INFORMED CONSENT/CONSENT TO RELEASE INFORMATION FOR RESEARCH

A. Information about the study.

Using everyday language, provide a clear and concise description of the study covering each of the following areas in a separate section or paragraph. You should modify the format and specific details in order to best represent your research project. The language used should be clearly written and easy to read with a ninth grade or lower vocabulary level.

1. Introduction:
Researcher's name and organizational affiliation. Title, purpose, and anticipated uses of the results of the study. If a BOP project, indicate the general authority permitting the Bureau to conduct the research [18 U.S.C. 4001(b) and 18 U.S.C. 4042(a)]. See the **"What is this study about and why are you doing it?"** section of the example.

2. Procedures:
Description of the procedures involved and the duration of the participation. Clearly describe what will happen during the study from the perspective of the participant. When needed or unclear, identify which procedures are experimental. See the **"What are you asking me to do if I agree to be in this study?"** section of the example.

3. Benefits:
Description of possible benefits, to participants and others, to be gained from the study. Participation incentives are not considered benefits and are not allowed when the participants are inmates. See the **"How will this study help me?"** and the **"Why should I participate in this study?"** sections of the example.

4. Risks or discomforts:
Description of possible risks or discomforts from participating in the study. Potential risks or discomforts may include–but are not limited to–physical risk, psychological risk, emotional risks, breach of confidentiality, etc. See the **"Are there any risks or can I get hurt by being in the study?"** section of the example.

5. Steps taken to alleviate risks or discomforts:
Description of the steps taken to reduce the risks to the participants. For the majority of research conducted in the Bureau of Prisons, the primary risk to participants is from a breach of confidentiality. This issue should be addressed when appropriate. See the **"What steps are you taking to reduce these risks or discomforts?"** section of the example.

6. Required Information
If not already included, ensure the following important information is included in the consent document when appropriate.

- Your participation is voluntary, and you may refuse to participate at any time without penalty.
- (If inmate participants) Your decision whether or not to participate will not affect your release date or parole eligibility.
- (If inmate participants) If you decide not to participate or to stop participating, you will be returned to your regular assignment as soon as possible.

- (If identifiable data is obtained) All information (if exceptions, describe in the descriptive section above and note here) will be handled in the strictest confidence, and only the researchers working on the project will have access to information that is traceable to you.
- (If identifiable data is obtained) The only exception to this policy of confidentiality is information about intent to commit a future crime or to hurt yourself or someone else (If other exceptions, include them as well).
- Your data will be used for research purposes only, and you will not be individually identifiable in any reports or publications (if exceptions, describe in the descriptive section above and note here).
- (If anonymous data) Please help us make sure you cannot be identified as a participant in this study; PLEASE DO NOT write your name or register number (if inmate) on any of the following pages.

See the **"What else do I need to know?"** section of the example.

7. Contact Information:
Provide an opportunity for participants to ask questions. For questions about the study, list an address for someone knowledgeable about the study (e.g., the researcher, the major advisor, etc.). For concerns about the study, you must note that the participants can contact the Chief Psychologist of the institution. If the Chief Psychologist is a study investigator, then the Bureau's Research Review Board must be listed as a contact. You should note that the participant will receive a copy of the consent form if s/he chooses, or if an anonymous study, note that the participant may detatch and keep the consent information if s/he chooses.
See the **"Whom can I contact with questions or concerns?"** section of the example.

B. Signatures.

1. Written consent:
Add the following to the consent form when the IRB determines that written consent is required:

Participant's Agreement: I have read the above information (or it has been read aloud to me). The study has been explained to me. My questions have been answered. I voluntarily agree to be in this study

Name (printed)	
Signature	Date

2. Written consent with witness signature:
In addition to the participant's agreement, add the following when the consent form is read aloud to a participant because s/he is a poor reader:

Witness' Statement: The information in this consent form was accurately conveyed to the participant.

Witness' Name-Printed	Witness' Signature

3. Written consent including access to files or other special procedures:
In addition to the participant's agreement, add the following when the consent procedure includes access to files:

I give the researcher permission to review my central file for the reason described in this consent form.

Name (printed)	Register #

Signature	Date

In addition to the participant's agreement, use the following format to include permission for special procedures (note–these are examples):

I consent to the following (initial the items you agree to, and cross-out the items you do not agree to)

_____ My test results can be added to my Psychology Services file for future treatment purposes.

_____ I would like feedback from the researcher regarding my literacy needs.

EXAMPLE
Consent to Participate in a Research Study

Title: Measures of the Healthy People 2010 Objectives in a Federal Inmate Population

Researcher: Jane Doe, Doctoral Candidate, Yourtown University

What is this study about and why are you doing it?

I am doing a study called "Measures of The Healthy People 2010 Objectives in a Federal Inmate Population." The study is comparing inmates with the general public on ten measures of physical and emotional health. The results will help prison managers track progress on the Healthy People 2010 goals. It may also help prison managers create programs that promote healthy habits among federal inmates. I will publish this study as part of my college degree requirements.

What are you asking me to do if I agree to be in the study?

If you agree to be in the study, you will answer some survey questions about your smoking, eating, and exercise habits. You will also have an interview about your fitness needs and goals. I will need your permission to review your Central file for information about your general health. The survey takes about 30 minutes. The interview takes about 1 hour. The total time needed will be about 1 ½ hours.

How will this study help me?

You will receive no direct benefits from being in this study.

Why should I be in the study?

The results from this study may help improve future prison policies about inmates' physical and emotional health. It is important that we have as many people participate as possible so that our information is as accurate as possible.

Are there any risks or can I get hurt by being in the study?

I do not know of any risks or discomforts that are due to being in this study. However, you may feel tired toward the end of the session. Also, you may feel embarrassed when answering some of the questions. Personal information about you could be revealed if I do not properly protect the data. Personal information could also be revealed if I am required by law to reveal it-- most likely, this will not happen.

What steps are you taking to reduce these risks or discomforts?

You may take a break any time you feel tired. You may decide to not respond to any questions you find disturbing. I will do everything I can to protect the confidentiality of your personal information. You will be given a study ID number. This number will be used on your surveys and other research papers instead of your name or register number. I will not include personal information about you in any

report or paper.

What else do I need to know?

- Your decision whether or not to be in this study is voluntary.
- You may refuse to be in this study at any time and you will not be penalized.
- Your decision either way not will not affect your release date or parole eligibility.
- You will be returned to your regular assignment if you decide to not be in this study.
- I must report the following:
  1) if you seem suicidal,
  2) if you say you want to hurt yourself or someone else,
  3) if you tell me you plan to commit a crime in the future, or
  4) if you admit to unreported crimes committed while in federal prisons.

Whom can I contact with questions or concerns?

If you have questions please contact me at <insert address>. If you have concerns about the study, please contact the Chief Psychologist at your institution and contact the Institutional Review Board, Yourtown University <insert address>. You may have a copy of this form if you would like.

Participant's Agreement: I have read the above information (or it has been read aloud to me). The study has been explained to me. My questions have been answered. I voluntarily agree to be in this study.

Name (printed)	
Signature	Date

I give the researcher permission to review my Central file for the reason described in this consent form.

Name (printed)	Register #
Signature	Date