The intent of this instruction is to guide the research investigator when developing his/her study specific informed consent document (ICD). The goal of the informed consent process is to provide a research participant with sufficient information in an understandable format for making informed choices. It serves as a starting point for the necessary exchange of information between the investigator and potential research participants. This document must be cleared for Public Release.

1. General Information:
   1. Formatting Instructions:
      * Write consent in the 2nd person.
      * Use understandable, non-technical language at the 8th grade or lower reading level and limit the ICD to 10 pages. Check the reading grade level (Flesch-Kincaid or Seattle Readability) of the document. The uses of bulleted text, schemas, photos, etc. are useful in lowering the reading level. Please do not simply cut and paste technical language from the protocol into the ICD.
      * Allow space in the footer for the AFRL IRB approval period, version number and/or date to be included. The AFRL IR administrators will manage and insert the final version and approval period.
   2. The final ICD must fulfill the minimum requirements set forth in for 32 CFR 219.116 General Elements for Informed Consent. <http://www.ecfr.gov/cgi-bin/text-idx?SID=7e6f711f5d16ef08a7241859c45b190d&node=se32.2.219_1116&rgn=div8>

The ICD should also include other categories that may pertain to your specific research, i.e. HIV, Pregnancy, long-term storage of samples, genetic testing, and data sharing practices, if known.

* 1. Shaded areas are instructional text. Delete the shaded areas on final document.
  2. “Model/example language” is in *italics.* You may use comparable language.
  3. Required language is in **bold font.**
  4. A HIPAA waiver request is required if the medical records of subjects are going to be accessed without the subjects consent. If subjects will be signing an ICD and the investigator wants to access the subject’s medical records then the subjects should sign a HIPAA authorization form at the time of consent. HIPAA forms are available on the IR SharePoint site.

1. TITLE: The title on the consent form must be identical to the title on the research protocol, unless a specific justification (e.g. confidentiality issue, planned deception) for a different title is addressed in the research protocol.
2. INVESTIGATORS:
   1. Principal Investigator with his/her contact information on the title page.
   2. Rank/Name, Comm, DSN 000-0000, Organization/Office Symbol and official Email address.
   3. Ensure email addresses and phone numbers are current

**DELETE THIS FIRST PAGE OF INFORMATION AND ALL INSTRUCTIONAL TEXT OR NON-APPLICABLE TEXT PRIOR TO FINALIZING YOUR CONSENT FORM**

**Consent to Participate in Research**

**For**

**(*Insert title of research study exactly as it appears on the title page of the protocol*)**

**Principal Investigator: Rank/Name, Comm, DSN 000-0000, Organization/Office Symbol**

**Official Email address**

1. **INTRODUCTION**

This portion of the ICD should briefly introduce the study. It should state the study involves research, state the element(s) of the study that are experimental, provide relevant background information. Include the name of the main Sponsor of the study if not already stated elsewhere.

1. **PURPOSE**

Describe the purpose of the study, as defined in the study protocol in nontechnical language, include the goals of the study, and what is hoped to be found, the basic study design, how various experiments will be compared, and how subjects if eligible to participate will be assigned to a given group (randomly, like the flip of a coin).

* State the study involves research.
* Explain why the participant is being asked to take part.
* Include the number of subjects that will take part, if this is a multi-center study provide the combined total number of subjects that will be enrolled.
* If drugs or devices are used, indicate whether they are FDA approved or investigational.

