**TGH Informed Consent Form Template Instructions**

Below are instructions and helpful hints when completing the informed consent form.

As a general rule, the goal of the informed consent process is to provide sufficient information for a reasonable person to make an informed choice about participating in research. The consent form provides a summary of the research study, including risks and benefits, states the participant’s rights as a study subject, and documents the participant’s voluntary choice to participate. The consent form is, however, only one part of an ongoing exchange of information between the investigator and the study participant.

**General:** The Informed Consent form must match the budget and contract when and where appropriate. Prior to sending the ICF for sponsor/IRB approval, a final copy of the ICF must be reviewed by the TGH Office of Clinical Research for consistency with the budget and contract

**Instructions:** Any text in *blue* is intended to be replaced with language specific to the research study. Any text in *green* is intended to provide further instruction. Any statements that are non-applicable should be deleted unless otherwise indicated. The suggested language should be appropriate for most protocols; however, sections may be updated to more accurately reflect the study. Any section noted below with a **red title** implies that the section cannot be altered unless stated and approved by TGH Office of Clinical Research management.

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| **Study Title For Participants**  a. Provide a brief (<20 words) title for the study, stated in simple language.  b. Use vocabulary consistent with an eighth-grade reading level.  c. To make title concise, list the management approach generically (e.g., chemotherapy, radiation therapy, surgery) rather than providing specific names (e.g., docetaxel, IMRT, laparoscopy).  d. The study drug/device should be named in the study title, if applicable  f. This title will appear as the study title on the Research Authorization and the ICF signature page.  **Official Study Title**  a. Insert the study ID number and the official study title provided by the study sponsor.  b. Do not use bold font.  **Contact Information**  Insert according to directions  **Introduction**  Used to introduce the subject (or individual legally authorized to have the consent discussion) to what a research study is and the purpose of an informed consent form.  Per the new Common Rule changes, there are key elements that are required to be on the first page. For drug/device/procedure studies, **all bullet points must be included**. |
| **What am I being asked to do?**  Adapt the text examples, as appropriate, for the study. Include type of disease, injury, underlying condition, etc and, as applicable, relevant targeted mutations or treatment targets. |
| **Why is this research being done?**  Rewrite the primary objective of the study as a question. If this is a first in human trial, that information must be included in this section. |
| **What is the usual approach?**   1. The template text should be used for all studies; however, the language can be altered, if appropriate. 2. List the general treatment such as there are medications that have been used to treat your condition. 3. Adapt the following text examples, as appropriate, for the study. 4. Include the number of participants expected to be accrued per instructions. If there is no contractual accrual cap, an approximate, realistic, number of subjects accrued at study site must be included. The ICF will require an amendment if that number if exceeded. |
| **What are my choices if I decide not to take part in this study?**   1. The template text for this section should be used for all studies; however, the language can be altered for some types of studies (e.g., healthy volunteers). 2. Additional bullets should include, when appropriate, alternative procedures or interventions. 3. For comparative effectiveness studies in which two approved, commercially available approaches (tests, drugs, surgery, radiation, diagnostics, etc.) are being compared, the option of the participant’s receiving one of the approaches outside the trial should be stated. |
| **What are the study groups?**   1. Including a study schema is optional if there is no randomization. 2. Provide a brief, phase-specific description of the study groups. 3. Insert the names and types of drugs/agents/interventions as needed. 4. For randomized studies, if the group assignment is not 1:1, include a brief description of the assignment strategy. 5. Clearly identify the investigational arm(s). 6. If it is necessary to modify the template language, use simple, concise, vocabulary that is consistent with an eighth-grade reading level. |
| **How long will I be in the study?**   1. Include the total time of participation should the subject complete all visits. 2. If the study has multiple phases, each phase should be defined including the total time subjects will remain in each. |
| **What extra exams, tests, and procedures are involved in this study?**   1. This section MUST match the cost section. 2. List the exams, tests, and procedures that either would not be done for the usual approach or that will be performed more frequently than usual. The study intervention (e.g., drugs, surgery, procedure) should also be included in this section. 3. If the study includes a Study Calendar, be sure to include the amount of time needed for the research tests or procedures and refer to the calendar at the end of the list of tests and procedures in this section. Include the calendar at the end of the consent form, after the signature page. (You will have to insert a new page at the end of the document.)    1. The following text should also be added: A Study Calendar that shows how often these [*exams, tests, and/or procedures*] will be done is provided at the end of this consent form. 4. If any tests are optional, it should be stated that more information about the optional studies will be provided at the end of the consent form and that subjects will be asked to give permission. 5. If subjects are completing a pill diary, instructions for how to use the diary must be included. Subjects should also be advised to return any unused medication, if applicable. 6. Include information about samples collected for future research and/or genetic testing. Guidance is provided with the template. |
