# 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. READABLITY: 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 <u>stop</u> 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 – <u>extra</u> 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/