The Florida Institute for Human and Machine Cognition, Inc.
Institutional Review Board (IRB)

For

Human Participation in Research

Policies and Procedures

16 November 2010
Revised 4 May 2011
Revised 15 June 2012
Revised 20 January 2013
Revised 27 January 2014
Revised 27 June 2014
Revised 8 December 2014
Revised 17August 2017
Revised 23 October 2017
Revised 18 January 2018
Revised 5 June 2024
Revised 30 July 2025

TABLE OF CONTENTS

APPENDIX

Appendix A, Template Recruiting Statement
Appendix B, Template Consent Form
Appendix C, Example Consent Form
Appendix D, Example Debriefing Forms
Appendix E, Template HIPAA Release Form
Appendix F, NHSR Determination Worksheet

Appendix G:
For collaborating with external INSTITUTIONS that have active FWAs and IRBs, but are not part of SmartIRB:

IRB Authorization Agreement (IAA)-external IRB cedes to IHMC IRB
IRB Authorization Agreement (IAA)-IHMC IRB cedes to external IRB

Appendix H:
For collaborating with external INDIVIDUAL INVESTIGATORS who are not affiliated with an organization with an active FWA/IRB (individuals cannot affiliate with SmartIRB):

IHMC Individual Investigator Agreement (IIA)

I. INTRODUCTION

Section: I.A. Policy:

In accordance with DHHS 45 CPR Part 46, "Research" is defined as any systematic empirical or observational investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge.

Safeguarding the rights and welfare of humans who participate in research is an institutional policy of the Florida Institute for Human and Machine Cognition, Inc., a Florida Not-For Profit private research institute legislatively created (hereinafter referred to as "IHMC").

All research conducted at IHMC involving human participants must have an IHMC researcher as a project Principal Investigator (PI) or Co-PI(s). That individual will be responsible for the research project with respect to IHMCs policy for human research participation.

IHMC mandates that all research personnel possess an up-to-date CITI Program Training certificate, which is required for either the Biomedical Research Basic/Refresher course or the Social and Behavioral Research Basic/Refresher course. Both courses include the Belmont Report. Federal regulations mandate that all researchers conducting research involving human participants, including identifiable data and samples, and who have direct contact with participants, must submit a training completion report to the IHMC IRB. This report must demonstrate that the individual has completed the online training. The training can be accessed by logging onto citiprogram.org, as IHMC has an affiliation account with CITI. Additional guidance can be found in section III Review Guidelines, paragraph III E Certification.

Section: I.B. Legal Mandate:

Research involving human participants must follow certain legal guidelines mandated by federal law as administered by the US Public Health Service (45 CFR Part 46; effective date 19 August 1991; Federal Register vol. 56, No. ll7, pages 28008-28020) and by State law.

The purpose of these laws is to assure that all research conducted using human participants follows certain guidelines. Federal law mandates that (a) any institution receiving any type of Federal assistance; and (b) conducting research using human participants, must have in place an "Institutional Review Board" (hereinafter referred to as the "IRB") that is charged with assuring outside agencies that the research adheres to federal law concerning the ethical treatment of human participants.

Participants' rights include the following:

1. The right to written information about the nature of the research.
2. The right to not be exposed to undue stress or surprises.
3. The right to written information about any possible risks to physiological or psychological states.
4. The right to written assurance that any risks or stresses are minimized and justified.
5. The right to written assurance that the research is important and has benefits to science and society.
6. The right to decline to participate, for any reason, and without prejudice to any future activities related or not to the PI.
7. The right to ask any questions at any time.
8. The right to have their data kept confidential and anonymous, that is, individual results or data are not identified with individuals by name, and individuals are not identified by name in any reports, unless the participant agrees to be identified.

II. THE INSTITUTIONAL REVIEW BOARD (IRB), A COMMITTEE ON HUMAN PARTICIPATION IN RESEARCH (IHMC IRB)

The IHMC IRB has been established by the Chief Executive Officer (CEO) and is designated as IHMC's "Institutional Review Board." IHMC's IRB is charged with reviewing protocol submissions by members of IHMC for research involving human participants.

IHMC shall assure that all its activities related to human subjects' research, regardless of the source of support, will be guided by the statement of principles governing IHMC in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution as described in The Belmont Report and The Declaration of Helsinki.

II.A. Committee Structure and Function:

"Each Institutional Review Board shall have a minimum of six (6) members, with varying backgrounds to promote a complete and adequate review of research activities commonly conducted by the institution. The IRB will be sufficiently qualified through the experience and expertise of its members, and the professional diversity of the members, including individuals from various races, genders, and cultural and socioeconomic backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice" (Federal Register, Vol 566, No. 117, pp. 28014-28015).

II.A(1). Membership Makeup and Training:

Membership Makeup:

Number: The IHMC IRB will maintain a minimum of six (6) and a maximum of seven (7) primary members and a minimum of six (6) alternate members.

Selection & Appointment: IHMC IRB Members (primary and alternate) are selected by the current Board leadership based on the balance of skill sets of the serving membership. Once selected the member will be appointed to the IHMC IRB by the Institutional Official.

Gender: Federal law (45 CFR Part 46) prohibits IRB membership from consisting of entirely one gender.

Ad Hoc Appointment: Upon consultation with the IRB Members, the IHMC IRB Chair is authorized to appoint additional members on an ad hoc basis. The purpose of appointing additional members is to ensure review of submissions by individuals who possess submission-relevant expertise. Whenever practicable, these appointees will be individuals with prior IRB experience. Appointees will be required to familiarize themselves with the policies and procedures of the IHMC IRB and provide the IHMC IRB Chair with their current CITI Program training Completion Report. Upon approval by the IHMC IRB, these additional appointees may transition into permanent members.

Vulnerable Population Advocate Appointment: Federal law mandates that protocols involving the participation of individuals who have been classified as vulnerable (e.g., children, prisoners, pregnant women, the handicapped, and the mentally disabled) must be approved by a member of the IHMC IRB who can serve as an advocate of such individuals by virtue of their knowledge and experience, especially experience in conducting research with such participants (45 CFR Part 46). Although there has been disagreement in the Federal Register commentary on this aspect of the law, the Secretary of the DHHS continues to believe that there is a need for Institutional Review Boards to protect vulnerable populations.

Given this mandate, any research protocol that is submitted to the IHMC IRB that entails research using populations that might be regarded as vulnerable, will be reviewed by a IHMC IRB that includes an ad hoc member who can serve as an advocate.

Composition: IRBs generally include individuals whose primary concerns are both scientific and non-scientific. Additionally, IRBs generally include individuals with prior experience serving on IRBs, a community member not otherwise affiliated with (in this case) IHMC or related to someone who is affiliated with IHMC, and who, by virtue of their calling or profession is in a position to assess research (e.g., a member of the clergy, a public service employee, a school teacher, etc.).

Special Appointments: If a protocol submission must be reviewed expeditiously due to grant or other deadlines, and one or more of the IHMC IRB members is unable to contribute (e.g., on travel, indisposed, etc.) the IHMC IRB may temporarily appoint up to two (2) members to provide reviews. Appropriate and available prospective members must be individuals with prior experience in proposing or evaluating research that involves human participants. This may include members of the IRB of the University of West Florida, Pensacola State College or other regional institutions of higher education.

Consultants: The Chairperson may invite consultants to advise the IRB.

Term: Due to training requirements (as described below), all IHMC IRB Members (primary and alternate including the Chair and IRB Administrator) and Analysts must serve a minimum term of two (2) years.

Chairperson: The Chair of the IHMC IRB is nominated by a consensus of the entire IRB with the advice and consent of the Institutional Official and appointed by the IHMC Chief Executive Officer. The nominee must have served actively in a leadership position (Chair, Vice-chair, administrator, compliance officer, etc.) of an IRB or similar human research protections officer position (at IHMC or other human research participants focused organization) for at least two years prior serving as IHMC IRB Chair.

Training: IHMC IRB Members (primary and alternate) and Analyst must complete the IRB Member CITI Program training course in addition to either the Biomedical Research Basic or Social and Behavioral Research course (Basic or Refresher). The IRB Chair and vice-chairs must also complete and keep current the IRB Chair CITI Program training course. The IRB Administrator must also complete and keep current the IRB Administrator CITI Program training course.

Quorum: To ensure a quorum for monthly meetings alternate members can substitute for any absent primary member. A quorum shall be defined as a simple majority of the number of primary members (no fewer than four (4)). Only voting members (primary or alternate) can count toward the quorum.

II.A(2). Meetings

Meetings and Meetings Agenda: IRB business is conducted through in-person meetings that are usually held the Tuesday or Wednesday closest to the 15th day of each month (typically no earlier than the 12th of the month and no later than the 21st of the month). Protocol submissions are due the week before each monthly meeting for review at that meeting. A link to the meeting agenda is attached to the IRB member meeting announcement and discussed at the beginning of the meeting with all members. If any supplemental information is required to review a submitted protocol, it will be sent out electronically prior to the meeting.

Risk Designation: Following federal regulations, protocols deemed not greater than minimal risk (NGMR) that do not fall under one of the eight (8) established Exempt Research categories (Exempt Research Categories) or one (1) of the nine (9) established Expedited Review categories (Expedited Review Categories), and for all greater than minimal risk (GMR) protocols, the submission must be deliberated at a convened meeting by a quorum of IRB members. IRB decisions concerning GMR submissions must be made in a convened IRB meeting that, after exclusion of abstentions, consists of a quorum of voting members. Once the GMR study is presented to the board it will be assigned to at least one (1) primary and at least one (1) secondary voting member reviewer for protocol review. Additional voting members may be assigned or volunteer to serve as additional secondary reviewers.

Attendance: Principal Investigator(s) are invited to attend IHMC IRB meetings in which their protocol will be reviewed to provide additional context and answer questions from board members during submission review (initial or amendment). The IHMC IRB Chairperson can request attendance by ad hoc consultants or individuals who possess special experience or expertise in areas covered by protocols that are to be reviewed. All IHMC staff are invited to attend IRB meetings as non-voting observers.

Approval: During convened board review, the research protocol is presented and discussed. For the research to be approved, a majority of voting members must grant approval. Protocols that undergo convened meeting review (either at initial submission or associated with any modifications that make it no longer eligible for prior Exempt or Expedited research review), must be reviewed by convened board meeting review for all subsequent reviews (including continuing reviews without protocol changes).

II.A(3). Responsibilities and Functions of the IHMC IRB:

Responsibilities:

1. To operate in accordance with established guidelines for the purpose of protecting human participants in research.
2. To review and dispense protocol submissions (initial review, continuing review and amendments).
3. To retain all documentation and correspondence.
4. To cooperate with the IHMC administrators regarding human research protocol preparation.
5. To report on an annual basis to the IHMC leadership.

Minutes: IRB Records - Meeting Minutes:
Meeting minutes are documented through the IHMC currently are hosted via the iMedRIS electronic IRB software system for each meeting. The IRB Administrator or Analyst completes the minutes to include call to order, member attendance, old business, new business (to include discussion of any submitted protocols), motions voted on, and time the meeting is adjourned. Minutes are then routed to the IRB Chair for approval.