1. **PROCEDURES**

Include a description of the study procedures. Identifying which procedures are for research and which procedures are standard of care and which procedures are experimental. If blood or tissues samples will be collected as part of the research and stored for future research, describe the storage procedures under “Storage of Specimens for Future Use” section of the ICD. Describe the number of visits and length of time the subject will be asked to commit to (include any follow-up if applicable). Timelines, charts, schemas, photos may be useful and simplify information. Examples of model language, which you may use in the final ICD is as follows:

*If you decide to take part in this study, the study investigator will ask you to do the following:*

* *Provide permission for the researchers to look at your medical records to see if you are eligible to take part.*
* *Complete questionnaires about your experience with video games.*
* *Answer questions about your health.*
* *Have an MRI of your brain to look at how your brain responds when seeing pictures or words.*
* *Permit the research staff to collect a teaspoon of blood from a vein in your arm to check your overall health.*
* *The results of these research tests will not be shared with you.*
* *You will be asked to come back to the clinic for 20 weekly visits. Each visit will last approximately one hour.*

1. **POTENTIAL RISKS and/or DISCOMFORTS**

Risks included in the protocol, must also be included in the consent form and described in layman terms. Insert a description of any foreseeable risks or discomforts to the participant (physical, emotional, social, and financial, loss of employability, reputation and breach of confidentiality). Risks similar to those experienced in routine daily life, e.g. office environment, computer work, etc., risks associated with the experimental research component should be listed as well as any discomforts and risks from procedures used to assess the subject’s response. Remember to include any information regarding interactions between tests if more than one is required for this study. Describe the precautions that will be taken to protect the participant. When possible quantify the risks in percentages (e.g. common 10-20%, infrequent 1-10%, rare less than 1%. The following is an example of model language to choose from, which you may use in the final informed consent. Use ‘bullets’ for risk categories to simplify the information presented. You may also use comparable language.

*Below is a summary of possible risks with the research procedures and taking part in the study:*

* 1. *Blood drawing: We will draw blood from a vein in your arm. This may be slightly uncomfortable. There may be a small risk of bruising and/or infection at the site.*
  2. *Fitness for Duty: In revealing something that may affect your health or fitness for duty, investigators will be required to report this information to appropriate medical or command authorities.*
  3. *Illegal activity:*

If the research study involves randomization, consider whether there may be risks associated with randomization particularly if one of the study arms is comparing standard of care. Consider the following model language:

*You will be assigned to a group by chance, which may prove to be less effective or have more side effects than the other study group(s) or alternatives.*

**Incidental Findings: Include if applicable**

For activities that could result in the discovery of an incidental finding that may have substantive or clinical importance include a brief description if and how the information will be conveyed to the subject.

1. **PREGNANCY RISKS**

It is difficult to draft language that anticipates the pregnancy risk for every study. Precautions must be considered for female subjects or subjects who are or may become pregnant during the course of the research study. Describe any additional precautions that may apply if any. In addition, researchers must consider the risks to partners of participants if applicable. For Greater than Minimal Risk protocols, the following required verbiage would be required if applicable.

***If you are female or if you are pregnant, plan to become or may become pregnant during the course of this study, you must read and sign the Briefing Addendum for Female Subjects prior to making a decision to consent to become a subject in this research study.***

1. **BENEFITS**

Benefits included in the protocol, must also be included in the consent form. Include a description of any potential benefits to the subject or others that may reasonably be expected from this research study. Do not overstate benefits. If there is no potential for direct benefit to the participant this should be stated. NOTE: Compensation for time, reimbursement for expenses, and study procedures are not considered benefits. For Compensation see section 10. Example of model language, which may be used in the final ICD, is as follows:

*If you agree to take part in this research study there may be no direct benefit to you. However, the information learned from this study may someday help us to better understand how the brain interprets and processes different sounds.*

1. **COSTS**

Include any additional costs to the participant: i.e., parking; travel etc. or the participant’s health insurer that might result from the research (tests, devices, drugs or copayments). If there is no cost to the participant, this should be stated. Example of model language, which may be used in the final ICD, is as follows:

*There will be no cost to you for the research study related visits, lab tests and study procedures. You will be responsible for your transportation and parking fees.*

1. **ALTERNATIVES TO PARTICIPATION**

Insert appropriate alternatives to participation in the study, if any, which might be advantageous to the subject. The following is an example of model language, which may be used in the final ICD.

