NEW 2018-Regulations
Informed Consent Guidelines

Obtaining the consent of a participant in research, is a critical part of the research process. The goal of the IRB is to protect the rights and welfare of research participants. The Informed Consent form is part of that protection process. The participant should be fully aware of what they are ***volunteering*** for and what will be expected of them.

The following guidelines are designed to help the investigator (researcher) solicit and enroll participants in an ethical manner. Following these guidelines may reduce the likelihood of complications during the research process.

The IRB process begins with the ***RECRUITMENT*** of participants. Participants must be provided with enough information to make a decision as to whether or not to participate in the study.

Recruitment material should include:

- The title of the project
- A brief description of the research
- Eligibility requirements; ex. "Experienced pilots over the age of 18."
- A realistic preview of any discomfort that may be caused by the research (***Risks***)
  Example: "The use of the simulator in this study can cause motion sickness. The symptoms of motion sickness include, fatigue, headache, and nausea."
- Estimated time of involvement
- A realistic description of rewards/compensation offered for participation (if any)

Upon arrival for the study, the participant must be briefed about what they may expect to happen during the study. This briefing can be done orally and/or as part of the ***informed consent*** process.

1) The participant must be provided sufficient opportunity to discuss and consider whether or not to participate in the study. This must be done in a way that minimizes the possibility of coercion or undue influence.
2) The information provided to the participant should be in language that is understandable to the participant.
3) The prospective participant must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

   a) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective participant in understanding the reasons why one might or might not want to participate in research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
   b) Informed consent, as a whole, must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective participant's understanding of the reasons why one might or might not want to participate.

The Chair of the IRB CANNOT approve any project without the required elements in the Informed Consent document in this EXACT order: **[§46.116]**

1) A statement that the ***study involves research***, an explanation of the ***purpose(s)*** of the research and the ***expected duration*** of the subject's participation, a ***description of the procedures*** to be followed, and identification of any procedures that are experimental;

2) A description of any reasonably foreseeable ***risks*** or ***discomforts*** to the subject;

3) A description of any ***benefits*** to the subject or to others that may reasonably be expected from the research;

4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5) A statement describing the extent, if any, to which ***confidentiality of records*** identifying the subject will be maintained;

6) For research involving **more than minimal risk**, an explanation as to whether any ***compensation*** and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7) An explanation of whom to ***contact*** for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

8) A statement that ***participation is voluntary***, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

9) One of the following statements about any research that involves the collection of ***identifiable private information*** or ***identifiable biospecimens***:

    a. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for ***future research studies*** or ***distributed to another investigator for future research studies*** without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

    b. A statement that the subject's **information** or **biospecimens** collected as part of the research, even if identifiers are removed, ***will not be used*** or distributed for future research studies.

Online anonymous surveys/questionnaires should include 1-8 above where appropriate. This can be done at the beginning of the survey. Use the format of the Example Informed Consent Form for Survey Research to ensure all regulations have been met.

For all other research, use the format of the Example Informed Consent Form for Non-Survey Research to ensure all regulations have been met.

Prior to any data collection, the participant must first read, understand and be willing to participate in the study. By signing the Informed Consent Form or checking "agree" for anonymous survey research, the participant has stated that he understands and has agreed to participate in the study.