

- No new forms were added with this release.

New/Revised Questions with this Release (By question) –

- Updates have been made to the questions in the project application. The newly added text and/or questions listed below will only appear on new project forms, MODs and MOD/CR forms that have not yet been submitted.
- **Question VI.31 has been revised –**
Former Text: “Describe how you will assess/obtain assent from participants who do not have the capacity to consent.”
New Text: “Describe how you will obtain assent from participants who do not have the capacity to consent.”
- **Question VI.32 has been deleted and a new question has been inserted**
Former Question: “Is this a therapeutic trial?”
New Question: “Describe why the inclusion of participants who cannot consent for themselves is necessary to meet the objectives of the study.”
- **Question VI.33 has been deleted and a new question has been inserted**
Former Question: “Describe why the inclusion of participants who cannot consent for themselves is necessary to meet the objectives of the trial.”
New Question: “Does this project involve participants who may lose the capacity to consent for themselves over the course of the study?”
- **Question VI.34 has been deleted and a new question has been inserted**
Former Question: “Does this project involve participants whose capacity to consent may change over the course of the study?”
New Question: “Describe how you will determine when participants can no longer consent for themselves.”
- **Question VI.35 has been deleted and a new question has been inserted**
Former Question: “Describe how you will determine when participants no longer have the capacity to consent for themselves.”
New Question: “Once it has been determined that participants can no longer consent for themselves, describe the following:
 - how you will obtain assent from the participants
 - how you will obtain consent from the legally authorized representatives”
- **Question VI.36 has been deleted and a new question has been inserted**
Former Question: “Once it has been determined that the participant can no longer consent for themselves, describe the following:
 - the plan to obtain assent from the participant
 - the plan to obtain consent from the legally authorized representative”**New Question:** “Describe why the continued inclusion of participants who can no longer consent for themselves is necessary to meet the objectives of the study.”
- **Question VI.37 has been revised -**

Former Text: “Describe procedures to ensure that the participant's representative is well informed regarding their role and obligations to protect the incompetent participant or person with impaired decision making capacity.”

New Text: “Describe procedures to ensure that participants' legally authorized representatives are well informed regarding their obligations to:

- make decisions based on what the participants would want, and
- protect the participants with impaired decision making capacity.”

• **Question VI.38 has been revised -**

Former Question (moved to VI.41): “Does this project involve prisoners as participants?”

New Question: “Does this project involve participants who may regain the capacity to consent for themselves?”

• **Question VI.39 has been revised –**

Former Question (moved to VI.42): “Explain why any possible advantages the prisoner might receive by participating would not unduly influence his/her ability to weigh the risks of the research in the limited choice environment of the prison (when compared to the general living conditions, medical care, quality of food, amenities and opportunities for earnings in the prison).”

New Text: “Describe how you will determine when participants have regained the capacity to consent for themselves.”

• **Question VI.40 has been revised –**

Former Question (moved to VI.43): “Describe why the risks involved in this research project are commensurate with risks that would be accepted by non-prisoner volunteers.”

New Text: “Once it has been determined that participants have regained the capacity to consent for themselves, describe how you will obtain their consent.”

**All subsequent questions in Section VI. (regarding prisoners) are the same as before, but have been renumbered accordingly beginning with VI.41 noted above.*

• **Question VIII.2 has been revised –**

Former Text: “What have you done to minimize the risks?”

If applicable to this study ALSO include:

- How you (members of your research team at WUSTL) will monitor the safety of individual participants.
- Include a description of the availability of medical or psychological resources that participants might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)”

New Text: “What have you done to minimize the risks?”

If applicable to this study ALSO include:

- How you (members of your research team at WUSTL) will monitor the safety of individual participants.
- Include a description of the availability of medical or psychological resources that participants might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)

- Provide a description of the procedures being performed already for diagnostic or treatment purposes.”
- Updates have been made to the following Modification application questions:
 - **Question XIV.6.a has been revised –**
Former Text: “How will participants be notified? (Be sure to modify the content in the applicable section(s) of this project application and include the revised/new documents as attachments.)”
New Text: “How will participants be notified? (Also go to section VII.D and ADD a description of the notification/reconsent process in the question(s) describing your consent and enrollment process. Be sure to include the revised/new documents as attachments to the application.)”

New Features Added/Enhancements –

- No new features or enhancements were added with this release.