IRB Records - Submissions: Initial submissions are assigned a unique protocol number in the format of IRB-YYYY-NNNN as well as a unique six-digit serial number. Each amendment submission shares the same protocol number as the initial submission but is assigned a unique serial number. Once a review cycle has completed, the reviewed version of the protocol cannot be edited and persists in the protocol

submission history. Documents supplanted by later revisions can be archived (and retrieved) by the IRB but not deleted from the persistent record. All protocol submission histories are kept indefinitely.

II.B. Empowerments:

Federal law, as outlined in 45 CFR Part 46, empowers the IRB and grants it decision-making responsibilities, such as:

1. The power to require modifications to research procedures and materials (consent forms, debriefing forms, other materials) to bring the plans into compliance with ethical guidelines and federally mandated requirements.
2. The power to order the suspension of research when there is evidence that there has been misconduct or noncompliance in the treatment of human participants.
3. The power to commence a procedure for reporting apparent misconduct or noncompliance to the federal government (in cases where the research is funded by the federal government).
4. The power to terminate research when there is evidence of misconduct or serious or continuing noncompliance in the treatment of human participants.

II.C. Decision Rule for Protocol Review:

For standard submissions, the IHMC IRB decision to approve a protocol submission must be unanimous of the quorum. (For exceptions, see Section V.) Any concern of any IRB member about a protocol will be addressed by the Principal Investigator, with the support of the IRB. Only after all concerns of all IRB members have been dealt with to the satisfaction of all IRB members can a motion be made to vote on a submitted protocol. Once the motion is proposed and seconded, the IRB Chair will call for a verbal vote of members for approval and then for any disapproval. Votes are counted and documented in the meeting minutes. Any stipulations will be noted along with the vote in the meeting minutes. Also documented is a count of the number of members who abstain from the voting process. Once the vote is complete this constitutes as an authorization of the IRB Chair to note in the official meeting minutes that the protocol is "Approved", "Disapproved (returned for corrections)," or "Approved with stipulations (returned for corrections)."

The IHMC IRB Chair is empowered to designate another IHMC IRB Member to serve as Acting Chair, to be responsible for managing and finalizing the submission review process in such cases as:

(a). The IHMC IRB Chair is a PI, Co-PI or co-investigator on a submission to the IRB and must recuse themselves, or

(b) A submission references technical topics, methods, or other material that entails a need for a specialist Member of the IRB to be appointed Acting Chair.

III. REVIEW GUIDELINES

III.A. Review Focus

The evaluation of protocols is based on an analysis of adherence to government regulations and professional ethical guidelines.

Ethical guidelines that are appropriate to research depend to some extent on the discipline (e.g., guidelines for medical versus psychological versus sociological research). Guidelines for research in social sciences are specified by the American Psychological Association ("Ethical principles in the Conduct of Research with Human Subjects." American Psychological Association, Washington, DC, rev. ed. adopted 2002, went into effect June 1, 2003)

In general, the guidelines provided by disciplinary professional organizations are in accord with the guidelines that are given as specifications in federal law, and vice versa.

IHMC IRB review takes into consideration the scientific merit and considerations of research design and methodology, and the IHMC IRB may offer feedback to PIs on such matters. The pertinent legal guidelines specify that participants must be assured in writing that the research has benefits to science and to society.

The PI and affiliated researchers have the responsibility to use reasonable care to protect the life and the health of participants while the research is being conducted. The PI and affiliated researchers are obligated to familiarize themselves with the pertinent guidelines that are specified by their profession.

In a IHMC IRB review, special attention is given to studies that involve risk to participants, or the appearance of risk, whether the risk is minimal or significant, and whether it is of a psychological or a physiological nature.

There are three (3) main mechanisms that are used to structure the process of assuring adherence to ethical and legal guidelines: (1) the Committee's assessment of the "risk-benefit ratio;" (2) the reliance on consent; and (3) appropriate debriefing forms and methods.

III.B. Scientific Merit

Because of the requirement that participants be assured that the research has scientific merit, the IHMC IRB members are required to consider scientific merit in their reviews of submissions. The IHMC IRB defines scientific merit according to the definition adopted by the National Science Foundation. Review for scientific merit means only that the IRB evaluation ensures that the research has met the general standards of conduct of a particular scientific discipline. Considerations include soundness of methodology and its alignment with the questions posed, the appropriateness of the research design (e.g., sample size), the appropriateness of the tasks that the participants will experience, the potential for the study to answer the research questions posed, the potential to contribute to the exiting body of knowledge, and whether the potential benefits that might outweigh any potential risks.

Some secondary review organizations require a scientific review performed by a senior scientist separate from the IRB reviewing members. In this case, the PI should recruit this independent scientist and provide him or her with the project specific review template acquired from the PIs project program manager.

III.C. Special Consideration on Sampling: The Inclusion of Women and Minorities

Federal law (The NIH Revitalization Act of 1993; FR 59 1450814513) mandates that all research funded by the National Institutes of Health include women and minorities as participants, unless there is a clear and compelling justification for their exclusion based on health issues or the purposes of the research.

III.D. Assessment of Risk-Benefit Ratio

The IHMC procedure for determining the risk of research involving human participants is presented in section VIII B.4. A risk analysis of a study is included in submissions to the IHMC IRB.

Risk is assessed in terms of categories described in the Code of Federal Regulations (45 CFR 46).

No Greater than Minimal Risk (NGMR): A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102[j]).

Greater than Minimal Risk (GMR): A risk is greater than minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. These can include moderate- and high-risk protocols. A designated Medical Monitor is required for all GMR studies. At least one (1) team member with documented current training on Basic Life Support (BLS) and/or Cardiopulmonary Resuscitation (CPR) Automated External Defibrillator (AED) must always be present in the study area when participants are onsite (pre, per and post participation). This documentation must be uploaded under the "other supporting documents" in iMedRIS.

Moderate Risk: GMR studies that include low-to -moderate probability of serious adverse effects that might occur because of participation in a research study.

High Risk: GMR when a moderate-to-high probability of serious adverse effects might occur because of participation in a research study.

- Review involves the assessment of the risk-to-benefit ratio:
- The potential benefits of participating in the study should outweigh the risks,
- As in any study, procedures should be conducted only by qualified persons,
- The protocol should contain provisions for appropriate professional consultation for participants if complications arise because of participation in the research,
- At all times, the privacy and confidentiality of the individual should be safeguarded.

To support the IRB's review of risk, PIs must follow the procedure for Risk Analysis described in Section VIII and complete their Risk x Severity Table in their Submission Form. The Members of the IHMC IRB, and the entire IRB, have the right and responsibility to challenge a risk analysis, or require additional information cases where an adverse outcome might be conceived as having have worse consequences or be more likely than the proposing PI might suggest.

III.E. Medical Monitor

The IHMC IRB will maintain a list of individuals who have agreed to serve as Medical Monitor for IHMC protocols. All Medical Monitors will be required to complete the appropriate Collaborative Institutional Training Initiative (CITI) Program training for human research. IHMC PIs may also nominate other Medical Monitor candidates who must be approved by the IRB prior to assignment to any protocol.

- Candidate Medical Monitors must provide proof of CITI training (completion report) and current curricula vitae.
- Medical Monitors must have a current Florida license as a provider (MD, MBBS, APRN, PA, etc.).

Prior to inclusion in a research protocol, the Medical Monitor must receive a briefing on the study design, goals and participant tasks from the project PI and must affirm (a) the lack of potential conflicts of interest (COI), (b) their availability; and (c) assent to serve.

All GMR protocol research study team personnel who interact directly with participants must have access to the medical monitor contact information (such as office and cell phone numbers and email) and understand the medical monitor role related to the study.

- For **moderate risk GMR**, the Medical Monitor must be available via phone or web teleconference to the research study team executing the protocol for consultation with team members or the participant during participant activities.
- For **high risk GMR**, the Medical Monitor must be in the local area of the participant activities (e.g., in Pensacola, FL, for studies conducted at IHMC's main campus) and be available for

consultation with team members or the participant during participant activities in person or via phone or web teleconference during participant activities.

- For certain types of high risk GMR studies, the IRB may require the Medical Monitor to be present in the research space(s) during participant activities (e.g., to evaluate paraplegic exoskeleton users for latent skin, bone or joint injury before, during and after participation in a study trial).

The research team must coordinate with the Medical Monitor to verify their availability prior to participant arrival. If the Medical Monitor is unavailable for a participant session, the project PI will contact other Medical Monitors on the IRB approved list to identify an alternate Medical Monitor. The project PI will brief the study design, goals and participant tasks to the alternate who must affirm lack of potential COI, availability and assent. The project PI must notify the IRB via email (IRB@ihmc.org) of temporary change related to the change in appointment Medical Monitor. For permanent change of Medical Monitor, the project PI must submit an amendment submission via iMedRIS.

The Medical Monitor is an adjunctive health management position. The project PI is responsible for minimizing potential health risks in the study design and maintaining study team training and protocol compliance. In all cases, should a potential medical emergency arise, study team members should first activate the emergency medical system (EMS) by calling 911.

III.F. Monitoring and Verification

Project Leadership Team: Prior to approval, the project PI has overall responsibility for submission of protocol applications with all supporting documentation to the IRB. Following approval, the project PI has overall responsibility for maintenance of study team training and any required licensures (CITI training, CPR, AED, etc.), adverse event reporting, submission of study modifications and continuing reviews and study team adherence to IRB, DSMP and other cognizant oversight requirements, if applicable.

- For **moderate risk GMR**, at least one (1) member of the project leadership team (PI, Co-PI, Co-I), must be available via phone or web teleconference to the research study team executing the protocol or the participant for consultation during participant activities.
- For **high risk GMR**, at least one (1) member of the project leadership team (PI, Co-PI, Co-I) must be present in Pensacola for studies conducted at IHMC's Pensacola campus and available to the research study team executing the protocol or the participant during participant activities for in person consultation. For remote site locations, at least one (1) member of the project leadership team (PI, Co-PI, Co-I), must be available to the research study team executing the protocol or the participant for consultation via phone or web teleconference during participant activities.
    - **For certain types of high risk GMR studies**, the IRB may require that at least (1) one member of the project leadership team (PI, Co-PI, Co-I) be present in the research space(s) during participant activities to ensure oversight of study team activities.

Institutional Review Board: The IRB is responsible for overseeing the safety of human research participants and has the authority to suspend or terminate human participant research that:

- Is not being conducted in accordance with IRB approved protocols.
- Unexpected serious harm to human participants has occurred.