*Your alternative is to choose not to participate in this research study. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You must notify one of the investigators of this study to discontinue.*

1. **YOUR PARTICIPATION IS VOLUNTARY**

Include the following statement in the consent filling in the contacts and phone numbers.

**The decision to participate in this research is voluntary on your part. No one may coerce or intimidate you into participating in this program. Participate only if you want to. (Rank/Name), or an associate, should adequately answer all questions you have about this study, your participation and the procedures involved. If you have any further questions, (Rank/Name can be reached at (000) 000-0000). (Rank/Name), or an associate will be available to answer any questions concerning procedures throughout this study. You may withdraw from this research study at any time without penalty.**

**If significant new findings develop during the course of this research, which may relate to your decision to continue participate or may affect the risk involved, you will be informed. Additionally, the investigator or Research Monitor of this study may terminate your participation in this study if she or he feels this to be in your best interest. If you have any questions or concerns about your participation in this study or your rights as a research subject, please contact the AFRL IRB at (937) 904-8100 or AFRL.IR.ProtocolManagement@us.af.mil.**

**If you are removed from the study, the study investigator will contact you to answer any questions you may have.**

**If you intend to include Wright State students include the following statement:**

**If you are a Wright State student and you have any questions about your rights as a study subject, questions, concerns or complaints, you may call the Wright State IRB Office at (937) 775-4462. You may discuss any questions about your rights as a subject with a member of the IRB or staff. The IRB is an independent committee composed of members of the University community, staff of the institutions, as well as lay members of the community not connected with these institutions. The IRB has reviewed this study.**

1. **COMPENSATION**

Per DoDI 3216.02\_AFI 40-402.Enclosure 3, Paragraph 11; Compensation to Human subjects for Participation in Research

a. (1) (b) Federal personnel (civil servant or Service members) participating as human subjects in DoD-conducted research **while on duty** may only be compensated for blood draws as described in this paragraph and may not be otherwise compensated for general research participation.

a. (2) (b)Federal personnel (civil servant or Service members) **while off duty** may be compensated for research participation other than blood draws in the same way as human subjects who are not Federal personnel (i.e., compensated for participation in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research). However, payment to off-duty Federal personnel for research participation other than blood draws must not be directly from a Federal source (payment from a Federal contractor or other non-Federal source is permissible).

If there is any compensation to any subject discuss source of funds. Payments are to be pro-rated and not held until completion of the study. If participant payments are tied to completion of specific study benchmarks, these stipulations should be noted in this section as well as other reimbursement specific to the study e.g. parking, meal tickets, gift cards etc. Specify what test/procedures will result in compensation, as well as the amount. Explain the method of prorating the payment(s) if applicable. Consider including a payment schedule. If subjects will not receive compensation simply state “there are no plans to provide compensation for participation in the research.” If compensation is provided then state “there are no plans to provide other compensation beyond that described in the informed consent document

If participants receive $600 or more in a calendar year from their participation in research, include the following statement:

*You are responsible for paying any State, Federal, Social Security or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from the payment for your participation.*

1. **RESEARCH-RELATED INJURY**

Include the following required language in all consent forms.

**Your entitlements to medical and dental care and/or compensation in the event of injury are governed by federal laws and regulations. If you desire further information you may contact the legal office (711 HPW/JA, 986--5666 at Wright-Patterson AFB). In the event of a research related injury, you may contact the Principal Investigator, Rank/Name, of this research study at (000) 000-0000) [or Research Monitor if applicable].**

**For Minimal Risk:** PI is not required to include a communication plan for research related injury.

**For Greater than Minimal Risk (GMR):** PI is required to include a communication plan for research related injury. Include the following language in all Greater than Minimal Risk protocols:

**If an unanticipated event (medical misadventure) occurs during your participation in this study, you will be informed. If you are not competent at the time to understand the nature of the event, such information will be brought to the attention of your next of kin or other listed emergency contact.**

