National Consent Working Group

Instruction Guide for ICF Authors

Purpose

This document provides instructions to consent authors to follow when writing informed consent forms (ICFs) for many types of oncology trials. It recognizes the significant differences between various types of trials and provides phase-specific examples of suggested ICF language. The ICF template is not meant to be fully comprehensive. However, the lay language used and the format of the information should be followed as closely as possible when applying it to a specific study. In all cases, ICF authors should use clear and concise language.

General instructions will be provided on different aspects of the consent such as length, language and formatting, followed by detailed specific instructions for certain sections of the consent.

The process of obtaining informed consent and the documentation of informed consent must comply with the national and international requirements for the protection of human subjects participating in clinical trials.

General Instructions

* **Form Length and Language:** It is recommended that the ICF should not exceed 16 pages, excluding the “Optional studies” section. Suggestions for making the informed consent more concise include:
1. Focus on what makes the study different from the care a patient would typically receive. Instead of trying to cover everything that might happen during the trial, limit the information to the research issues.
2. Avoid repetition of information.
3. Use lay language and explain concepts simply. Use short words and sentences. Replace complex medical terminology with common, easily understood words.
4. To support equity, diversity and inclusion [EDI] for all participants in research trials the language in the consent and all participant materials, should be inclusive – i.e., references to men/women, male/female should be avoided.
[How to integrate sex and gender into research – CIHR (cihr-irsc.gc.ca)](https://can01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcihr-irsc.gc.ca%2Fe%2F50836.html&data=04%7C01%7Calison.vannie%40oicr.on.ca%7Cfeae3e264a834e1fe80708d98d973e5b%7C9df949f8a6eb419d9caa1f8c83db674f%7C0%7C0%7C637696503032869543%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=2UVCT8UkWENmt97L176ctvMoAkg77CE19icKpT5x%2B64%3D&reserved=0);
[Making Clinical Research Inclusive: Strategies to Include the LGBTQIA+ Community in Research Trials - WCG IRB](https://can01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.wcgirb.com%2Finsights%2Fmaking-clinical-research-inclusive-strategies-to-include-the-lgbtqia-community-in-research-trials%2F%23%3A~%3Atext%3DInformed%2520Consent%2520Language%2520%2520%2520%2520Exclusive%2520%2526%2C%25E2%2580%259CEach%2520study%2520participant%2520must%2520allow%2520acces%2520...%2520&data=04%7C01%7Calison.vannie%40oicr.on.ca%7Cfeae3e264a834e1fe80708d98d973e5b%7C9df949f8a6eb419d9caa1f8c83db674f%7C0%7C0%7C637696503032879529%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=ETRTiVAFcaXaDXTrkeGshY2ii0vNgE0Ictta11onunw%3D&reserved=0)
5. Use online readability tools to assess the reading level of the informed consent form. Health Canada recommends a sixth to eighth-grade reading level, depending on the population. Information about readability assessments can be downloaded from the CTEP ICF website. If possible, ask participants or community members to review the form before submitting it to the REB. They can help identify potential comprehension challenges for participants.

<https://www.canada.ca/en/health-canada/services/science-research/science-advice-decision-making/research-ethics-board/requirements-informed-consent-documents.html#cons>

<https://ctep.cancer.gov/protocolDevelopment/docs/NCI_Informed_Consent_Template_Readability_Assessments.pdf>