The IRB may, at its discretion:

- Perform monitoring of studies both for-cause (e.g., alleged noncompliance) and not-for-cause (e.g., random review for quality assurance purposes) in addition to evaluating information received through the initial application, any amendments, annual SCRs, and analyses of interim reports, such as AEs (considering the frequency and nature of AEs reported to-date) and audit reports. For example, the IRBs may choose to undertake extra monitoring for

research which presents greater than minimal risk, or to gauge the progress of recruitment of vulnerable participants, or to follow the research progress on controversial subject matter

Criteria for additional monitoring may include, but is not limited to:

- Complex projects involving unusual levels or types of risk to participants
- Projects conducted by PIs who previously have failed to comply with applicable regulations, institutional or IRB requirements
- Projects where other concerns about possible material changes occurring without IRB approval have been raised (e.g., major changes to the study protocol were made without an amendment)
- Projects involving vulnerable populations
- Complaints received regarding the study
- Multi-site projects where a U-M IRB serves as the sIRB
- One or more of the projects of a single PI in consideration of the experience of the PI or as follow-up to previous reports of complaints, non-compliance, or prior IRB interactions with the individual

Monitoring actions may include, but are not limited to, evaluating study materials (including providing the IRB copies of or access to materials) or any of the additional measures as necessary:

- Signed informed consent documents
- Study files and research records
- Drug dispensing/Research Pharmacy logs
- Participant records
- Lab test procedures, results and raw data
- Observation of study activity (e.g., witnessing the informed consent process)
- Review of study by an outside auditor
- Interviews of study personnel
- Interviews of research participants
- Site visits to research locations
- Monitoring reports/findings
- Independent third-party monitoring reports
- Projects involving vulnerable populations
- Reports by the Data and Safety Monitoring Board (DSMB)

III.G. Certification/Training

Any institution receiving federal funds and conducting human subjects research must conform to the Code of Federal Regulations, which includes policies and procedures described in this IHMC Policy document. Failure to conform puts IHMC at risk of losing all its federal funding. Thus, adherence to the Code of Federal Regulations is very important.

Medical monitors and all researchers who have direct interactions or contact with research participants or interact with participant personally identifiable information (PII) must have a current CITI (Collaborative Institutional Training Initiative) program certification in at least biomedical research and/or social, behavioral research.

The universal resource locator (URL) link to the current two-page CITI Program completion reports for all key support personnel must be included in all submissions to the IHMC IRB. The training expiration date must extend past the anticipated duration of the approval process by at least thirty (30) days. This applies to IHMC personnel as well as any protocol collaborators from outside of IHMC.

Outside collaborators must sign and submit an individual investigator agreement (IIA) if their organization does not have its own IRB. If the outside collaborator has a cognizant IRB, they can provide an IRB authorization agreement (IAA) via hard copy or via SmartIRB.

The CITI Program Training can be taken by going to https://www.citiprogram.org. IHMC has an affiliation with CITI. Researchers must complete either the Biomedical Research Basic/Refresher course (or equivalent) or Social and Behavioral Research Basic/Refresher course (or equivalent), or both. If specific protocols require additional training modules (e.g., blood borne pathogens, laboratory safety, radiation safety), the project PI must ensure that all key study personnel complete the required additional training. It is the responsibility of the PI to make sure all researchers involved in a study have completed all required CITI training.

The CITI Program course consists of several modules, various documents to read (especially the "Belmont Report"), followed by a series of multiple-choice tests. It takes approximately eight (8) hours total to complete all modules. The purpose of the training is to inform researchers of the ethical responsibilities in the conduct of human subject's research.

Upon completion of the training, the CITI Program will email a link to the completion report and completion certificate. All research participants are required to forward their completion report URL link to the IRB Administrator and the Principal Investigator of the study. Requirement for renewal for CITI Program training will be dependent on the training expiration date (usually three (3) years from date of completion).

Additional training beyond that for human research participants alone may be required for specific protocols (e.g., lab safety, CPR, AED). The Project PI should note these requirements in the protocol submission and upload the study team record as a supporting document with the IRB submission.

IV. INFORMED CONSENT AND DEBRIEFING

All IRB protocol submissions must include a consent form and a debriefing form. The purpose is to ensure that participants are aware of their rights and have an opportunity to exercise any such right. Once the protocol submission and associated documents are approved by the IHMC IRB, the consent form will be stamped "approved" and dated at the bottom of each page, along with the expiration date which is relative to the day and month of the initial submission approval in iMedRIS. The consent form with the approved date will serve as the official document for the study. If there are changes to be made to the approved consent form, a modification must be submitted to the IHMC IRB.

IV. An Informed Consent

Informed consent involves a written form that is signed by both the participant and the PI. The form must include:

(a). The phrase "Institute for Human and Machine Cognition," to suggest that the research has been approved or sanctioned.
(b). A general statement of the background of the project and the project objectives.
(c). An explanation of the procedures to be followed and their purposes, identification of any procedures that are experimental, and a description of probable risks attendant to the procedures.
(d). A description of any benefits to the participant or to society at large, that might reasonably be expected.
(e). A description of any reasonably foreseeable risks or stresses or discomforts, and a description of the steps taken to mitigate them.
(f). A description of appropriate alternative methods or treatments, if any, that might be available or advantageous to the participant.
(g). An offer to answer any queries of the participant concerning procedures or other aspects of the project.

(h). An instruction that the participant is free to withdraw consent and to discontinue participation in the project or activity at any time without prejudice, penalty, or loss.
(i). An instruction that, if services or treatment are involved in the setting or context of the project, neither will they be enhanced nor diminished because of the participant's decision to volunteer, withdraw or not to volunteer participation in the project.
(j). An explanation of the procedures to be taken to ensure the confidentiality of the data and information to be derived from the participant. If participants are to be identified by name in any write-up or report, permission for same should be obtained in the Informed Consent Form or otherwise obtained in writing.
(k). A listing of the names of the sponsors of the research and the titles of the funding programs and when required by the sponsor, a statement to the effect that the sponsor may request access to and inspect any of the records concerning the project.
(l). A statement that participation is voluntary.
(m). A statement about alternative choices the participant might have for participation in research.
(n). A statement that the participant may ask the researchers any questions related to the study.
(o). A final statement to the effect: "Your signature below indicates that you have read and understood this consent form and wish to begin participation."

In addition, the study PI should provide participants with the names of all the researcher(s), including titles, affiliations, if not IHMC, addresses, and telephone numbers, and that any of the researchers can be contacted if questions arise concerning the research, including questions about participant rights.

In addition to these general provisions, other provisions pertain, especially to physiological research. PIs are directed to see the Federal Register, Vol. 56, No. 117, page 2807.

A template Consent Form and example Consent Forms are in the Appendix Section.

IV.B. Debriefing

A printed Debriefing Form also is required, especially if the participant intentionally misinformed or withheld information before participating in the research.

The Debriefing Form must include the following:

(a). A full explanation of the nature and purposes of the research and the manipulations that were involved; participant's questions must be answered to their satisfaction.
(b). A description of any benefits accrued by the participant or to society because of participation.
(c). Participants must be given an explicit offer to withdraw their data without prejudice or penalty.
(d). The confidentiality of all data and results is once again assured.
(e). If future research may be compromised by discussion of the procedures and/or results, the participant may be asked to keep their participation confidential,
(f). The PI and IHMC IRB contact information for post participation questions regarding the study or the participants' rights.

Participants who request a copy of the Debriefing form will receive one.

See the Appendix Section for the Debriefing Form template and an example Debriefing Form.

V. PROCEDURES FOR SUBMISSION (INITIAL AND MODIFICATION) AND REVIEW

V.A. Protocol Submission

Initial Submission of a protocol will be completed through the IHMC IRB web portal (iMedRIS) at https://irb.ihmc.us.

All PIs whose projects involve human subjects research (HSR) must complete the IRB review and approval process before the recruitment or testing of any participant. Projects may execute more than one (1) HSR protocol throughout its duration, and protocols may be conducted at more than one (1) location.

- Independent designs: separate protocol submissions are required for each intervention set, if the project requires data collection from different populations executing different interventions and the data will be analyzed independently for each population.
- Between groups or multi-arm designs: if the project requires data collection from different populations executing the same or different interventions, with data analyzed across the population set, it will require a single protocol submission that describes each arm.
- Submissions can be amended to account for minor changes in target population(s) and sample size, interventions and staffing, but changes in risk to participants or hypothesis (es) will require a resubmission.

Step 1. The Principal Investigator submits an initial request.

This consists of a completed IHMC IRB Submission, Consent Form and Debriefing Form. Other supporting documents also are included in the initial submission (letter of support, demographics survey, recruiting material, and other supporting surveys/forms). The initial request typically includes representative examples or illustrations of research materials, as appropriate. See the checklist in the IHMC IRB Submission Form in the Appendix Section. The PI will make the initial determination if the protocol is biomedical or social, behavioral, educational, and/or public policy research of a hybrid study that includes aspects of both (Section "1.1 TYPE OF REVIEW" in the iMedRIS submission form).

In Section "1.2 REVIEW LEVEL", The PI must request a full committee review for NGMR studies that do not fall under any Exempt or Expedited research categories. If the PI indicates their determination and uses the check boxes to indicate to which categories the protocol adheres, the IRB can affirm or refute the PIs Exempt or Expedited research determination. If the IRB affirms, the review process is escalated from Exempt to either Expedited or Convened meeting review. If the IRB refutes, the review process is escalated from Expedited to Convened meeting review.

Step 2. The IHMC IRB screens the submission.

The initial submission undergoes a screening process by the IRB Administrator to ensure its completeness. Subsequently, an analyst is assigned to the submission by the IRB Administrator. The review type, such as full committee, expedited, exempt, etc., is determined and the submission is assigned to an IRB Meeting where it will be discussed (if applicable). Reviewers also are assigned to the submission.

Step 3. The IHMC IRB reviewers conducts its review.

The IHMC IRB has a choice of three actions on a protocol: (1). Approve, (2). Disapprove (returned for corrections), (3). Approve with stipulations (returned for corrections).

"Approval" means that:

(a). Risks are minimized by using procedures that are consistent with sound research design and do not unnecessarily expose participants to risk (whenever possible, procedures that are already being performed, e.g., for diagnostic or treatment purposes).

(b). Risks are reasonable in relation to the anticipated benefits to the participants and the importance of the knowledge that may result (other than long-range applications).

(c). The research includes acceptable procedures for informed consent and debriefing.

(d). Subject recruitment and compensation plan are detailed and specifically include recruitment materials, compensation methods, and limits on who can recruit participants.

For a submission reviewed at a convened meeting to be "Approved," it must be approved by a quorum of voting IHMC IRB primary and/or alternate members.

For Expedited review submissions, both the primary and secondary reviewers assigned to the review must approve the submission.

For Exempt research undergoing limited review, the single reviewer assigned to the protocol will indicate if the IRB provides "Affirmation" or "Refutation" of the PIs determination as to whether the submission meets the requirements for Exempt research.

A decision of "Disapproved" (or "Refutation" for Exempt submissions) will be accompanied by a written statement from the IHMC IRB explaining the reasons for the decision and suggesting potential corrections. A re-submission must undergo the same level of review as the original submission.

A decision of "Approval with modifications/stipulations" requires a written statement from the IHMC IRB outlining the stipulations that must be addressed before research can commence. Since the study has been approved, the primary reviewer evaluates the submitted responses to each stipulation.

In IRB review, judgments concerning the intellectual content, validity or soundness of the research are withheld. However, suggestions are often made concerning, for example, the wording of the experimental materials, suggestions for control groups, methodology, risk mitigation, etc.