**Emergency contact information:**

**Name Phone#\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **SIGNIFICANT NEW FINDINGS**

Indicate that significant new findings identified during the course of the research study that may relate to the participants’ willingness to continue participation will be provided to the participant by the principal investigator or his/her research staff. The following is an example of model language

*You will be told by the study investigator or study staff if new information becomes available that might affect your choice to stay in the study.*

1. **CONFIDENTIALITY**

The terms ‘privacy’ and ‘confidentiality’ are often used interchangeably and for the informed consent form they are not interchangeable. Federal regulations differentiate between privacy & confidentiality. Privacy concerns people. Confidentiality concerns data. PRIVACY refers to a person’s desire to control access of others to themselves. CONFIDENTIALITY refers to how the researcher will protect private information provided by a research participant and how the subject’s private data will be managed, disseminated and protected by the researcher from release. It is a Federal requirement to describe the extent, if any, to which confidentiality of records identifying the participants will be secured. This section should describe the specific methods for assuring confidentiality; indicate where research study records will be kept, how they will be maintained and how the principal investigator will be responsible for them.

In addition include the following required language on Confidentiality.

**Records of your participation in this study may only be disclosed according to federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations and the Health Insurance Portability and Accountability Act (HIPAA), and its implementing regulations, when applicable, and the Freedom of Information Act, 5 U.S.C. Sec 552, and its implementing regulations when applicable.**

**Your personal information will be stored in a locked cabinet in an office that is locked when not occupied. Electronic files containing your personal information will be password protected and stored only on a secure server. Organizations that may look at and/or copy your medical and/or records for research oversight, quality assurance and data analysis include:**

* **the researchers named above,**
* **the study’s Research Monitor or Consultant,**
* **the AFRL Wright Site IRB,**
* **the Air Force Surgeon General’s Research Compliance office,**
* **the Director of Defense Research and Engineering office or**
* **other IRB(s) involved in the review and approval of this protocol.**
* *Add any others that may be granted access*

Include and revise as applicable to your protocol:

**You will be identified by a code, and personal information from your records will not be released without your written permission unless required for military personnel. Information related to health and fitness for duty may be required to be reported to appropriate medical or command authorities. Complete confidentiality for military members cannot be promised. You will not be identified in any publication or in the sharing of your data about this study.**

Include only if applicable, otherwise delete:

**Your participation in this study may be photographed, filmed or audio/videotaped. The purpose of these recordings is (\_\_\_\_\_\_\_\_\_\_\_\_describe specifically the purpose and audience).**

Include additional detail if data will be placed /stored in a central repository. Include the purpose of the repository, intended future use of the data, who will be permitted access to the data and who will be responsible for repository oversight.

*After the study is completed, the data may be placed in a central storage location. The purpose is to make study data available to other researchers. [Specifically state whether it will be stored in a de-identified manner or with identifiers]. These data [select one will/will not] include your name or other information that can identify you.*

*(or)*

*When no longer needed for purposes of this research study your information will be destroyed in a secure manner (explain exactly when and what the destruction method will be for hard copy, electronic files, video/audio recordings and bio specimens).*

**Complete confidentiality cannot be promised, in particular for military personnel, whose health or fitness for duty information may be required to be reported to appropriate medical or command authorities. If such information is to be reported, you will be informed of what is being reported and the reason for the report.**

**FUTURE RESEARCH STUDIES**

**Include only if applicable, otherwise delete.**

**If you agree, we may contact you in the future to notify you of other research studies. If you agree to be contacted, your name, phone number, address and/or email address will be kept in a subject pool contact registry used by 711 HPW only to notify you of future research studies. Your name and contact information will be kept separate from any research data collected as a part of this research study or future research studies. Future research will be reviewed by an IRB and there will be a new consent process for those future studies. Either researchers from this study, or other researchers from 711 HPW who have IRB approval could re-contact you to let you know of similar research participation opportunities in the future. You may update your contact information at any time or you may also change your mind at any time and contact *[Investigator name]* whose contact information is listed on the first page of this consent form to have your name removed from the list.**

**Please indicate your permission by initialing below:**

**\_\_\_\_\_\_\_\_\_I AGREE** to be re-contacted to be informed of future research studies.

**\_\_\_\_\_\_\_\_\_I DO NOT** agree to be re-contacted to be informed of future research studies.

1. **PRIVACY ACT**

Include only if applicable, otherwise delete.