* **Use of Text Examples:** Edit the text examples as necessary to make the language specific to the study question since many statements throughout the template are generic. Examples are not given for every study situation. Consent authors should review all examples in a section, even if the example is for a different study type, to identify language that may apply to their study.
* **Formatting:**
1. Use 1-inch margins for top, bottom, and sides of the page.
2. Use Calibri size 14 font and bold the main section headings.
3. Use Calibri size 11 font for the body of the form.
4. Do not use all capital letters or italics to call attention to information. Use other formatting sparingly.
* **Color-Coded Information:**
	+ Brief instructions to consent authors are in *italics and highlighted in turquoise*. This text should be removed prior to REB submission, i.e. not included in the consent form for participants.
	+ Sections where consent authors should enter or modify text are *(in blue italics and listed between parentheses)*. Adapt and enter the text as necessary. Remove the parentheses, and format as normal body text in the consent form for participants.
	+ The provincial form should not be on local letterhead, nor include local contact information.
	+ Instructions for centre-specific information are in *italics and highlighted in yellow*
	+ Centres should keep the version date of the approved provincial form and add local contact information and all pre-approved administrative changes. Centre-specific pre-approved changes also may be added.
* **Study Schema:** It is recommended to include a simplified study schema in the consent. The schema should be placed in the section, “What are the study groups?”
* **Use of More Than One Consent in a Single Study**: Consider using more than one consent form to improve participant understanding when the study has distinct components (e.g. for trials with separate pre-screening component). In these cases, the consent forms should reference each other appropriately and avoid duplication of information.
* **Participant Study Calendars:** Consider providing an easy-to-read-and- understandable participant study calendar. A Participant study calendar may be included as an appendix or included in the main consent document. Highlight the study appointments and procedures on the calendar that are required more frequently than with the usual approach and, if appropriate, the approximate duration of the procedures and/or visits.

Instructions for Authors Related to Specific Content of the Informed Consent Form

Instructions will correspond to the content sections and numbered questions of the consent form. Instructions do not exist for every section/question; when instructions exist, consent form indicates:

***See Instruction Guide***

**Study Titles**

1. Section length limit: Both titles together should take up no more than one-quarter page.
2. Include 2 titles:
	1. The reader-friendly lay title, which is called the “Study Title for Participants.”
	2. The official title, which can be used by potential study participants for Internet searches.
3. For the lay title:
	1. Provide a brief (about 20 words) title of the study in lay language.
	2. Use general terms.
	3. To make the title concise, list the usual approach generically (e.g., chemotherapy, radiation therapy, surgery) rather than providing specific names (e.g., docetaxel, IMRT, laparoscopy). However, the investigational drug or other investigational item or procedure should be named.
	4. Use bold size 12 font for Study Title for Participants. Then list the actual title using size 14 font without bold. Do not capitalize all letters.
	5. This title should be the same as the lay title that will be used on <http://www.ClinicalTrials.gov>
4. For the official title:
	1. Insert study ID number, e.g., Protocol 0000, and, in quotes, the official study title as provided by the study sponsor.
	2. Use bold size 9 font for Official Study Title for Internet Search on <http://www.ClinicalTrials.gov>. Then list the actual title using size 14 font without bold. Do not capitalize all letters.

**Overview**

1. Section length limit: 3.5 pages.
2. This section introduces participants to research and the research study.

**4. What is the standard of care for my (select from options)?**

1. Adapt language from the examples or use other language specific to the study. Provide a brief description of the standard of care or a usual approach, which should not be overly specific or detailed, allowing the research to be placed into context. Indicate whether the usual approach includes Health Canada-approved treatments. Include an estimate of the expected outcome of the usual approach when/if it is known.
2. For chemoprevention trials, state the precancerous condition or high-risk status (e.g., current or former smoker, oral leukoplakia) and the usual intervention received if not participating in a study.
3. Avoid naming specific drugs as these could change with the availability of new treatments, except where a particular agent is so commonly accepted that it provides the easiest explanation.
4. Use sentences from different examples and add additional sentences or modify the provided examples as necessary to provide an appropriate description of the usual care for these participants. The blue text indicates sections that may commonly be adapted, but should be edited to provide information appropriate for the study.

**6. What will happen if I decide to take part in this study?**

1. This section should include the length of time that study participants will be on active treatment or receiving the intervention and in follow-up.
2. Adapt the text examples provided to appropriately describe the study. The blue text indicates sections that may commonly be adapted, but should be modified as appropriate for the study.
3. Adapt the second paragraph text to describe the length of study follow-up.
4. If therapy could be withdrawn or withheld for the purpose of the research, inform participants of the anticipated consequences.

**7. What are the risks and benefits of taking part in this study?**

**Key study risks**:

In a bulleted list, identify the most important risks, similar to the information that a doctor might deliver in the clinical context in telling a participant how sick the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study. This should be a brief list (generally around 5 although more may be necessary), including the most important reasonably foreseeable risks and discomforts. Note that for investigational agents or combinations, it may be important to highlight that there may be important unknown risks.

