NCI Informed Consent (IC) template At-a-Glance

The IC document supplements and guides the consent process, helping the patient to make an informed choice.

KEYS: Limit to 6 to 9 pages. Focus on what makes the study different from regular care. Eliminate repetition of information. The IC document can include educational attachments. READABILITY: Use active voice, small words, short sentences, personal pronouns, and a clear page layout with ample borders. Adapt / use text examples / language provided in NCI template (NCI-T)

OVERVIEW OF REQUIRED ELEMENTS

1. Study Title for Study Participants: (Lay title also in bold type) Adapt NCI-T

2. Official Study Title for Internet Search on www.ClinicalTrials.gov (not bold)

3. What is the usual approach to indication? Limit: 5-9 sentences; ¼ page; Avoid naming specific drugs; include estimate of outcome for usual approach.
   Adapt NCI-T for phase and type of study: You are being asked ...

4. What are my other choices if I do not take part in this study? Limit to ¼ page. For CER type study, inform that approaches can be used off study.
   Use NCI-T: If you decide not to take part ...

5. Why is this study being done? Limit to 5 or 6 sentences; ¼ page
   Include # of people taking part in study.
   For single-arm phase 2, indicate what is known about approach & amount of expected improvement.
   For randomized design indicate type of improvement expected if study is positive (e.g. PFS).
   Adapt NCI-T for phase or type of study: The purpose of this study is to ...

6. What are the study groups? Limit to 7-10 sentences; ¾ page
   Clearly identify study drug names.
   Adapt NCI-T for phase-specific examples.
   If randomized, clearly identify investigational arms; include simplified schema;
   Use NCI-T explaining randomization: A computer will by chance assign you ...

7. How long will I be in this study? Limit to 1 or 2 sentences
   Use NCI-T: You will receive xxx for xxx. After ...

8. What extra tests and procedures will I have if I take part in this study
   Limit to two to 4 pages
   Include only mandatory research-related procedures that are not part of regular treatment or that are done more frequently; specify frequency.
   Use NCI-T to describe risks related to extra exams: Most of the exams, tests, and procedures ...

   Group by: Before you begin the study and During the study

   If applicable: adapt NCI-T for mandatory specimen collections: Small pieces ...
   If applicable: note that left over specimen will be stored for Biobanking and that this will be discussed in Optional Studies section;
   Use NCI-T to describe how test results will be stored to protect privacy “Your privacy ...
   Use NCI-T to describe risks related to genetic testing: There is a risk someone could ...
   If a study calendar will be attached, use NCI-T: A study calendar that shows ...

9. What possible risks can I expect from taking part in this study? Limit to 2 to 4 pages
   Use / adapt NCI-T for following sections:
   1) reasonably foreseeable non-physical side effects, 2) general info and points about side effects, 3) most common/serious side effects for each study drug in table format.

   For 1, use / adapt NCI-T: If you choose to take part in this study, there is a risk that: time off from work; asked private questions, risk to access to personal information if genetic testing; for randomized trials, the study approach might not be better, could be worse...

   For 2, use NCI-T: There is also a risk that you could have side effects from the study drug(s) / study approach. Here are the important points about side effects: Some may go away soon ...

   For 3, adapt NCI-T using bullets in table format: COMMON, SOME MAY BE SERIOUS
   In 100 people receiving XYZ, more than 20 and up to 100 may have:
OCCASIONAL, SOME MAY BE SERIOUS
In 100 people receiving XYZ, from 4 to 20 may have:

RARE AND SERIOUS
In 100 people receiving XYZ, 3 or fewer may have:

NOTE: CTEP provides plain language side effects for many study drugs.

If applicable, adapt NCI-T to explain risks for radiation and imaging studies:
The type of scan that you will receive in this study

10. What possible benefits can I expect from taking part in this study?
Limit to 2 and 3 sentences.
Adapt NCI-T specific to study question, phase, or type of study.

11. Can I stop taking part in this study?
Use NCI-T: Yes. You can decide to stop ....

12. What are my rights in this study?
Use NCI-T: Taking part in this study is your ...
Use NCI-T providing contact information for questions

13. What are the costs of taking part in this study?
Use NCI-T: The study drug will be supplied at no charge ... You and your health plan will need to pay for ...

14. What happens if I am injured or hurt because I took part in this study?
Use NCI-T: If you are injured or hurt as a result ...

15. Who will see my medical information?
Use NCI-T: Your privacy is very important to us ...

16. Where can I get more information?
Use NCI-T: You may visit ...

17. Who can answer my questions about the study?
Use NCI-T: You can talk to the study doctor (name and phone contact) ...

ADDITIONAL STUDIES SECTION:
Indicate clearly to participants that this is a separate section. Provide YES/NO options at each decision point. Delete types of optional studies that do not apply. If applicable, Use NCI-T: This part of the consent form is about optional studies that you can choose to take part in ...

1. Optional imaging study – extra scan
If applicable, adapt NCI-T:
If you choose to take part in this study, you will ...
Please circle your answer: I choose to .... YES NO

2. Optional Quality of Life Study
If applicable, adapt NCI-T:
If you agree to have this ...
Please circle your answer: I choose to .... YES NO

3. Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies
If applicable, adapt NCI-T:
Researchers are trying to learn ...
Some studies are about genes ...
If you choose to take part in this study ...
Please circle your answer: I choose to .... YES NO

WHAT IS INVOLVED?
Use NCI-T from items 1 – 5

WHAT ARE THE POSSIBLE RISKS?
Use NCI-T from items 1 – 5

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?
Use NCI-T from items 1 – 5

WHAT ARE THE POSSIBLE BENEFITS?
Use NCI-T from items 1 – 5

ARE THERE ANY COSTS OR PAYMENTS?
Use NCI-T: There are no costs to you or ...

WHAT IF I CHANGE MY MIND?
Use NCI-T: If you decide you no longer want ...

WHAT IF I HAVE MORE QUESTIONS?
Use NCI-T: If you decide you no longer want ...

SAMPLES FOR THE LABORATORY STUDIES
Use NCI-T: I agree to have ... YES NO

SAMPLES FOR FUTURE RESEARCH STUDIES
Use NCI-T: I agree to have ... YES NO

My Signature Agreeing to Take Part in the Main Study
Use NCI-T: I have read this consent for ...

Adapted from the May 2013 version of NCI Informed Consent Template by Karl Schwartz (for educational purposes only)
The original IC template and related resources are available for download: http://ctep.cancer.gov/forms/