditional studies and ICFs, investigators and ethics committees continually face considerations regarding how to apply for, carry out, and review the informed consent process. In this consensus, several basic principles and scopes of application are proposed for the above issues for the reference of investigators and ethics committees.

1.2. Basic principles

The consensus contains two parts: the ICF and the informed consent process.

The drafting of ICFs, the implementation of informed consent, and ethics reviews focus on the core purpose of protecting participants, following the relevant provisions of the Declaration of Helsinki[6] and the Good Clinical Practice quality standard,[1] as well as the ethics review principles prevailing in China and other countries, including Ethics Review Methods of Biomedical Research Involving Humans,[7] Guidelines for the Construction of Ethics Review Committees for Clinical Research Involving Human Subjects of China,[8] and International Guidelines for Health-related Research Involving Human Subjects of the Council for International Organizations of Medical Sciences (CIOMS) (2016 Edition).[9] The corresponding content of informed consent for cancer clinical studies is added according to the characteristics of cancer clinical practice, such as targeted/immune agents combined with multidisciplinary treatments; biomarker sample delivery to a central laboratory for detection; central evaluation of imaging and pathology; long-term survival follow-ups; continuation of treatment or cross-dosing after disease progression; extended dosing after the summary of the study.

The consensus introduces the routine informed consent process for participants in cancer clinical studies in detail and explains the precautions in the whole informed consent process. In addition, for special informed consent, including waiver of informed consent and electronic informed consent, the scope of application is defined according to the actual situation of cancer clinical studies, and the basic principles that should be followed in the special informed consent process are clarified.

2. Main content and review points of the ICF

2.1. Basic requirements and key points for the ethics review of the text of ICFs for cancer clinical studies

2.2. General template of the ICF for cancer clinical studies

This template (Appendix) serves as the main ICF for interventional clinical trials for adult patients with cancer. The sub-consent form and ICF for other types of cancer clinical studies can be found in Section 2.1. The text of the template should be written by the sponsor and investigator according to the actual situation. The content in brackets is suggested information.

3. Informed consent process

3.1. Routine informed consent process for cancer clinical study participants[1]

1. The process of informed consent should be conducted in a quiet and separate environment with a certain degree of privacy.
2. The authorized investigator should use language understandable by the participant, avoid using technical terms as far as possible, and

explain all the contents of the ICF to the participant or his/her guardian. For interventional clinical trials, clinicians in relevant oncology specialties should be available to explain the contents of the ICF to the participant on site.

3. The investigator must not coerce, unduly influence, or induce the participants to participate or continue in the study in any way. Patients with advanced tumors without standard treatment options are more likely to be influenced by their treating physicians' recommendations for follow-up treatment and are in a relatively "vulnerable" position, so investigators should pay attention to objectively describing the risks, benefits, and alternative treatments in therapeutic clinical trials and should respect the participants' autonomy.
4. The investigator should give participants and guardians sufficient time and opportunity to read the ICF carefully, consider whether they are willing to participate in the study, and provide detailed answers to any content or questions raised by participants or guardians to ensure that participants providing informed consent are fully aware of and understand the necessary information related to the clinical study. The guardians of cancer patients may require the investigators to conceal the disease from the patient. For patients with full civil capacity, the investigators should still be aware of the patients' request, communicate with the guardian, fully inform the patient of all necessary information about the clinical study in an appropriate manner, and conduct a written informed consent process with patients.
5. Informed consent continues throughout the entire study process, and investigators should answer any questions about the study from participants or guardians at any time.
6. Provision of the ICF

Participants sign an ICF after voluntarily making the decision to participate in the study. The ICF should be signed and dated by both the subject and the investigator who conducted the informed consent process.

For the participants without capacity for civil conduct, if the ethics committee agrees in principle and the investigators believe that the participation in the trial is in their own interests, these participants may also enter the trial, and their guardians may agree and sign the ICF. For non-therapeutic clinical trials in the field of oncology, such as pharmacokinetic trials in healthy volunteers or tolerance studies of new drugs at dose with very low biological effect, the participants should sign the ICF in principle.

In case of children, informed consent should be obtained from their guardians and sign the ICF. When children have the ability ($\geq$ 8 years old) to decide to agree to participate in clinical trials, their own consent should also be obtained.

If the participants or their guardians are unable to read, an impartial witness should be present to witness the entire informed consent process. The investigators should explain the detailed content of the ICF and other textual documents to the participants or their legal guardians and witnesses. If the participants or their guardians give verbal consent to participate in the trial, they should sign the ICF to whatever extent possible if they are able to do so.

If the ICF is revised in writing and sent to the ethics committee for review and approval, any participants who are still in the study will be required to give informed consent again and sign a new version of the ICF. For interventional cancer clinical trials, participants in the screening and treatment stages should give written informed consent again, but it is often inconvenient to make on-site visits to participants in the survival follow-up stage. When the revision of informed consent is related to the participant's safety or subsequent diagnosis and treatment, the investigators can obtain informed consent via telephone or other remote methods.

The informed consent process should be clearly documented in the medical records.

The signed ICF is provided in duplicate copies: one is given to the participant and the other is stored in the investigator's file.