**Benefits**

Adapt the following text examples to describe the study benefits, making the language as specific as possible based on the study question. The blue text indicates sections that may commonly be adapted, but it should be modified as appropriate for the study.

**10. What is the purpose of this study?**

1. Section length limit: This section should be no more 1/2 of a page.
2. Provide a brief, phase-specific description of why the study is being done.
3. Insert the names and types of investigational drugs/agents/interventions/biomarkers where indicated.
4. Insert the number of study participants overall, taking part in the study.
5. If modifying the template language is necessary, use simple, concise, lay language.

**10g. Investigational Biomarkers**

The “what is the purpose of this study?” section should describe biomarkers which are essential for conducting the study (e.g., define eligibility, stratification, disease monitoring, or study endpoints) and are investigational.

**11. What are the study groups?**

1. Section length limit: This section should be no more than 1 page without a schema, or 2 pages with a schema.
2. Provide a brief, phase-specific description of the study groups.
3. Insert the names and types of the study drugs/agents/interventions, and the route of administration, dosing, where appropriate, and treatment schedule (e.g., how often, duration of infusions, etc.).
4. Clearly identify what intervention(s) are being evaluated.
5. Clearly identify which study drug(s)/arm(s) and study biomarker or imaging screening tests are considered investigational and/or are not Health Canada-approved in this setting.
6. When applicable, identify whether or not participants will be able to continue receiving study drug after the study or their participation in the study has ended.
7. If study-related procedures include for example, retreatment, treatment beyond progression, re- challenge, second course treatment, or cross over, include this information in this section of the consent with details including the following elements:
* Identify the treatment arm(s) included in each [retreatment/treatment beyond progression, etc.] scenario;
* Identify that a discussion with the study doctor will be important prior to considering this option (indicate that the option is voluntary);
* Identify the risks and benefits of [retreatment/treatment beyond progression, etc.] (include any additional risks: for e.g., re-exposure to the study drug, being unable to enroll in other studies);
* Indicate that the Main Consent Form will be re-reviewed with the participant at the time of [retreatment/treatment beyond progression, etc.] to ensure all elements of the consent are presented to the participant (with source documentation of this process and of the participant’s ongoing consent).
1. For studies with multiple groups, indicate how many participants will be in each group, if known.
2. For randomized studies, include the probability of being assigned to each arm. If the assignment is not 1:1, include a brief description of the assignment.
3. If modifying the template language is necessary, use simple, concise, lay language.
4. Use of a simple study schema in this section is strongly encouraged regardless of study design. The schema should not be a duplication of the protocol schema, but should be adapted to highlight the information most relevant to potential study participants, comply with plain language principles, and improve participant comprehension.

**12. What exams, tests, and procedures are involved in this study?**

1. Section length limit: This section should be as brief as possible and take no more than 3/4 of a page. If this section includes a mandatory research procedure, specimen collection, or quality of life study, the length can be expanded to 1 1/2 pages.
2. In this section, it is important to highlight to potential participants what would change in their care if they took part in the study.
	1. Do not list exams, tests, or procedures that are related to the usual approach of cancer care for participants, such as clinically appropriate staging studies, lab tests, and exams.
	2. Optional exams, tests, and procedures that are related to the study objectives may be briefly mentioned in this section and then noted that they will be described in the “Optional Studies” section at the end of the consent. Bio banking samples for future unspecified use should be described and may be included here or in a separate optional consent form. This main section should focus on those exams, tests, and procedures that are mandatory for the main study.
3. Indicate whether the exams, tests, or procedures would only happen in certain study groups.
4. Exams, tests, and procedures to monitor participant safety and health: This section should only list those exams, tests, and/or procedures required to prevent complications and/or monitor the effects of the study agent(s), device, or other interventions on participant safety that are:
	1. Done more frequently or on a different schedule than the usual approach; or
	2. Not otherwise needed or necessary for the usual approach.
	3. Note: Any exam, test or procedure listed for (a) and (b) should provide the timing and/or frequency of when they are needed during the study.
5. Exams, tests, and procedures for research: This section should also list any research exams, tests, and/or procedures (including imaging studies or specimen collections) that are not part of clinical management such as those listed above in #4. This includes all mandatory research specimen collections that are considered “integral” to the study.
6. Note: Optional correlative science studies, including specimen collections for integrated and/or exploratory biomarker tests and quality of life/participant-reported outcomes collections may be briefly mentioned here but should be listed as “optional.” They need to be described in detail at the end of the ICF under the “Optional studies” section and provide participants with the opportunity to opt in or out
7. If a study includes the return of secondary or incidental genetic test results, explain what this would involve. However, the risks associated with these test results should be described in the risks section of the ICF.
8. Make sure that all procedures described here align exactly with what is described in the protocol and what is described in other sections of the consent.
9. An attached study calendar is highly recommended. It can be included in this section or referenced in this section, and may be attached as an appendix to the consent.
10. If HIV and Hep testing are mandatory for the study include the following language include as applicable*:*