The decision of the IHMC IRB is conveyed to the PI. The PI will be given the opportunity to respond to the IRB, including modification and resubmission of the protocol.

IHMC IRB Members must recuse themselves from review of their own protocols including the Chair of the IHMC IRB, who is required to appoint a substitute ad hoc IRB member to act as the Chair for review of their protocol.

Step 4. Approval letter.
Once a protocol has been approved by the IHMC IRB, the IRB will create an approval letter for execution by the IHMC Signatory Authority (or determination letter for Exempt studies) that will be attached to the submission in iMedRIS, which will be sent to the PI. Upon receipt, the PI may initiate the research, unless the study sponsor requires a secondary level of review.

Step 4a. Secondary level of approval. The PI must determine with the study sponsor if the submission requires a secondary level of review (e.g., a Department of Defense Human Research Protection Office (HRPO)). If required, the PI must prepare and submit any required secondary documentation. If a secondary level review is required, PIs may not initiate the research until that sponsor provides approval. Typically, during contracting negotiations, the sponsoring organization informs the PI of this obligation and the specific secondary review requirements. The IRB will assist the PI in responding to requests from the secondary review organization (e.g., for the inclusion of specific terms). However, it is the PI's responsibility to communicate with the secondary review organization and secure its approval. Once the PI receives notification of secondary review approval, they can commence research.

(see section VII Special Considerations in Review, VII.F for more guidance).

Step 5: Follow-Up.
The PI must make available upon request from the IHMC IRB, all research-related records, and must retain all records (data, consent forms, etc.) for a minimum of five (5) years after the conclusion of the research.

V.B. Submitting a modification for an approved protocol:

Some protocols will require slight and relatively straightforward modifications to the materials, tasks, or research design based on research progress. "Minimal change" means any change that would not alter the evaluation regarding the primary ethical criteria of minimal risk, balance of risks with benefits,

respect, beneficence, justice, and participant rights. Most commonly these include typographical errors and changes in project personnel identified in the prior approved submission due to staff turnover. These such modification will be reviewed administratively.

If there are to be greater than minimal changes in materials, tasks, or methods, the PI must include these modifications in the continuing review submission form to be submitted to the IHMC IRB. Note that such a submission will also have to include an updated protocol application revision with changes incorporated (to include personnel changes), consent form, and all other study documents associated with the modifications. As with initial protocol submissions, modifying an approved protocol requires the PI to log into irb.ihmc.us. From the PI's Dashboard, the PI will (a) select the approved protocol that necessitates the modification; and then (b) select the option to create a new modification form. It is the PI's responsibility is to promptly submit protocol modifications to ensure their approval before the modified protocol can be administered.

The PI will select the "study modification form" and then "add new form". The form will include the following fields that will need to be completed:

Type of modification
Description of modification
Rationale of modification
Impact of modification

All personnel changes must be included in modifications (both in the study application revision under "Assign Key Study Personnel (KSP) access to the study" **AND** section 12.0": Qualifications of Key Study Personnel." A revision of the current approved protocol application **must be attached** to the modification form, as well as any new protocol documents that require changes (informed consent, debrief forms, etc.).

For protocols approved under expedited review, subsequent amendments may be reviewed under expedited review only if they do not increase the risk or reduce the benefit to participants and do not include substantial changes to the protocol that would otherwise make them ineligible for expedited review (escalated to convened review).

For protocols initially approved under convened review, amendments will be assigned to convened review. However,

> If the amendment solely involves personnel changes that exclude modifications to the PI/Co-PI, minor typographical corrections, and does not alter the protocol or supporting documents, the IHMC IRB chair may elect to assign the amendment to a protocol approved under convened review for expedited review under 45 CFR 46.110 (b)(1)(ii).

If the prior submission has not expired or closed, the study may continue under the previous (unmodified) protocol; the amended protocol may not be implemented until approved by the IHMC IRB and any sponsor required secondary cognizant review organizations. Upon receipt of the IHMC IRB approval letter by the IHMC IRB, the PI may switch to using the amended methods, unless the sponsor requires a secondary review. It is the PI's responsibility to prepare and submit any required secondary level documentation of the modification. If secondary level review is required, the PI may not initiate the research until the sponsor also provides amendment approval.

VI. SPECIAL CONSIDERATIONS IN INFORMED CONSENT

VI.A. Special Consideration: Alternatives to Requirement to Document Written Informed Consent

Government regulations (45 CFR46 116[f]) permit waivers of the requirement to document Informed Consent under certain circumstances:

(1) The research must be minimal risk,
(2) The waiver will not adversely affect the rights or welfare of the subjects, and
(3) The research could not be carried out without a waiver.

For NGMR research conducted, IHMC allows for web-based electronic consent for exempt and expedited review studies; surveys or questionnaire-based studies conducted at meetings using paper media used oral consent; and implied consent or waiver of informed consent. In all such cases the subjects are still to be informed of their rights as detailed in standard Consent Forms (see Appendix Section). Furthermore, before commencing their participation subjects are to be informed either in writing, on the web site, or by direct communication with the following:

"***Your initiation of this study is taken as an indication that you understand your rights as a research participant and consent to begin participation***."

PIs submitting protocols to the IHMC IRB may select "Provide online 'eConsent' using any E-Signature system" of their choice (as approved by the IHMC IRB) or "Click through a link in a survey or email after reading about the study and then complete the study online (electronic consent)" or " Complete the study activities and turn in materials, as in the case of a completed survey that is placed in a drop box or mailed to the study team (implied consent)" in section: "6.4 CONSENT METHODS" of the iMedRIS submission form.

VI.B. Special Consideration on Consent Forms: Misleading or Incomplete Information

The Institutional Review Board (IRB) of the IHMC can waive certain provisions for Consent Forms if it can document that the research poses no or minimal risk, that the waiver will not negatively impact the rights and well-being of the participants, that the research cannot be conducted without the waiver or alteration, and that participants receive a comprehensive disclosure of the nature and rationale of the waiver during the Debriefing stage.

Waivers are sometimes needed for psychological research in which full awareness, on the part of the participants, of the purposes, goals, and hypotheses of a psychological study might significantly affect the participant's behavior (the "demand characteristics" of psychological research). In such cases, the consent form describes the general nature of the tasks, materials, etc., but withholds information about the underlying purposes and goals of the research or sometimes provides a bogus "cover story" to describe the research.

The true purposes and goals of the research are subsequently explained in the Debriefing. This explanation provides insight into why the withholding of information, or the presentation of misleading information was necessary. Additionally, an offer is made to discard the participant's data if they have any objections to how the procedure was conducted.

VI.C. Special Consideration on Consent Forms: Government-mandated Consent Forms

Some government sponsors require that protocols for human subject's research be reviewed and approved by their own offices (e.g., the Army Human Research Protection Office, the Navy Human Research Protection Program and the Air Force Surgeon General's Office) (see Section III.K, below). These sponsors sometimes require that PIs utilize a Consent Form that follows a particular format and contains certain information, rather than a Consent Form based upon the PIs institutional IRB templates.

The IHMC IRB recognizes this and allows PIs to use a Consent Form that follows the requirements of the government sponsor.

The IHMC IRB is nevertheless obligated to ensure that a Consent Form accompanying a submission to the IHMC IRB conforms to federal regulations by explicitly covering all the informational points that are in the IHMC IRB's Consent Form template (see the Appendix Section).

PIs who are submitting to the IHMC IRB will be required to prepare and submit a Consent Form that adheres to IHMC IRB guidelines and utilizes the template Consent Form even though they may be required by the government sponsor to prepare, submit, and utilize a Consent Form having a format and content dictated by the sponsor.

VI.D. Special Consideration of Informed Consent: The Participation of Vulnerable Individuals

(1) The participation of individuals who are younger than age 18 years of age must have the informed consent of one who is legally responsible for their welfare (FL State law).

(2) The participation of individuals who have been classified as vulnerable (children, the retarded, the emotionally disturbed, etc.) must have the informed consent of one who is legally responsible for their welfare (45 CFR Part 46).

Consent should be obtained in the form of an affirmative agreement of the legal guardian of the individual to participate in a study based on:

(a). An understanding of what they will be expected to do or what will be done to them,
(b). An understanding of the basic purpose of the research,
(c). The opportunity to decide freely whether to participate.

VII. SPECIAL CONSIDERATIONS IN REVIEW

VIIA. Special Consideration in Review: General Submission

Federal funding agencies often require IRB approval of a more general, less specific, protocol to release human research participant funding tranches. The nature of research projects often precludes the development of fully defined and detailed protocols until some portion of the research has been completed. In these cases, PIs may submit for IHMC IRB review, a submission describing the general aims and steps anticipated of the participants. While this submission, should be as detailed as possible (i.e., it should describe a fully powered and logical study with scientific validity that could stand alone as an executable protocol). The IRB may approve the general submission with the caveat that the PI will submit a fully detailed protocol through the amendment process before initiating research with human participants. Once the general protocol is approved the PI can request release of human research related funding from the sponsor.

VII.B. Special Consideration in Review: Exempt Research (Limited Review)

The Code of Federal Regulations (45 CFR Part 46; 32 CFR 219.10; 45 CFR 690) recognizes that certain human subjects research is exempt from the policies that govern IRBs (see 45 CFR Part 46.104).

Under the "Common Rule" revision effective July 2018, PIs are assigned the responsibility of determining whether their proposed study design is exempt research. However, sponsoring agencies (e.g., the Department of Defense) may have additional requirements for documentation of exempt status. Therefore, the IHMC IRB will provide a limited review of a study that a PI has determined to be exempt research. The limited review will be conducted by a designated member of the IHMC IRB, who will either affirm or refute the PI's determination. A letter of affirmation will be provided to the PI with a determination date rather than an approval date. Research may commence on the date of receipt of the determination letter, unless the sponsor requires secondary level review. Refuted exempt submissions will be returned for corrections, either for limited review as exempt or escalation to expedited or convened meeting review process.

For a study to qualify as exempt, it must:

(1). Present NGMR to the participants.
(2). Participant involvement will be limited to only activities described in one or more of the eight established categories of exempt research (Exempt Research Categories).
(3) Not involve vulnerable populations (pregnant women, human fetuses, neonates, prisoners, children).

The designated IRB reviewer will review the details provided in the exempt study submission by the PI and provide affirmation or refutation of the materials presented. If affirmed, the affirmation pertains only to the content provided by the PI in the submission. If the PI desires to amend the exempt protocol, he or she must submit an amended application for limited review before continuing with the amended protocol. The IHMC IRB reviewer must affirm the PI's determination, as must sponsor required secondary review, before the PI begins research under the amended protocol.

It is the policy of the IHMC IRB that exempt research must respect all the rights of research participants and must involve the use of an appropriate Recruiting Statement, Consent Form, and Debriefing Form.

Even for exempt research, all researchers who have direct interaction or contact with research participants must be certified by the CITI Program Training, and their CITI link to completion report must be appended to a submission to the IHMC IRB. (See III.E, above).

While the Code of Federal Regulations recognizes that research involving human participants can be exempt from (full) 46 CFR 45, and that exemptions can be affirmed by the IHMC IRB, some government sponsors (e.g., Department of Defense) reserve the final authority for exempt research determinations for their cognizant secondary level review organizations (e.g., human research protections offices).

