The intent of this instruction is to guide the research investigator when developing his/her study specific protocol.

1. General Information
   1. Formatting Instructions:
      * Use Times New Roman font 12 pt.
      * 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 protocol should 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.
   3. Shaded areas are instructional text only, and should be deleted in the final protocol version.
   4. A HIPAA waiver request is required if the medical records of subjects are going to be accessed without the subject’s consent. If subjects will be signing an ICD and the investigator wants to access the subject’s medical records then the subjects should also sign a HIPAA authorization form at the time of consent.
2. TITLE: The title on the research protocol must be identical to the title on the consent form, unless a specific justification (e.g. confidentiality issue, planned deception) for a different title is addressed in the research protocol.
3. INVESTIGATORS:
   1. A list of all investigators with their contact information must be included on the title page.
   2. Rank/Name, DSN 000-0000 and COMM, Organization/Office Symbol and Official Email address (no personal email accounts are permitted).
   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 PROTOCOL**

1. **Principal Investigator**

Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address, contractor affiliation if applicable.

1. **Associate Investigators**

Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address, contractor affiliation if applicable.

Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address, contractor affiliation if applicable.

Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address, contractor affiliation if applicable.

1. **Research Monitor**

Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address, contractor affiliation if applicable.

1. **Facility/Contractor**
   1. **Sponsor:**
   2. **Funding Source and Funding Amount:**
   3. **Contract #/CRADA #/Cooperative Agreement #:**
   4. **Activity location(s) (where activity will be conducted):**
2. **Conflicts of Interest**

State “None” or provide description of conflict. Include any financial interests, duty position conflicts (e.g., Investigator and Program Manager in same study), along with plan to manage such conflict in this study.

1. **Background Information and Scientific Rationale**

Briefly describe pre-trial data, current experience with procedures and any other relevant information to justify and support the research. Include detailed literature review with most current citations that serves as the foundation for your research.

1. **Study Objective(s) and Purpose** 
   1. **Purpose:**
   2. **Primary Objective:**
   3. **Secondary Objective(s):**
2. **Study Design**
   1. **Description of Study Design:**

* Include the sequence and timing of study procedures.
* Consider including schemas of the study visit schedule/timetables.
* Distinguish research procedures from those that are clinical standard of care if applicable.
* Study duration and number of study visits, total time commitment for each visit and for the study overall that is required of the research participants.
* Blinding, randomization including justification or decision for not blinding and justification if applicable.
* Justification of placebo or non-treatment/control group.
* Definition of participant removal criteria.
* Description of what happens if study ends or participant’s participation ends prematurely (either participant choice or PI choice).

1. **Subject Selection**
   1. **Inclusion Criteria:**

A subject who has met all of the following criteria is eligible for participation in the study:

* 1. **Exclusion Criteria:**

A subject who meets any of the following criteria is disqualified from participation in the study:

* 1. **Recruitment Plan**

Describe the recruitment plan in detail. Where will subjects be recruited, by whom and how, (e-mail, social media, advertisement, flyers) attach copies of email text or flyers to be used. Recruitment material must be cleared for Public Release before advertising the study.

If an investigator intends to send emails/written notification to former participants, the PI must ensure that the participants prior consent was collected, documented and IRB approval was given and include the following statement in this section of the protocol: *“Investigator intends to send [chose method of notification e.g. emails/written notification] to former participants from the [include the AFRL IRB protocol number]study who have previously provided written permission on an informed consent form to be contacted and notified of new research studies”.*

* 1. **Consent Plan**

Unless the AFRL IRB has received a request and granted a waiver of consent or documentation of informed consent, the PI will ensure that any volunteer subject signs and receives a copy of the consent document before they participate in the study. Describe how and when subjects will be consented (by whom, where, how and when).

* 1. **Compensation**

Describe if and how subjects will be compensated for their time and participation. For example; parking will be provided or paid, gift cards in the amount of $$ will be given, mileage will be reimbursed at $$/per mile etc. 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.”