*Hepatitis Testing:*

*This study involves testing to determine your Hepatitis xx status. This test is required for this research study to find out if (provide the reason for the test if not described elsewhere in the consent - e.g., you meet the eligibility requirements, etc.) If you test positive for Hepatitis xx, you will not/will be able to participate in this study.If you test positive for Hepatitis xx your doctor will be required to share your identity and the results of your test(s) with Public Health. If you have concerns about being tested for Hep xx, and the consequences of testing positive, you should speak to your study doctor or your usual doctor before providing your consent to be tested.*

*HIV Testing*

*This study involves testing to determine your HIV status. This test is required for this research study to find out if [provide reason for the test if not described elsewhere in the consent – e.g., you meet the eligibility requirements, etc.]. If you test positive for HIV, you [will not/will] be able to participate in this study. In order for you to be tested for HIV you will need to provide your consent for the testing. Before providing your consent, you should know that you have the option of going to an anonymous HIV test site to get your test results privately, and you can choose not to share this information.*

*If you consent to be tested for the study, the results of your HIV tests, like all other laboratory test results, will be provided to the Sponsor, your study doctor and your usual doctor.*

*If you test positive, your doctor will be required to share your identity and your HIV status with Public Health. The people you may have exposed to HIV will have to be notified either by you, your usual doctor or by Public Health. If you have concerns about being tested for HIV and the consequences of testing positive, you should speak to your study doctor or your usual doctor before providing your consent to be tested.)*

**12a. Mandatory specimen collections for research purposes**:

1. Describe when the specimen will be collected.
2. Briefly describe how the specimen will be collected.
3. Briefly describe how the specimen will be used for research purposes, including where specimen(s) will be kept and for how long.
4. Indicate if any test results will be returned.
5. If applicable, refer to any additional consent forms that may be needed, e.g. for a biopsy or banking samples for future unspecified use.
6. Do not describe any risks associated with the specimen collection here. Risks should be included in the risks section.
7. Do not include identifiers associated with the specimen collection here. Identifiers should be included in the “Who will see my medical information?” section.

**12e. Study Calendar**

Participant study calendars are strongly recommended, and may be included in the consent or as a REB-approved attachment to the consent.

13. What risks can I expect from taking part in this study?

1. Section length limit: Limit this section to no more than 4 pages. If a study has a very long list of study drugs/treatment side effects and genetic testing risks, it may be up to 6 pages.
2. This section should include all reasonably foreseeable study risks, including those from the investigational drugs, agents, and/or treatments and also risks associated with any mandatory integral biomarkers, investigational biomarkers, research tests, procedures, and exams.
3. This section should focus on what risks might change or be different from what they would be if the individual chose not to participate in the study.
4. Trials that include investigational testing of biospecimens that may have the potential to reveal germline mutations (or suspected germline mutations) should include associated risks to participants and their family members.
5. Note: Risks associated with optional and other non-mandatory tests and procedures should be included in the “Optional studies” section.
6. Reproductive risks: specific methods to prevent pregnancy do not require inclusion in the consent. A supplementary information document may be provided to the study doctor if required. Reproductive responsibilities are addressed in #14.