VII.C. Special Consideration in Review: Expedited Processing

The criteria that the IHMC IRB employs to determine whether a proposed study qualifies for expedited review are the same as those of the 2018 Common Rule (45 CFR Part 46; 32 CFR 219.101).
For a study to qualify for Expedited review, it must:

(1). Present NGMR to the participants,
(2). Involve only procedures listed in one or more of the nine established Expedited review categories as posted in the Federal Register (expedited review categories),
(3) Not involve classified research with human participants

The PI's submission to the IHMC IRB should indicate all categories that apply to their NGMR research protocol. If the IHMC IRB Chair reviewer agrees that the protocol qualifies for expedited review, the Chair and one other IRB member will conduct an expedited review. The review does not have to coincide with a convened IRB meeting and then final consideration by the IHMC IRB's Signatory Official. The determination that a protocol qualifies for expedited review will be stated in the IRB's approval letter and will include citation of the relevant exemption categories listed in the Federal Register.

VII.D. Special Consideration in Review: Research with no Interaction or Contact with the Research Participants

In some research, IHMC PIs have no direct interaction or contact with the research subjects. An example would be research involving the analysis of personally identifiable data collected by researchers at some other institution.

The IHMC IRB must have assurance that the data were collected using a protocol that was approved by a government certified institutional IRB. Such assurance can take the form of a completed and approved

institutional IRB submission from that other institution. The IHMC requires that all researchers involved in research using human subjects take the required CITI Program Training course(s).

VII.E. Special Consideration in Review: Research Involving a Collaboration of IHMC With Other Institutions

IHMC is a member of SMART IRB (https://smartirb.org), an integrated, comprehensive platform that allows for flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation. SmartIRB allows IRBs to pre-register their willingness to cede to other SmartIRB members while providing protocol oversight at their institution, reducing duplication of effort to create and manage multiple IRB submissions to multiple organizations.

This now allows IHMC to enter into reliance agreements with other institutions (e.g., Florida State University, Ohio State University, University of Florida) and have one reviewing IRB (single IRB) as required by the Department of Health and Human Services for multisite research.

Under single IRB, one organization's IRB acts as the lead (sIRB) and the other(s) cede protocol review to the sIRB. Each agreement can specify what is ceded and sIRB designations are per protocol.

> For example, under the same project, one organization can cede to the other for one protocol, while serving as the sIRB for a different protocol. The IHMC IRB recommends that the PI chose the sIRB for a specific protocol based on which organization will have the most direct contact with the participants or the required to execute the data collection.
>
> If the interactions are equally distributed and no specialized facilities/expertise are required, then the prime awardee organization should serve as the sIRB.

VII.F. Special Consideration in Review: Government Secondary Level Review of IHMC IRB-Approved Studies

Some government sponsors require that protocols for human subject's research be reviewed and approved by their own offices (e.g., the Army Human Research Protection Office, Air Force Research Laboratory Human Research Protections Office) after they have been reviewed and approved by the PI's institutional IRB.

The procedure for government approval of IHMC IRB-approved protocols is for the PI to determine what documentation is required by the government sponsor and the method of transmittal of the required documentation. The PI is responsible for forwarding the IHMC IRB-approved protocol to the government sponsor secondary level review and may not initiate research activities under the IHMC IRB approved protocol until approval is received from the secondary level review organization.

The PI will negotiate with their cognizant government officer to prepare and transmit all requested content. The IHMC IRB Chair and Signatory Official will assist IHMC PIs by completing reviews and IRB board related requests from government offices in a timely manner.

VII.G. Special Consideration in Review: Participants Who Are Minors

Special considerations of federal and state law come into play when and of the participants are minors. PIs of projects that might involve minors as participants should consult the IHMC IRB Chairperson. See the "Consent Form: (Vulnerable Individuals and Minors)."

VII.H. Special Consideration in Review: Research Involving Collection or Analysis of Existing Medical Records.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), effective April 14, 2003, specifies a review procedure for studies that involve the collection and analysis of existing medical record information obtained from a third-party source and the use of medical records for the identification of potential research subjects. PIs must include a separate HIPAA consent form with the submission to access, generate and/or retain medical records and information. PIs must indicate how the HIPAA information will be included in the study (section "11.7-10 HIPAA APPLICABILITY"). The Appendix provides an IHMC HIPPA template.

VIII. ADVERSE EVENT POLICY AND PROCEDURE & REPORTING REQUIREMENTS

Should a serious adverse event (anticipated or unanticipated) occur that results in perceived or measurable instability of the health of a participant the study team should execute the following order of action:

1) Remove the participant from the study task (e.g., move from treadmill to chair), if the symptoms do not immediately resolve then,
2) Provide first aid/CPR/AED and contact 911 for transport to local hospital
3) Notify study leadership (PI, Co-PI, Co-I), if not already in the study area
4) Notify the Medical Monitor, if not already in the study area

Within 48 hours,

5) Complete and submit a serious adverse event report to the study sponsor and the IRB.

VIII.A. Definitions

Most adverse events occurring in human subject research are anticipatable. A small proportion of adverse events are unanticipated problems, and unanticipated problems include other incidents, experiences, and outcomes that are not adverse events.

Unanticipated problems (UAPs), in general, include any incident, experience, or outcome that meets **all** the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.
2. Related or possibly related to participation in the research (in this guidance document, *possibly relate* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

*Adverse event*s (AEs), include any event that meets one of more of the following:

1) Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).
2) Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

3) In the context of multicenter clinical trials, adverse events can be characterized as either *internal adverse events* or *external adverse events*. From the perspective of one particular institution engaged in a multicenter clinical trial, *internal adverse events* are those adverse events experienced by subjects enrolled by the investigator(s) at that institution, whereas *external adverse events* are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial. In the context of a single-center clinical trial, all adverse events would be considered *internal adverse events.*
4) In the case of an *internal adverse event* at a particular institution, an investigator at that institution typically becomes aware of the event directly from the subject, another collaborating investigator at the same institution, or the subject's healthcare provider. In the case of *external adverse events*, the investigators at all participating institutions learn of such events via reports that are distributed by the sponsor or coordinating center of the multicenter clinical trials.

Serious Adverse Events (SAEs) include any untoward medical occurrence during human subjects research that meets one or more of the following:

1. Results in death
2. Is life-threatening, or places the participant at immediate risk of death from the event as it occurred
3. Requires or prolongs hospitalization
4. Results in persistent or significant disability/incapacity
5. May have caused a congenital anomaly/birth defect
6. Requires intervention to prevent permanent impairment or damage
7. Is another condition which investigators judge to represent significant hazards

Much of the research that has been and is likely to be conducted through the IHMC IRB involves the use of standard educational tests, cognitive tests, and interviews. Such studies generally involve minimal risk. Adverse events are generally thought of as being unlikely.

Some minimal risk research, however, involves tasks that require the participant to engage in mentally taxing activities such as vigilance, process control, etc. This can cause stress or fatigue (and such accompanying reactions as eye strain or headaches) that is greater than what is typically experienced in ordinary daily activities. It is anticipated that another possible adverse event in studies involving simulated control of aerial vehicles could be disorientation. However, it is believed that this type of event is unlikely to occur.

Some research involves tasks in which participants will be engaged in the testing of orthotic/prosthetic devices. It is anticipated that possible adverse events from this type or research could range from mild discomfort to physical fatigue, minor physical harm, and even falls.

VIII B. Risk Assessment Methodology

The IHMC procedure for risk assessment adopts certain aspects of the NASA Continuous Risk Management System (Dezfuli, et al., 2007) and the FDA Medical Device Risk Assessment Methodology (2006). While the NASA system involves populating a risk-severity matrix to calculate overall risk levels, the procedure is more complex than is needed for research involving human participants, because of NASA's broad focus on engineering safety. While the FDA process is simpler and still allows for risk calculation, it focuses exclusively on research on medical devices that entail significant risk (i.e. implants). The IHMC Process consists of the following steps:

(1) The PI must list potential adverse outcomes for participants.

(2) For each outcome, the PI is responsible for determining the likelihood of occurrence, using these three (3) categories:

a. "Low" means the outcome might occur for no more than 10% of the participants during the experiment.
b. "Medium" means the outcome might occur for 10% to 20% of the participants.
c. "High" means that the outcome could occur for more than 20% of the participants.

(3) For each outcome, the PI must determine the severity of the consequence using these three (3) categories: low, medium or high severity of consequence.

An example of a low severity event would be mild stress due to mental workload that is induced by performance of the task. Low severity is usually understood as being no different from the sorts of stresses or discomforts that an individual may experience in ordinary daily activities.

An example of high severity would be changes in physiological parameters following a blood draw. High severity is usually characterized as such events as fainting or body injury.

The IHMC IRB receives several health-related IRB submissions. As the IRB reviews these submissions, IRB Members must pay particular attention to the definition of "likelihood" of adverse events and review the protocols very carefully. For example, if an adverse event has very low likelihood but the possible adverse event is high severity, the IHMC IRB would flag that protocol for possible modifications to the protocol or additional requirements.

The members of the IHMC IRB, and the entire IRB, have the right and responsibility to challenge a submitter's rating or request additional information in cases where an adverse outcome might be perceived as having worse consequences or being more likely than the proposer suggests.

VIII.C. Process for Addressing and Reporting Events

Certain events that will trigger a reporting requirement include (a) Safety-Related Event, (b) Nonserious Adverse Events (AEs), (c) Serious Adverse Events SAEs and (d) Unanticipated Problems (UPs). Minor anticipated problems, as outlined in the protocol's risks and mitigations section and disclosed to participants in the consent form (such as mild nausea and headaches from wearing virtual reality headsets), should be logged by the PI but do not constitute an event for reporting purposes.

The IHMC IRB reporting procedure for a Safety-Related Event is as follows:

If an event occurs that suggests there may be a safety issue, including casual observations on the part of the PI, or staff acting at the direction of the PI, or research Participants, then the PI shall proceed as follows:

1) The PI will describe the safety issue in detail in the safety-related event report form (see the Appendix Section for a sample form) that is submitted to the IHMC IRB.
2) If the safety issue can be mitigated immediately, easily or in an ad hoc manner by the PI, the PI will mitigate or direct the issue to be mitigated immediately.
3) If the safety issue cannot be mitigated easily or in an ad hoc manner by the PI or at the direction of the PI then the study must be postponed, based on the PI's report, and report the safety-related event to the IHMC IRB.
4) If the safety issue arises in such a way as to trigger an Adverse Event, then the Adverse Event procedure, detailed below, will also be followed.

The IHMC IRB reporting procedure for Nonserious Adverse Events in NGMR Research are as follows:

The potential for stress or fatigue events is described in detail in the Submission Form provided by the IHMC IRB, including the anticipated nature of the stress or fatigue and the research design features that would induce the stress or fatigue and may require the PI to report the event to the IRB:

1) If the stress or fatigue experienced by a participant is greater than that typically experienced by study participants, or
2) If a Participant asserts that they have begun to feel too stressed or uncomfortable, including ways not causally related to the experimental protocol, then,
3) Their participation will be terminated, and
4) They will be allowed a sufficient period to rest and/or recover, and
5) The PI will engage in a full and open discussion with the Participant, while documenting the Participant's comments in detail and assuring the Participant that the discontinuation will in no way be punitive.