**Personal Identifiable Information to be obtained for this study includes *(\_\_\_\_\_\_\_\_specify exactly what information is going to be obtained for use or disclosure in the course of the study)*. Signing this document in no way alters your ability to obtain medical treatment that is not part of this study. Any Private Health Information obtained in the course of this study may be used by the investigator unless you revoke authorization to do so in writing.**

1. **STORAGE OF SAMPLES and/or INFORMATION FOR FUTURE USE**

INCLUDE THIS SECTION IN YOUR CONSENT IF APPLICABLE

(When research involves plans for banking specimens for future genetic testing use separate Bio Banking template).

*We are asking your permission to store (choose one or none: extra/ leftover/unused) samples of biological specimens (e.g., blood, tissue, urine or identifiable or de-identified data) collected during this study to be used in the future for research not yet planned by whom (Government, Department of Defense, Commercial entity, PI). These research studies may or may not be related to the study of \_\_\_\_\_\_\_\_\_\_\_\_ (fill in blank with words such as ‘hypobaric, \_\_\_\_\_\_\_ disease’ or ‘\_\_\_\_\_\_\_\_’ etc.).*

*Please indicate your response below:*

*\_\_\_\_\_\_\_ I* ***agree*** *to allow the storage of my samples and data collected in this research study to be used for research not currently planned.*

*\_\_\_\_\_\_\_I* ***do not*** *agree to allow the storage of my samples and data collected in this research study to be used for future research not currently planned.*

Include only if there will be public release of the video/audio:

**We may wish to present some of the video/audio recordings from this study at scientific conventions or use photographs in journal publications. If you consent to the use of your image for publication or presentation in a scientific or academic setting, please sign below.**

**I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_agree to allow the use of photographs, video and/or audio records of my participation.**

**Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **STUDY PARTICIPATION AGREEMENT/CONSENT**

**Taking part in this research study is completely voluntary. Your signature below shows that:**

* **You agree to be in this study**
* **The researcher has explained the study to you and you have read and understand the information you have been given**
* **You were given the opportunity to ask questions about the study and all of your questions have been answered to your satisfaction**
* **You understand that signing this consent does not take away any of your legal rights**

**You will be given a copy of this signed consent form for your records**

**Volunteer Signature Date**

**Volunteer Name (printed)**

**Advising Investigator Signature Date**

**Investigator Name (printed)**

**Witness Signature Date**

**Witness Name (printed)**

**Privacy Act Statement (if applicable)**

**Authority: We are requesting disclosure of personal information. Researchers are authorized to collect personal information on research subjects under The Privacy Act-5 USC 552a, 10 USC 55, 10 USC 8013, 32 CFR 219, 45 CFR Part 46, and EO 9397, November 1943.**

**Purpose: It is possible that latent risks or injuries inherent in this experiment will not be discovered until some time in the future. The purpose of collecting this information is to aid researchers in locating you at a future date if further disclosures are appropriate.**

**Routine Uses: Information may be furnished to Federal, State and local agencies for any uses published by the Air Force in the Federal Register, 52 FR 16431, to include, furtherance of the research involved with this study and to provide medical care.**

**Disclosure: Disclosure of the requested information is voluntary. No adverse action whatsoever will be taken against you, and no privilege will be denied you based on the fact you do not disclose this information. However, your participation in this study may be impacted by a refusal to provide this information.**