**13a. Genetic Testing Risks**

Instructions to ICF authors on how to present risks associated with genetic or other testing that is investigational or non-standard:

1. Risks associated with using investigational genetic or other test results to direct treatment by determining study eligibility or study group assignment:
	1. If the test is investigational as used in this study, describe the risks associated with using the test results for direction of treatment. For studies where the test results will be used to determine participant eligibility in the trial, or for studies where the test results will be used to assign the participant to a study group, these risks include (1) the possibility of incorrectly being found eligible or (2) receiving an incorrect assignment due to an error in the test, and thus, the participant may not receive the best treatment option.
	2. For any study that requires waiting for test results before beginning treatment, there are possible risks to delaying treatment.
2. Risks associated with nonstandard genetic testing (testing not used as part of the usual care in this disease) that might identify mutations that are potentially inheritable:
	1. If the test will only be used on tumor tissue, the test cannot conclusively determine if a mutation is inheritable. This determination would require additional testing and expense outside of the study if a participant wanted to know if the mutation was inheritable.
	2. There may be implications of finding potentially inheritable mutations for the participant and the participant’s family.
3. Risks associated with the potential for secondary/incidental findings that are found using a clinically validated test:
	1. **Note: Any plan to return secondary/incidental results (which are actionable) should be described in the “What exams, tests, and procedures are involved in this study?” section and must be approved by the REB.**
	2. Consider how likely it is that there will be secondary/incidental findings given the planned testing. Secondary/incidental findings are more likely with more extensive testing. The description of the related risks should indicate how likely researchers believe they are to occur.
	3. If the testing is being done in a certified lab, investigators will return the results of clinically validated tests and secondary/incidental results will be discussed with the participant.
	4. If the testing is being done in a research lab and the study is designed to return the results to the participant’s study doctor, the doctor would need to discuss with the participant if they are interested in learning more about the results using clinically validated tests. This would entail additional testing and the potential for an expense outside of the study to confirm any secondary/incidental results in a certified lab before they could be provided to the participant.
	5. If the participant chooses to receive information about secondary/incidental results, there may be implications for the participant and the participant’s family and learning this information may cause concern for the participant and their family members.
4. Note: For any study using genetic testing, there is a slight risk that in the future, someone not involved in the research might access and misuse the genetic information of trial participants. **This information should be included in the section, “Who will see my medical information?”**

**13b. Drug Risks**

Instructions to ICF authors on how to present possible side effects:

1. Side effects of study group(s):
	1. For single-arm studies, list all possible side effects of the study drugs per the recommendations below.
	2. If the investigational arm consists of the usual treatment drugs/regimens (the control arm) plus investigational agent(s)/drug(s), the Table of Possible Side Effects for the usual treatment may be included, if required.
	3. The following statement should appear before the Possible Side Effects for the investigational drugs/agents: “In addition to side effects listed above for Group 1 and Group 2, people in Group 2 may also have some of the following side effects of (insert name of research drug).”
2. Side effects of procedures:
	1. When describing risks for procedures, describe risks only for procedures that are a change from what would be considered as occurring during the usual treatment approach.
	2. Examples of procedures that are not part of the usual treatment approach could include an unusually large amount of blood to be drawn for PK, central line placement to administer the investigational agent, research biopsy, etc.
3. Side effects of supportive drugs named in the ICF:
	1. Non-experimental supportive drugs should not have their side effects listed unless they are being used outside their approved indication.
4. Side effects of classes of medications:
	1. If general classes of approved medications/standard of care drugs, such as a hormonal therapy or anti-emetics – where no specific drug is named – are required by the protocol, these and their related side effects do not need to be listed in the ICF.
	2. Extremely specific possible side effects which are not perceived by the study participant, such as minor changes in lab values, should not be included in the ICF. Lab value changes that could be perceived by the study participant, or could be indicative of harm, should be listed in terms they can understand. For example, the phrase “you could have liver damage,” would be more understandable to the study participant than “you could have elevated liver enzymes” or “you could have an elevation in (such-and-such lab value).”
5. Definitions of frequency categories:
	1. “Common, some may be serious” – There is no standard definition of the frequency of risks included in this category. However, as a guideline, “Common, some may be serious” can be viewed as occurring in greater than 20% and up to 100% of patients/participants receiving the drug/agent.
	2. “Occasional, some may be serious” – There is no standard definition of the frequency of risks included in this category. However, as a guideline, “Occasional, some may be serious” can be viewed as occurring between 4% and 20% of patients/participants.
	3. “Rare, and serious” – Side effects that occur in less than 3% of patients/participants do not have to be listed unless they are serious, in which case they should appear in the “Rare, and serious” category.
	4. “Serious” is defined as side effects that may require hospitalization or may be irreversible, long-term, life-threatening, or result in serious impairment of normal life functions or death.
	5. “Possible, some may be serious” – This is a frequency category that may be used for informing study participants of possible side effects related to IND agents for which the frequency of individual side effects has not yet been determined due to limited experience in humans (fewer than 100 participants).
6. Note on stating possible side effects for imaging agents: Certain regulations may need to be considered when imaging agents are used depending on the imaging agent (IND vs. commercial) and the protocol Radiation Safety Committees may also require the mention of certain radiation-related information in the informed ICF.
7. Use of CTEP-provided tables: when relevant
	1. CTEP maintains tables of possible side effects for its IND agents as well as for many other drugs commonly used in cancer treatment trials. These tables should be inserted as illustrated below for the agents/drugs used in the cancer treatment trial.
	2. Tables of Possible Side Effects for commercial anti-cancer drugs are available on CTEP’s website at: http://ctep.cancer.gov/protocolDevelopment/informed\_consent.htm.
	3. Tables of Possible Side Effects for investigational agents are not posted to this public website. Rather, these tables are sent by CTEP to investigators with approved studies to include in their protocol.
	4. If a study uses a drug for which CTEP has not built a Table of Possible Side Effects, tools and instructions for custom-building a table are provided at <http://ctep.cancer.gov/protocolDevelopment/informed_consent.htm>.
	5. For custom-built tables of possible side effects, the same format and frequency categories may be used.