The PI must submit an adverse event report form through iMedRIS to the IHMC IRB. The IHMC IRB will review the report, to determine if the occurrence is likely to repeat, given the nature of the experimental protocol, and, if appropriate, require the PI to institute changes to the protocol to mitigate against reoccurrence, including the possibility of discontinuing the study.

It is the responsibility of the PI to (a) follow-up with the Participant, as appropriate to the nature and extent of the adverse reaction; and (b) submit to the sponsor of the study all documentation, including adverse event reports, including any NGMR research study for which adverse events induced the IHMC IRB to discontinue approval.

The IHMC IRB reporting procedure for Adverse Events in GMR Research are as follows:

If any Participant experiences physical harm, ranging from minor physical harm to falling, then the PI shall:

1) Cease the Participant's activity in the study and allow the Participant to rest and recover, as needed.
2) Take immediate steps to deal with the physical harm (if any).
3) The PI will engage in a full and open discussion with the Participant, while documenting the Participant's comments in detail.
4) The PI will submit an Adverse Event Report Form through iMedRIS to the IHMC IRB.
5) The IHMC IRB will review the report, to determine if the occurrence is likely to repeat, given the nature of the experimental protocol, and if determined then require the PI to institute appropriate changes to the protocol to mitigate against reoccurrence, including the possibility of discontinuing the study.

It is the responsibility of the PI to (a) follow-up with the Participant, as appropriate to the nature and extent of the adverse reaction; and (b) submit to the sponsor of the study all documentation in a timely manner, including adverse event reports, and potential mitigations on any study adverse events in GMR research including protocols discontinued on the authority of the IHMC IRB.

VIII. D. References

Dezfuli, H., Youngblood, R., & Reinert, J. (2007). Managing risk within a decision analysis framework. In Proceedings of the Second IAASS Conference. Amsterdam, The Netherlands: International Association for the Advancement of Space Safety. [http://www.congrex.nl/07a02/]

Food and Drug Administration (2006). "Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors." Good Clinical Practice Program, HF-34, Office of Science & Health Coordination, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD [http://www.fda.gov/oc/gcp/guidance.htm].

DATA MANAGEMENT POLICY

Exemptions from full IRB review do not hold for research that involves the recording of information that would allow the identification of individuals or disclosure of information about individuals. IHMC research record keeping must avoid the recording of information that would allow the identification of individuals or make possible the disclosure of information about individuals. Thus, signed Consent Forms are to be archived separately from data or results for no less than five (5) years. Participants are to be identified in the data archive solely by some form of identification number. Research that requires the identification of individuals must be given special consideration by the IHMC IRB.

IHMC policy is that data from research participants will be stored in a way that maintains the anonymity of the participants, and is durable and physically or electronically secure, for no fewer than five (5) years, in forms and formats appropriate to the nature of the data, which is the responsibility of the PI. PIs are required to follow the data storage policies of IHMC. Questions concerning the IHMC Policy on Data Management should be referred to the IHMC Chief Security Officer.

CONTINUING REVIEW SUBMISSIONS

All research protocols (including Exempt, Expedited and Convened Meeting reviews) must be reviewed at least annually, typically 12 months from the specified Approval Date indicated on the IHMC IRB Approval Letter. It is the IRB Chair's responsibility to determine if any protocol submissions require IRB review more frequently than annually. If this is determined during the review process, the PI will be notified, and it will be documented in the approval letter provided to the PI. In some cases, such as multiyear projects, PIs need to extend protocols to continue beyond the initial expiration date. It is in consideration of this that the IHMC IRB has a procedure for submission, review and approval of continuing review (CR) of an approved protocol. CRs may contain no changes from the prior approved protocol and supporting documents, but the PI must still create a revision and attach to the iMedRIS CR form of at least the protocol application and the consent form, for tracking and stamping.

It is also common for CRs to involve some modifications, and the PI may include amendments via the iMedRIS CR form as per Section.

All submissions proposing a continuation of research will consist of a completed IHMC IRB Continuing Review Submission Form in iMedRIS. This form should be submitted at least thirty (30) days prior to expiration date. Amendments that must be reviewed more than ninety (90) days from protocol expiration should be submitted as a separate protocol amendment, in advance of the CR.

If the original submission received expedited review, then a CR having minimal changes can also receive expedited review.

If the initial review of the protocol was conducted as a convened meeting review, then the CR will also be assigned for convened meeting review.

The IHMC IRB chair may elect to assign an CR to a protocol approved under convened review to expedited review under Expedited review Category 8, if the remaining activities meet one or more of the following criteria:

1) The research is permanently closed to the enrollment of new subjects AND all subjects have completed all research-related interventions AND the research remains active only for long-term follow-up of subjects, or
2) Where no subjects have been enrolled and no additional risks have been identified, or
3) Where the remaining research activities are limited to data analysis.

The IRB Chair is responsible for determining any protocol that would require verification from outside sources (other than the PI) that no material changes have occurred since the initial or subsequent IRB review of the protocol. If this is determined to be a requirement for any protocol it will be noted in the approval letter provided to the PI.

IX. DISCLOSURE POLICY

Federal requirements mandate the disclosure to research participants, in the Consent Form stage of a study, any information that might be perceived or interpreted as reflecting a conflict of interest.

1) The Consent Form in all IHMC research involving human participants will indicate whether each funded partner's or partnering organization's contribution is for profit or not-for-profit.
2) The Consent Form in all IHMC research involving human participants will inform the Participants of their rights to information concerning the identity of the funding source.
3) The Consent Form in all IHMC research involving human participants will identify the funding source.

An exception to item (3) above will be considered when the sponsor has specific requirements or restrictions concerning nondisclosure of the funding source in correspondence or research activities. In such cases the Consent Form may specify the sponsor's parent organization (e.g., U.S. Department of Defense for a study sponsored by the U.S. Special Operations Command) as specified in the source's contract or grant with IHMC, provided that the Consent Form states the sponsor's restrictions. The "U.S. Government" may not be used in lieu of the direct sponsor or that sponsor's parent command or department.

PIs should be aware that a Participant has the right to refuse to participate if a funding disclosure is not forthcoming.

X. Not-Human Subjects Research (NHSR) Limited Review

Some research and development activities that require involvement of humans may not be considered human subjects research (HSR). For example, PIs developing a wearable exoskeleton need to evaluate the performance of a design, mechanical component or software. A person must wear the exoskeleton during the evaluation. This could represent either HSR or Not-Human Subjects Research (NHSR) depending on the goals of the activity. If the task limits evaluation to the device function or performance, it is likely NHSR; if the activity includes assessment of the performance or other subjective or objective evaluation of the human operator when using the exoskeleton, it is likely HSR.

Under the "Common Rule" revision effective July 2018, PIs are assigned the responsibility of determining whether their proposed study design is research and if so, if the research is human subjects research (HSR) However, sponsoring agencies (e.g., the Department of Defense) may have additional requirements for documentation of NHSR determination. Therefore, the IHMC IRB will provide a limited review of activities that a PI has determined to be NHSR research. The PI will complete the IHMC IRB NHSR worksheet (see Appendix) to describe the proposed effort and indicate their determination. The project PI may also provide additional information to the IRB. The IRB will provide a limited review conducted by a designated member of the IHMC IRB, who will either affirm or refute the PI's determination. A letter of affirmation will be provided to the PI with a determination date rather than an approval date. The described activity may commence on the date of receipt of the determination letter, unless the sponsor requires secondary level review. Refuted NHSR submissions will be returned for corrections, either for re-review as NHSR or escalation to an HSR review process. For an activity to be considered research, it must:

(a). Represent a systematic investigation (research, development, testing or evaluation) with designed activities (e.g., they are intentional) that employ accepted scientific method(s).
(b). The goal is to develop or contribute to generalizable knowledge.
(c). The activities are not exclusively comprised of one or more of the following:

i. Scholarly and journalistic activities.
ii. Public health surveillance activities.
iii. Collection and analysis of information biospecimens or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
iv. Authorized operational activities (as determined by each agency) in support of intelligence homeland security defense or other national security missions.

For the research to be NHSR, the following conditions must be met:
(a). The subjects of the research are living people and/or the study is about living people, and,

i. The investigator obtains information or biospecimens, through intervention or interaction with the individual and use, study, or analyze the information or biospecimens, and/or
ii. The investigator will obtain, use, study, analyze or generate identifiable private information or identifiable biospecimens.

The designated IRB reviewer will review the PI provided the NHSR worksheet and any additional information provided by the PI and provide affirmation or refutation of the PIs determination based on the materials presented. If affirmed, the affirmation pertains to the content provided in the submission. If the PI desires to amend the effort, he or she must submit an amended worksheet for limited review before continuing with the new activities. The IHMC IRB reviewer must affirm the PI's determination, as must sponsor required secondary review, before the PI begins research.

Appendix A

Template Recruiting Statement

Greetings,
My name is: _____. Our team from the Florida Institute for Human and Machine Cognition (IHMC) is inviting you to participate in a research study.

The study is sponsored by: provide name of the sponsor

The title of this study is: provide study title

Provide a brief description/background of the study.

The study will be conducted at: provide a description/summary of where the study will be conducted, and any other important information associated with how the study will be conducted (where to park, where to check in, etc.)

Your participation in this study will involve: provide information about what the participants will need to complete the study, to include any type of written or hands-on testing, the time required for participants to complete the study, and how many visits are required for the participants, and if anything is required before the first visit.

The risks to you as a participant: provide risks to the participants.

The results of this study may be published in scientific research journals or presented at professional conferences. However, your name and identity will not be revealed and the data we collect from you will be coded only with your identification number.

Participation in this study may benefit you by serving as an opportunity to experience novel HMIs and learn about human factors evaluation methods.

Your participation will benefit our research program by helping us understand more about the performance effects of new methods of providing information to users of future human-machine team operational concepts.

You can choose not to participate. Your participation is voluntary. Your participation will have no influence on anything that falls outside of this research context. A decision to not participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time and for any reason. If you do decide to participate, you may withdraw from this study at any time and for any reason.

If you have questions about this research study or questions about your rights as a research participant, you can call Meredith Yeager at (850) 202-4462, Administrator of the IHMC Institutional Review Board.

Do you have any questions for me at this time?
Would you be interested in participating? There are a couple of options here;

- you can provide a sign-up sheet if you are recruiting before a large group and after the recruiting brief interested people can sign their info on the sign-up sheet; the investigator collects after everyone is complete with sign-up

- you can send a copy of the consent form to anyone interested in participating
- you can provide a POC (name, email and IHMC phone number) to interested people

Thank you for your time.

Appendix B

Template Consent Form: <*Research Project Title*>

All researchers who conduct studies using human Participants are bound by professional ethical standards for the conduct of such research. These standards are mirrored in the rights that are guaranteed to research Participants by federal law (NIH regulation 45-CFR-46). The purpose of this document is to inform you of these rights and obtain your assurance that you have been made aware of your rights.