| **What risks can I expect from taking part in the study?**  This section is intended to capture both physical risks and non-physical risk (ex missing time from work). For non-adverse events, follow template instructions.  Presenting possible side effects:   1. Side effects of study group(s):    1. For single-arm studies, list all possible side effects of the study drugs according to the recommendations given in sections 2-6 below.    2. For multiple-arm studies with a control arm, the Table(s) of Possible Side Effects for the control arm should appear first, followed by the Table(s) of Possible Side Effects for the drugs/agents used in the experimental arm(s).    3. If the experimental arm consists of the usual treatment drugs/regimens (given in the control arm) plus experimental agent(s)/drug(s), the Table of Possible Side Effects for the usual treatment should not be repeated. The following statement should appear before the Table of Possible Side Effects for the investigational drugs/agents: In addition to the side effects outlined above for participants in Group 1 and Group 2, participants in Group 2 may also experience possible side effects of [insert name of research drug] listed below. 2. Side effects of Phase I/First-in-human studies (determined by the study sponsor of industry-sponsored trials, or by the Principal Investigator in investigator-initiated trials):    1. If a drug has been tested only in animals, the side effects reported in the animals should be included as a bulleted list. Rephrase, as necessary, side effects reported in animals that may also occur in humans. Do not include animal-specific side effects (e.g., your tail may fall off).    2. If there is limited data on side effects in humans, the industry sponsor (or for IITs, the Principal Investigator) should decide whether only these effects should be listed, or whether the side effects in animals should be included.    3. The industry sponsor (or for IITs, the Principal Investigator) will decide whether it is necessary to list the side effects of a drug (or drugs) in a class similar to the phase I study drug. 3. Side effects of procedures:    1. When describing the risks of procedures, describe only the risks beyond those that would ordinarily occur during the usual treatment approach. (Determining whether a procedure is part of the usual treatment approach is the decision of the Principal Investigator.)    2. Examples of procedures that are not part of the usual treatment approach include an unusually large amount of blood drawn for PK testing, central line placement to administer the investigational agent, a research biopsy, etc. 4. Side effects of supportive drugs named in the consent form:   Do not list the side effects of non-experimental supportive drugs unless they are part of the research question. For example, side effects of filgrastim need not be listed unless filgrastim is part of the study question.   1. Side effects of classes of medications:   If the study participants will receive one or more of a general class of FDA-approved medications, such as a hormonal therapy or an antiemetic, with no particular drug being named, it is not necessary to list these drugs or their possible side effects.   1. Side effects that cannot be perceived by the study participant, such as minor changes in lab values, should not be included in the consent form. Changes in lab values that can be perceived by the study participant, or that could indicate possible harm, should be listed. “You could have liver damage” is more easily understood than “You could have elevated liver enzymes” or “You could have an elevation in [lab value X].” 2. Frequency categories/tables for drug studies [Please note that although the headings of the frequency tables cannot be changed, the occurrence figures may be altered to conform to available data.]:   **Most Common**: There is no standard definition of the frequency of risks included in this category; however, as a guideline, “Most Common” can be thought of as risks occurring in more than 20% and as many as 100% of subjects who receive the drug/agent.  **Less Common**: Again, there is no standard definition of the frequency of risks included in this category; however, as a guideline, “Less Common” can be thought of as risks occurring in 4% to 20% of subjects.  **Rare**: Side effects that occur in less than 4% of subjects need not be listed unless the effects are serious, in which case they should be listed in this category. Note: This categorization must be modified for prevention studies.   * 1. For device studies, if % of occurrences is unknown, list the side effects as one group. For sponsored-studies, the side effects must match the sponsor’s ICF and must also follow guidance in #6 above, where possible.  1. Note on stating possible side effects for imaging agents: FDA regulations must be considered when imaging agents are used, depending on the imaging agent (IND vs. commercial) and the protocol. 2. Include relevant pregnancy risks and contraception language as written per protocol. |
| **What are my responsibilities in this study?**  Section should remain as-is except for completing sponsor information. |
| **Will I benefit from taking part in this study?**  Template language intentional vague and should be updated, as appropriate. |
| **Is there a potential conflict of interest for this study?**  Template suggestions must be followed. |
| **If I decide to take part in this study, can I stop later?**  Section should not be altered, but can be modified for any bullets that do not exist (ie for a registry study becoming pregnant would not warrant a subject’s removal from study) |
| **What are the costs of taking part of this study?**  ***\* All study agent(s), assessments, exams, procedures, etc that will be paid by the sponsor MUST be confirmed with the budget.***   1. If appropriate, add the following sentence: There is no additional cost for taking part in this study. 2. Do **NOT** list out items that may be billed to the subject or subject’s insurance. Only those that are confirmed as **NOT** billed to the subject or subject’s insurance should be listed. These should be itemized and will match the budget. |
| **Will I be paid for taking part in this study?**   1. If applicable, insert a description of any payment for participation (e.g., money, gift cards) or for reimbursement of expenses (e.g., travel expenses, meals, transportation). 2. Provide additional information on how payment is received by subjects. 3. Subjects will need to opt-in/out of payment. |
| **What happens if I am injured because I took part in this study?**  Complete section with requested information. Any injury language must be confirmed with the contract prior to submitting for review/approval. |
| **Who can answer my questions about this study?**  Complete section with requested information. |
| **Optional sub-study section**   1. Complete section, as applicable. If specimens are being stored future use you must include the acknowledgement of agreement for use and storage of information section. 2. A meaningful explanation of the sub-study should be provided, unless it was explained earlier in the consent form. |
| **Research Authorization**   1. Do not edit the Research Authorization template. Insert protocol-specific language only where indicated. 2. The signature page may be edited if the patient population is specified and not captured appropriately. For example, if the research study does not allow for LAR consent, then all references to LAR may be removed. |