**14. What are my responsibilities in this study?**

1. Section length limit: This section should be no more than 1/2 of a page.
2. This section should include information about the responsibilities of study participants and should not include any exculpatory language that could be used to excuse or appear to excuse investigators or other persons, or institutions involved from liability for their negligence or other fault.

**15. What are the costs of taking part in this study?**

* + - 1. Section length limit: This section should be no more than 1 page.
			2. If appropriate, state which study agent(s), tests, or procedures are provided free of charge.
			3. If appropriate, include any expected expenses/costs that may be incurred by the participant.

**17.** **Who will see my medical information?**

1. Section length limit: This section should be no more than 1 page.
2. Note: The list of potential entities is intended to describe some of the organizations that may see the medical information. It is not intended to be an exhaustive list, as this is not feasible. Please consider limiting the list to key organizations of which a participant should be aware.
3. Additional required text should be included as necessary noting concerns around genetic testing and its potential impact on privacy.
4. Where can I get more information?

Section length limit: This section should be no more than 1/2 of a page.

20. Optional studies that you can choose to take part in

1. Section length limit: If the study mandates that any of these optional studies be included, the text should be as brief as possible and take up no more than 5 pages.
2. All the regulatory elements of consent included in the primary consent form pertain to the embedded optional studies. If any do not apply, they must be addressed in the discussion of the optional studies.
3. Provide yes/no options at each decision point and do not require initials.
4. After choosing which optional studies included below pertain to the specific research, delete the studies that do not pertain.
5. If modifying the template language to include other optional studies is necessary, such as consent for a 3rd party locator company, or consent for the Greenphire reimbursement programme, use simple, concise, lay language.

e.g., Third party contact permission: for studies in which a company such as Omni Trace will be used to trace participants who are ‘lost to follow up’, the following information should be included:

* Name of company and purpose for their involvement [ e.g., tracing participants who are ‘lost to follow up’, who have not withdrawn their consent for ongoing participation in the study]
* Personal information disclosed to the company [e.g., name, phone number, address], its use and retention period
* Sources of information that will be used for tracing purposes [e.g., public records/media, secondary contacts]
* Role of company in tracing the participant and relaying any new contact information back to the study doctor for follow up
1. If participation in some optional studies will be limited (e.g., to certain institutions) make sure that this is clearly noted in instructions.

**20d. Optional sample collections:**

1. Section title and content should be modified as applicable based on whether the study has optional collections and/or biobanking.
2. Whole genome sequence/whole exome sequence (WGS/WES): 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).” Authors should be sure that this information is included when known future studies will use WGS/WES. This information should also be included for any protocols where specimens are banked for future unspecified research.

**21. Instructions to ICF authors for Signature section.**

1. Section length limit: This section should be no more than 1 page.