1). Before deciding whether to participate, it is your right to be presented with an overview of the project that explains the purposes of the research.

Research Overview
The overall objective of this research is ... In this study, you will be asked to (*high level summary*) *1.* *2.* *3.* *...* All test activities will be led by trained, qualified research staff.

2). Before deciding whether to participate, it is your right to be presented with a description of the general research approach and methodology.

Our study relies on the following method(s);
Identify:

1. *Organizations involved in the study (i.e., IHMC and any collaborating organizations/personnel)*
2. *Location, time(s) and duration of participation*
3. *Stepwise enumeration of the specific tasks required of the participant for preparation and execution of the protocol and total time for by step and in total (and per session for multi-session protocols). You may want to include a participation timeline diagram for more complex protocols*
4. *Please use commonly used within your participant population rather than technical terminology where possible (e.g., for protocols that require blood sampling, describe collection amounts in number of teaspoons in addition to number of milliliters)*

3). Before deciding to participate, it is your right to understand any risks or stresses that may be involved in your participation.

Enumerate any protocol specific risks by name and include a short paragraph describing the risk (e.g., any stress, however minimal, due to mental workload, discomforts, risks, embarrassments, ill effects, inconveniences, etc.). If the study entails no physical risks, say so. If the study involves no deception, say so. If it does involve deception, special material will have to be included in a debriefing form. For each risk, indicate if it has high, medium or low likelihood of occurrence.

POTENTIAL RISKS

Loss of Confidentiality (low likelihood): Participant demographic information (PII) will be documented for the study and could be accessed by unauthorized persons.

For every risk enumerated above, provide a short paragraph describing how each will be mitigated in the protocol design.

RISK MITIGATIONS

Loss of Confidentiality: All of your data will only be recorded with your assigned randomly generated identification number, and no connection to your personally identifiable information will be generated or maintained. The data will be stored only on limited access, password protected servers.

For research involving more than minimal risk, include an explanation as to whether there will be any compensation for harm, and an explanation as to whether any medical treatments will be provided if injury occurs and, if so, what they consist of, who will pay for these treatments, and where further information may be obtained.

4). Before deciding to participate, it is your right to understand any alternative experiences or courses of action.

Include the following statement:
"Your participation is completely voluntary."

Government instructions refer to informing "subjects" about "alternative treatments." This reflects options related to medical device, treatment, drug, etc., studies and does not apply to most psychosocial and behavioral research; you may include the following statement, as appropriate: "The alternative course of action is to not participate."

If participants will receive course credit, you may include a statement such as the following:
"You participant are free to decide to not participate in this study and instead participate in some other course approved activity, as defined by your instructor."

5). Before deciding to participate, it is your right to understand how you might benefit from your participation in this study.

Enumerate specific benefits that can be expected for participation. For many studies, participants gain no direct benefit, but may receive abstract benefits. You may state: Participating in this study will not directly benefit you other than gaining an understanding of the process of human participants research.

6). Before deciding to participate, it is your right to understand that the data are to be kept confidential.

All data will be coded and kept confidential in a de-identified format. Specifically, the data we collect from you will be archived in terms of identification codes, such that your name will not be associated with particular data or statements.

The names of individual Participants will not be identified in any analyses, reports, or write-ups of the results. Participants may only be identified in terms of their general characteristics (e.g., age, education level, experience, etc.).

Data may be submitted to forms of statistical analysis. Data analyses, groupings, or summaries of this type will bear no annotations that identify the Participants.

Most federally funded research requires data sharing. If this project if federally funded, please add the following language:

Once de-identified, the data collected in this protocol may be shared with other researchers or re-analyzed under future research protocols. De-identified data may be used for replication of current project analyses, analyzed to test new hypotheses, and made publicly available on data sharing sites that meet requirements for federally-funded research.

Most Department of Defense (and some other) funded research requires additional review and oversight of human research by Human Research Protections Offices (HRPOs) or Offices of Human Research Oversight (OHRO). If this project requires additional funded, please add the following statement:

The U.S. <*Department of Defense*> and their personnel responsible for the protection of human subjects will have access to research records to ensure protection of research participants. Authorized representatives from the <*Sponsor-specific Human Research Protection Program*> may review and/or obtain identifiable information related to your participation in this research study as part of their responsibility to protect human research participant volunteers. Information related to individual participant health, cases of injury and reports of non-compliance will be reported to <*Sponsor-specific Human Research Protection Program*>.

OPTION, *for use as appropriate*

I understand that the researchers may want to use a short portion of any photographic, video or audio recording for illustrative reasons in presentations of this work in the classroom or at professional meetings. Please initial the appropriate line below the indicate if you agree with the following statement: I give my permission to do so provided that my identity (name, face, etc.) is not revealed.

No (do not use) _____ Yes (you may use my photo, video, audio) _____

7). Your participation is voluntary. Your participation will have no influence on anything that falls outside of this research context. A decision to not participate will involve no penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time and for any reason.

8). Before deciding to participate, it is your right to understand that *DURING* the research itself you can continue to exercise your rights.

In research of this kind, there are no "right" or "wrong" answers. There is no such thing as "incorrect" behavior. You are encouraged to simply be yourself and exercise your knowledge and skills as appropriate to the research tasks that you will be asked to perform.

You can ask any questions you may have, at any time.

It is your right to discontinue your participation at any time. You may do so for any reason, and you are not required to disclose your reason. Should you choose to discontinue your participation, this will not in any way affect or influence anything outside off this research context.

9). Whom to contact for answers to pertinent questions about the research and participants' rights, and whom to contact in case of a research-related injury

For questions about the research or if there is a research related injury, please contact <*Project PI Name*> at <*Project PI email*> or by phone at <*Project PI Phone Number*>. For questions about subject rights please contact <*Choose one IRB official who is not affiliated with this study: Anil Raj, Jeremy McAdam, Meredith Yeager, Chair/Vice-chair*> of the IHMC IRB, at <*IRB Officer*>@ihmc.org or by phone at (850) 202-4462 <*Use Main IHMC Phone Number*>.

10). Before deciding to participate, it is your right to understand that *AFTER* the research itself you can continue to exercise your rights.

Your performance at the research tasks will not in any way affect or influence anything that falls outside of this research context.
Should you choose to discontinue your participation, this will not in any way affect or influence anything outside of this research context.
Once your participation is over, it is your right to request that all data you have provided be discarded. You may do so for any reason, and you are not required to disclose your reason. This will not in any way affect or influence anything that falls outside of this research context
It is your right to be given a copy of this Consent Form to keep.

11). (For use when appropriate.) Before deciding to participate, it is your right to understand the way in which you will be compensated.

Please include a short. Paragraph describing the nature of the compensation. Describe if the compensation is to be monetary (cash, gift card, EFT, etc.) or non-monetary (challenge coin, course credit, none, etc.) Receipt of the compensation cannot be dependent on the participant's performance. That is, compensation cannot be withheld if the participant fails to follow instructions, fails to cooperate, does not complete the study, etc.

12). Before deciding to participate, it is your right to understand the sponsorship of this research.

This study is sponsored by <*Name of Sponsor*>, a <*federal/public agency/private not-for-profit foundation, etc.*>, which is supporting the costs of conducting the research < *through award, contract, etc.*> to <*Prime Contractor Name, if not IHMC, and*> IHMC. To ensure that this research conforms to federal regulations, including regulations on the protection of the rights of research participants, officials of <*Name of Sponsor*> and its Human Research Office may inspect records from this research for purposes of regulatory oversight.

13). (For use when appropriate.) Before deciding to participate, it is your right to understand the interests of the researcher(s).

A typical situation will be one in which IHMC and/or the PI are being funded by a sponsor of this research but will not have a significant financial interest in the sponsor. Only in cases where there might be a conflict of interest, or the appearance of a conflict of interest, should there be an explicit entry for this Item. Select and adapt, as appropriate:

Both IHMC and <*Project PI Name*>, the investigator conducting this study sponsored by <*Name of Sponsor*>, have a significant financial interest in the sponsoring company.

or

<*Project PI Name*>, the investigator conducting this study, has a significant financial interest in <*Name of Sponsor*>, the company sponsoring this study.

or

IHMC has a significant financial interest in <*Name of Sponsor*>, the company sponsoring this study.

or

Neither IHMC, nor <*Project PI Name*>, will receive any financial benefit based on the results of the study.

If you have any questions now, please feel free to ask them.

Your signature below indicates only that you have read and understood this Consent Form and wish to initiate participation.

Participant's Signature	
Researcher's Signature	
Date	

Principal Investigator's full name, address, and contact information (recommend using the main IHMC number)	

Appendix C

Example Consent Form

Consent Form: *Psychometric Evaluation of the Cognitive Assessment of Aviation Performance and Evaluation of State.*

All researchers who conduct studies using human participants are bound by professional ethical standards for the conduct of such research. These standards are mirrored in the rights that are guaranteed to research participants by federal law DHHS regulation 45-CFR-46. The purpose of this document is to inform you of these rights and obtain your assurance that you have been made aware of your rights.

Research Overview
The United States Air Force School of Aviation Medicine developed the Cognitive Assessment of Aviation Performance and Evaluation of States (CAAPES) previously known as the Performance Assessment Tool (PAT) to provide a common aviation relevant psychometric tool to document the performance effects of common environmental stress states known to be associated with military aviation such as hypoxia, fatigue, dehydration, heat stress, and high-G exposures. Currently it is difficult to associate cognitive and psychomotor effects with different phases of a high-G profile. Most cognitive and psychomotor tasks require a minimum of one to two minutes to accumulate enough stimulus-response trials for the measure to perform in a psychometrically reliable way to detect performance effects. CAAPES-HCE will fill these capability gaps by adding an expansion package developed specifically for high-G centrifuge research and training. The new expansion will capture tracking performance in psychometrically stable epochs from two to ten seconds in length. Tracking epoch duration will be adjustable through the graphical user interface to accommodate a wide variety of high-G profiles. Visual design elements will be added into CAAPES-HCE that demonstrate the effect of high-G exposures on color vision, for instance, color features will be added that will disappear to the occupant at high-G loads. A 'Seek and Destroy Mode' will be added to CAAPES that will require the participant to lock the tracking crosshairs on the green tracking circle and pull the trigger to destroy it. The current study is not an inferential effort, but a simple psychometric evaluation of an existing tool following a new round of updates to the system. The metric that is being established is the test-retest reliability of the CAAPES across the overall score and the four subtask scores (Tracking, Math, Manikin, and Memory). The primary objective of this effort is to re-establish the test-retest reliability of the primary CAAPES metrics. The secondary objective of this effort is to get anecdotal information about CAAPES gameplay, setup, and data generation.

1) Before deciding whether to participate, it is your right to be presented with an overview of the experiment that explains the purposes of the research.

2) Before deciding whether to participate, it is your right to be presented with a description of the general research approach and methodology.