Changes to Attachments –

*Note: Several of the changes described below were made to existing template documents. Several of these changes are described here. To view the **full** revisions made to a particular template, please use the link provided below to view a track changed copy of the document.*

- **A new Phone Screen Consent template exists:**
The template is available under the Consent/Assent Documents and Information Sheets for Exempt Studies attachment category in the template selection menu.
- **Revisions affecting all of the Consent Templates, including the [Biomedical Consent Document \(for teenagers and older\)](#), the [Behavioral Consent Document \(for teenagers and older\)](#) and the [Behavioral Consent Document with PHI \(for teenagers and older\)](#):**
 - The local phone number for HRPO has been removed from the contact information in the consent template documents. The 1-800 number has remained, unchanged. ****For currently open studies, when submitting your next modification or continuing review, you should update any consents to remove the local HRPO number as it is being deactivated.****
 - The introduction has some minor wording changes noting participant responsibilities. A more detailed listing of participant responsibilities has been added to the signature block
 - Wording changes to the paragraph “Will you save my samples or research data to use in future research studies?”
 - Under the section labeled “What are the benefits of this study?” the following text option was revised:
Former Text: “We don’t know if you will benefit from being in this study.”
New Text: “You may or may not benefit from being in this study.”
 - Under the section labeled “Is being in this study voluntary?” the following text has been added:
 - Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.
 - Under the section labeled “What if I decide to withdraw from the study?” the following instructional text and template text has been added:

- **[Include the following if you want to continue follow-up or further data collection subsequent to the participant withdrawing from the interventional part of the study. You will need to obtain separate written consent for this ongoing participation when this occurs. This consent form may be submitted for approval at the time of the New Project application or as a Modification to an approved study.]**

If you withdraw from the study we will ask your permission to continue to **[describe follow up activities such as telephone calls, collection of information from your health care records, etc.]** Should this occur we will ask you to sign a separate consent form before collecting this information.

- **Revisions affecting only the [Exempt Information Sheet](#):**

- **The following text has been added:**

- If the study involves collecting information about cancer or people with cancer: “The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, identifiable information about you relating to your participation in this study (including your social security number) will be stored in a secure database at the Siteman Cancer Center. This database and also your treatment records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.”
- If a research team member has a financial conflict of interest: “[Name of researcher] [Describe the nature of the financial interest, e.g., is a paid consultant, owns stock in (or is employee/officer of) a company. If the financial interest is associated with a company, include the name of the company.]”
- “You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.”
- “You will not be penalized or lose any benefits for which you otherwise qualify.”

- **Revisions affecting only the [Consent Letter](#):**

- **The following instructional text has been added:**

- Include a meaningful description of any health information that will be collected
- Briefly describe confidentiality measures.

- **The following instructional text and template text has been added:**

- **[If your study includes the collection of protected health information (PHI) include the following language]**

As part of this study we will generate Protected Health Information, or PHI. PHI is health information that identifies you and is protected by law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this study you must give the research team permission to use and disclose your PHI as explained in this letter. The research team will follow state and federal laws and it is possible that other people may become aware of your participation in this study and may inspect records pertaining to the research. This could include university representatives, to complete university responsibilities and government representatives, (including the Office for Human Research Protections and the Food and Drug Administration) to complete federal or state responsibilities, **[if sponsored/funded, add name of agency/organization/company]** and **[indicate other entities with whom PHI may be shared and the purpose of sharing]**.

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this letter. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this letter. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you do not provide authorization for us to use your PHI it will not affect your treatment or the care given by your health provider, insurance payments or enrollment in any health plans, or any benefits to which you are entitled. However, it will not be possible for you to take part in the study. If you verbally agree, you authorize the use of your PHI for this research, and your authorization will not expire. You may later change your mind and not let the research team use or share your information.

In order to revoke your authorization, you will need to complete a withdrawal letter. Please contact the Human Research Protection Office for more information on how to revoke your authorization or contact the research team to request the withdrawal letter. If you revoke your authorization, the research team may only use and share information already collected for the study. Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons. You will not be allowed to continue to participate in the study. **[End of HIPAA authorization language]**"

- **The following changes were made to the Instructions for Writing a Consent –**

- Use of headers with multiple consent documents
- A description of what information auto-populates in the consent document
- A reminder that copies of the consent forms should not be saved outside of the system for future use.
- The use of "you/your" in the consent document when your study involves minors
- The use of the track changes feature when submitting revisions to the consent form
- The use of consent addendums
- Signature blocks

Note: It is strongly recommended that the Instructions for Writing a Consent document be shared with the sponsor of the research project if there are any questions about using the consent template.

- **The following changes were made to the Instructions for Signature Lines –**

- Information about the use of signature lines for studies involving minors and individuals that are decisionally impaired
- When a witness should be used when obtaining consent
- How to consent an individual that is hearing impaired

- **The following changes were made to the Assurance Documents –**

- New instructional text stating the documents shouldn't be altered was added, notations were added regarding the types of signatures that can be accepted, the PI name and title were added to the header on page 2, and the spacing was reformatted to minimize the number of page that must be printed.