3.2. Special informed consent process

3.2.1. Waiver of informed consent[3,8]

Conditions for waiver of informed consent:

1. The possible risks to the participants do not exceed a minimal level. Note: Informed consent can only be waived in the case of non-interventional cancer clinical studies.
2. The waiver of informed consent will not adversely affect the rights and welfare of the participants.
3. For studies using human specimens or data with identifiable information, the participants can no longer be found, and the study does not involve personal privacy concerns or commercial interests.

Note: For cancer clinical studies, the feasibility of informed consent must be determined by considering the nature of the study, whether it contains personal information that identifies the participant, and the survival data for different cancer types. Typical scenarios in which informed consent is not feasible include studies using de-identified databases or retrospective studies using previous medical records or specimens without active survival follow-ups or for which most of the medical records or specimens have been stored for longer than the expected survival time of the relevant patients. Details are provided in Section 3.2.2 "Specific cases."

4. Biological sample donors have signed the ICF and agreed that the donated samples and related information can be used for all medical research.

Note: This includes patients/participants with cancer who have signed a broad ICF in previous clinical practice or research, and who agree that their medical records or specimens may be used for future medical research.

5. Waiver of informed consent does not indicate waiver of review by the ethics committee.

For studies using medical records and biological specimens obtained in previous clinical practice or research, consideration should also be given to the following:

1. The privacy and confidentiality or anonymity of the participants should be guaranteed.
2. Previous studies have obtained written consent from participants to allow other researchers to use their medical records or specimens, and this study meets the conditions of the original informed consent permission.
3. Patients/participants have the right to know that their medical records or specimens may be used for the study. If patients/participants have previously clearly refused the use of their medical records and specimens in future studies, the relevant medical records and specimens may be used only when required by public health emergencies.
4. Participants have the right to request the destruction or anonymization of biological samples, medical records, or parts they believe are particularly sensitive (such as photos or video materials).
5. Whenever possible, appropriate relevant information should be provided to the participants at an appropriate time after the study.

3.2.2. Specific cases

Case 1: The study planned to collect the diagnosis and treatment information from the previous medical records of patients diagnosed with early stage non-small-cell lung cancer (NSCLC) in a local hospital from 2012 to 2019, and follow-up the patient outcomes until death or loss to follow-up. The investigator applied for waiver of informed consent for all participants by the ethics committee.

In this study, the investigator needed to actively follow the participants' outcomes, and considering the survival time of patients with early stage NSCLC, most patients diagnosed in recent years were still alive.

Therefore, informed consent was possible for participants undergoing follow-up. The ethics committee deemed that the informed consent of all participants in this study could not be waived, but that a waiver might be considered for participants who had died or been lost to follow-up before the start of the study, that is, partial waiver of informed consent.

Case 2: The study planned to collect diagnosis and treatment information from the previous medical records of patients diagnosed with advanced NSCLC in a local hospital from 2012 to 2016, without follow-up procedures. The investigator applied for waiver of informed consent for all participants by the ethics committee.

In this study, the investigator did not actively follow the participants' outcomes, and considering the survival time of patients with advanced NSCLC, most patients have died by the year 2020. Therefore, the feasibility of obtaining informed consent from the participants was low. The ethics committee considered that the informed consent of all participants could be waived.

Case analysis: Cancer clinical studies often involve the secondary use of previous diagnostic and treatment data or biological samples. In most cases, informed consent should be obtained according to strict ethical principles. However, the notion of "post-hoc informed consent" is "feasible" but practical operation is difficult, especially for some registries with large sample sizes. Given that the inconvenience of obtaining informed consent cannot be a sufficient condition for waiving informed consent, researchers and medical ethics professionals have been searching for appropriate ways to more conveniently complete the informed consent process under the premise of protecting the rights and welfare of participants, including remote forms such as telephone or electronic informed consent.

3.2.3. Electronic informed consent[5]

Electronic informed consent refers to the use of electronic systems and procedures, including text, images, audio, video, broadcast media, interactive websites, biometric devices, and readers, to convey study-related information and to obtain and record informed consent. The basic principles to be followed in the use of electronic informed consent include: protecting the safety and rights of participants, facilitating the understanding of information presented in electronic ICFs to the participants, ensuring that appropriate consent documents are obtained when obtaining informed consent using multiple electronic systems and procedures, and ensuring the quality and integrity of electronic informed consent data.

Electronic informed consent may be used to supplement or replace written informed consent, but must contain all the elements of informed consent, and may use interactive electronic technologies such as charts, images, and videos. The process should be easy to perform and hyperlinked if necessary. Electronic informed consent should be obtained by the study personnel and cannot be delegated to the electronic system manager. The informed consent process may be conducted at the study site or remotely.

The electronic system must confirm that the person signing the electronic informed consent is the participant or his/her guardian and that multiple means are allowed to create the electronic signature, including the use of a computer-readable identity card, biometric technology, digital signature, and a combination of username and password. It must be ensured that only the owner can use an electronic signature based on biometric technology. The ethics committee may request a statement from the electronic signature system provider describing how the signature is created and verifying that the system meets the relevant requirements.

A copy of the ICF provided to the participant may be written or electronic, including via electronic storage or mail. If electronic informed consent includes web links (such as to other websites or blogs), these links should be kept readily accessible until the study is completed, and the information in these links should be included in the paper copy provided to the participant.

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Declaration of competing interest

None declared.

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Appendix A. Supplementary data

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