1. **Experimental Plan**
   1. **Equipment:**

* If you are using a device or drug that could fall under FDA device/drug regulations, supply discussion of FDA status and supporting FDA documentation. Also include the manufacturer’s specifications as an attachment. Discuss whether the device/drug is being used within the manufacturer’s specifications. Include as an attachment the manufacturer’s user guide or package insert of product or device.
* Consider attaching a photo of any equipment that will be used.
* If multiple sub-experiments, discuss in detail each experiment (i.e., number of MRI visits, number and volume of blood draws, number of days/hours, etc.). If conducting surveys, questionnaires, interviews, reference AFI 38-501, Air Force Survey Program. If applicable AF survey office documentation must be submitted.
* Incidental Findings: for activities that could result in the discovery of an incidental finding that may have substantive or clinical importance; for example findings from

(1) Imaging procedures such as MRI, (2) records review, (3) EEG, (4) genetics, (5) surveys, questionnaires that may ask about illegal activity, describe the plan that will be followed if an incidental finding is detected. Plans should include sufficient detail such as the specific time frame for follow up of any clinical readings, reporting to the subject and/or the primary medical provider as applicable. The proposed time frame should be justified.

1. **Risk/Benefit Analysis**

Detailed risk analysis with mitigation plan and supporting references. Please note if you are using a device/drug that could fall under FDA device/drug regulations, please include risk assessment of device/drug as “significant” or “not significant” risk. Include medical risks as applicable.

* 1. **Benefits:**
* A description of probable benefits for the participant and for society. If no benefit to subject, simply state, “there is no benefit to the subjects”.
  1. **Risks:**
* List all research procedures, their major and minor risks and expected frequency.
* Include all foreseeable risks or discomforts to the participant (physical, emotional, social, and financial, loss of employability, reputation and breach of confidentiality) as applicable.
* Include steps that will be taken to minimize risks.

1. **Statistical Consideration and Plan**
   1. **Sample Size (Power analysis):**

Use the minimum number of subjects needed to meet the research objective or answer the research question**.**

1. **Safety Monitoring and Reporting**

The PI will ensure that mishaps or injuries sustained during research will be reported as required pursuant to AFI 91-204.

* Include plan for onsite safety review as applicable and attach a copy of (1) Safety review, (2) Radiation Safety Board review, (3) Laser Board review, (4) IBC review as applicable.
* Include plan for safety monitoring and reporting unanticipated problems or study deviation to applicable oversight entities (IRB, FDA etc.)

1. **Confidentiality**

The terms ‘privacy’ and ‘confidentiality’ are often used interchangeably and 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;

* Describe how data be maintained (identifiable or de-identified, coded etc.).
* Describe where research study records will be kept (locked files in a secure office).
* How will the principal investigator ensure oversight?
* When will data be destroyed, by whom and by what method?

**Future Contact** If an investigator intends to ask the new participants for permission to re-contact them to receive information about future research studies, the PI must describe how this will be done and how the list and the subjects privacy will be protected. The PI must include the following information in this section of the protocol: *“We will be asking new research participant for permission to re-contact them to notify them about future research studies. Subjects will be asked to indicate their agreement via a check box on the consent form.”* The investigator must include a detailed description of the following as it pertains to the re-contact list: (1) what contact information will be collected and retained [i.e. name, email/home address], (2) how will the information be protected [where will it be stored and how long will it be kept, (3) identify who will manage the list of names and describe who will have access (e.g. this PI only or all investigators listed on the study) and state it will not be shared with any third party, (4) include a statement that it will not be stored/associated with any research data.

1. **Data Management/ Data Sharing Plan**

The purpose of data sharing is to encourage a more collaborative and coordinated research environment. This is achieved by promoting rapid availability of important findings, making new discoveries available to the research community for further analysis and interpretation while extending the value of scientific data in all areas of DoD supported research. Please describe the data management plans and data sharing plans if applicable.

* Are there plans for data to be sent to a research data repository? If so
* Where is the repository?
* Who will manage the data repository?
* How will the data be stored (de-identified, coded).
* Who will be permitted access to the data?
* What securities are in place to ensure long term storage of data is secure?
* Intended future use of the data should be clearly specified.
* Include if/how the data will be shared with other entities and describe data sharing agreements.

1. **References**
2. **Attachments** (If applicable, include attachments, otherwise delete)

* Informed Consent Document (required unless waiver granted).
* Consent waiver request.
* HIPAA waiver request.
* Current Curriculum Vitae of investigators (Appropriate to experience/education).
* Questionnaires or surveys (if applicable).
* Subject recruiting materials (if applicable).
* Other attachments if applicable, such as: letters of collaborative support (data use agreements, CRADA, etc.), IND/IDE supportive documents, contractor assurances, and any other supportive documentation.
* Safety, Radiation, Laser, IBC Board reviews etc.