You will be asked to travel to the Florida Institute for Human and Machine Cognition in Pensacola, FL, to participate in the study. Once provided informed consent, the study staff will first walk you through the instructions for the four major components of CAAPES. After instructions on the task are described, you will play through ten, two-minute iterations of CAAPES as a practice session. During this time, you will be allowed to pause gameplay to ask questions. All practice sessions will be completed in practice mode with the difficulty levels changing throughout gameplay. After practicing CAAPES through ten complete two-minute iterations you will be asked to wait thirty minutes before continuing to the second phase of the study.

During the second phase of the study, you will play one, two-minute iteration of CAAPES every ten minutes until completing ten additional sessions. This will be completed in the Assessment mode, which locks in your ideal testing level across CAAPES subtasks and instruction screens are not provided.

After completing the tenth session of CAAPES in session two, you will be debriefed about the reason for the study and allowed to ask any questions you might have. You will then be asked to provide feedback regarding CAAPES game play and engagement. Total participation time will require an estimated 2.5 hours.

3) Before deciding to participate, it is your right to understand any risks or stresses that may occur during your participation.

There is no risk to the participants in this study except for the possibility of a data breech and others seeing their performance on a psychometric task.

Short paragraph describing how the risks, stresses, etc. will be mitigated.

The only tangible risk to the participants in this effort is the loss of confidentiality of the data and that an individual's psychometric data is associated with their name.

To ensure all participant data is kept confidential, participants will be identified by a randomly generated participant ID that will be used to track their CAAPES performance data. Participant names will only be linked with participant ID numbers on one physical list to be kept locked away from research staff. Roughly one month following data collection the list linking participant IDs with their names will be destroyed and the data will officially be de-identified.

4) Before deciding to participate, it is your right to understand any alternative experiences or courses of action.

Your participation is completely voluntary and will not affect anything outside of our research. The alternative to participation is to not participate.

5) Before deciding to participate, it is your right to understand how you might benefit from your participation in this study.

If you choose to participate, you will not receive any direct benefit associated with this study.

By participating, you will be contributing valuable information that can help assess and achieve CAAPES test-retest reliability of tracking performance and psychometric stability of measuring performance. Your involvement could potentially assist in creating a tool to better measure performance in future aviators.

6) Before deciding to participate, it is your right to understand that the data will be kept confidential.

All data will be coded, specifically, the data we collect from you will be archived in terms of identification codes, such that your name will not be associated with your CAAPES scores, or any other data. A master list will be kept that links your name to your participant number and will be encrypted and saved on a password protected folder. The MS Word256 bit Advance Encryption Standard will be used to encrypt the master list. The investigator and co-investigator will assign each participant a random participant code. Only the investigator and co-investigator will have access to the list that links your name to your participant number. One month following completion of data collection, the master list linking your identity to your subject number will be destroyed.The names of individual participants will not be identified in any analyses, reports, or write-ups of the results. Participants may only be identified in terms of their general characteristics (e.g., age, education level, experience, etc.). The data may be used by other researchers for additional statistical analysis. Data analyses, groupings, or summaries of this type will bear no annotations to identify the participants. The US Department of Defense id providing support for this research. The U.S. Department of Defense and DoD personnel responsible for the protection of human subjects will have access to research records to ensure protection of research participants.

OPTION, for use as appropriate:

I understand that the researchers may request to take pictures or video of me during my participation. If pictures or video recordings are made, I understand that they will only be used in presentations or conferences to illustrate the study setup, or for educational or promotional material to illustrate the kind of work that is performed at IHMC and will not be used for scientific purposes. I give my permission to do so provided that my identity (face, name, etc.) is not revealed.

Please circle and initial next to one of the following:

YES NO

7) Your participation is voluntary. Your participation will have no influence on anything that falls outside of this research context. A decision to not participate will involve no

penalty or loss of benefits to which you are otherwise entitled, and you may discontinue participation at any time and for any reason.

8) Before deciding to participate, it is your right to understand that DURING the research itself you can continue to exercise your rights.

In research of this kind, there are no "right" or "wrong" answers. There is no such thing as "incorrect" behavior. You are encouraged to simply be yourself and exercise your knowledge and skills as appropriate to the research tasks that you will be asked to perform.
You can ask any questions that you may have, at any time.
It is your right to discontinue your participation at any time. You may do so for any reason, and you are not required to disclose your reason. Should you choose to discontinue your participation, this will not in any way affect or influence anything outside of this research context.

9) Whom to contact for answers to pertinent questions about the research and participants' rights, and whom to contact in case of a research related injury.

For questions about the research or if there is research related injury, please call Dr. Jeffery Phillips at (205)239-6148 or email him at jphillips@ihmc.org. For questions about subject rights please contact Anil Raj (850)-452-4462 or by email at araj@ihmc.org.

10) Before deciding to participate, it is your right to understand that AFTER the research itself you can continue to exercise your rights.

Your performance on the research tasks will not in any way affect or influence anything that falls outside of this research context.
Should you choose to discontinue your participation, this will not in any way affect or influence anything outside of this research context.
Once your participation is over, it is your right to request that all the data you have provided is discarded. You may do so for any reason, and you are not required to disclose your reason. This will not in any way affect or influence anything that falls outside of this research context.
It is your right to be given a copy of this consent form to keep.

11) Before deciding to participate, it is your right to understand the way in which you will be compensated.

There will be no financial compensation associated with participation in this study.

12) Before deciding to participate, it is your right to understand the sponsorship of this research.

.

This study is funded by The United States Air Force School of Aviation Medicine (USAFSAM)

13) Before you participate it is your right to know how you will be treated medically if you are injured while taking part in this study.

This study is no greater than minimal risk, so there should be no risk of injury associated with participation. However, if a medical emergency arises, participants will be treated using common emergency medical services through 911.

14) Before deciding to participate, it is your right to understand the interests of the researcher(s).

Neither IHMC, nor Dr. Phillips will receive any financial benefit based on the results of the study. If you have any questions now, please feel free to ask them.

Participant's Signature

_____

Researcher's Signature

_____

Date

Your signature below indicates only that you have read and understood this consent form.

Jeffery B. Phillips

Senior Research Scientist

Florida Institute for Human and Machine Cognition

40 S. Alcaniz Street

Pensacola, FL, 32502

Appendix D

Example Debriefing Form

Debrief
Document

"Effects of Exogenous Ketone Esters on Acid Base Homeostasis and Operator Ventilation in Tactical Aviation"

The goal of this research project was to assess the effects of EKB consumption on carbon dioxide metabolism and respiration. As a part of this study, we collected your blood and expired air and monitored them for ketone, carbon dioxide, and oxygen levels, pH, and respiration volumes. It is your right to request that all data you have provided be discarded. You may do so for any reason, and you are not required to disclose your reason. This will not in any way affect or influence anything that falls outside of this research context. You will not be identified by name in any analyses, reports or write-ups of the results. You will only be identified in terms of your general characteristics related to this study (eg. age, sex, etc). Data may be submitted to forms of statistical analysis. Data analysis, groupings, or summaries of this type will bear no annotations that identify you. If you have any questions or concerns, or any other issues you feel are related to the study, please contact:

Dr. David Morris

Institute for Human and Machine Cognition 40
S. Alcaniz St.

Pensacola, FL 32502
dmorris@ihmc.org
251-391-0358

Dr. Anil Raj, IRB Chair araj@ihmc.org

850-202-4462

Appendix E

Example HIPPA Release Form

Authorization for Research Use of Protected Health Information
Protocol Title:

Principal Investigator:
Project Number:

The Federal Health Insurance Portability and Accountability Act (HIPAA) includes a Privacy Rule that gives special safeguards to Protected Health Information (PHI) that is identifiable, in other words, can be directly linked to you (for example, your name, Social Security Number, birth date, etc.). We are required to advise you how your PHI will be used.

1. **What information will be collected?**

Study specific data related to participant responses to the administration of the protocol tasks and treatment will be collected. In addition, PHI to be collected as part of the study includes:

2. **Who may use my PHI within the Military Healthcare System?**

The members of the Florida Institute for Human and Machine Cognition (IHMC) research team will have access to your health information in order to determine if you qualify to participate in this study, *to administer research treatments, to monitor your progress,* and to analyze the research data. Participating military physical medicine and rehabilitation staff will also have access to this data. Additionally, your PHI may be made available to health oversight groups such as the IHMC Institutional Review Board (IRB).

3. **What persons outside of the Military Healthcare System who are under the HIPAA requirements will receive my PHI?**

The members of the research team will have access to your health information in order to determine if you qualify to participate in this study, to administer research treatments, to monitor your progress, and to analyze the research data. Additionally, your PHI may be made available to health oversight groups such as the Human Research Protections Office Department and the Institutional Review Board to ensure your rights are being protected.

4. **What is the purpose for using or disclosing my Protected Health Information (PHI)?**

The research staff will need to know your health status to determine if it is appropriate for you to participate in the study protocol and to interpret your your responses.

5. **How long will the researchers keep my Protected Health Information?**

This authorization lasts for two (2) years.

You may stop this authorization at any time via written notification to the study principal investigator. If you stop authorization, we may continue to use your information already collected as part of this study, unless specifically directed not to by you. We will not collect any new information.

If you choose not to sign this authorization, or later stop authorization, you might not be able to continue to participate in the study.

6. **Can I review my own research information?**

You may request to review your research information at any time.

7. **Can I cancel this Authorization?**

Yes. If you cancel this Authorization you will no longer be included in the research study.

If you want to cancel your Authorization, please notify the Principal Investigator in writing.

8. **What will happen if I decide not to sign this Authorization?**

If you decide not to sign this Authorization, you will not be able to participate in this research study. Refusal to sign this Authorization will not result in any loss of medical benefits to which you are otherwise entitled.

9. **Can my Protected Health Information be disclosed to parties not included in this Authorization who are not under the HIPAA requirements?**

There is a potential that your research information will be shared with another party not listed in this Authorization in order to meet legal or regulatory requirements. Examples of persons who may access your PHI include representatives of the Responsible Conduct of Research Program, Bureau of Medicine Human Research Protection Program, the Food and Drug Administration, the Department of Health and Human Services (DHHS) Office for Human Research Protections, and the DHHS Office for Civil Rights. This disclosure is unlikely to occur, but in that case, your health information would no longer be protected by the HIPAA Privacy Rule. Research records will be stored in a confidential manner so as to protect the confidentiality of subject information.

10. **Who should I contact if I have any complaints?**

If you believe your privacy rights have been violated, you may file a written complaint with:

Anil Raj, MD
Chair, IHMC Institutional Review Board
Florida Institute for Human and Machine Cognition
40. S. Alcaniz St. Pensacola, FL 32503 (850) 202-4462 araj@ihmc.org

By signing this document, I authorize IHMC personnel to use and disclose my personal Protected Health Information collected about me for research purposes as described above. My signature below also acknowledges receipt of a copy of this authorization:

Signature: _____ Date:

If you are a parent, court-appointed representative, or acting as power of attorney, indicate your authority to act for the participant: _____

Print Name: _____

A copy of this signed Authorization will be provided to you.

Appendix F

NHSR Determination Worksheet

FLORIDA INSTITUTE FOR HUMAN & MACHINE COGNITION

DETERMINATION
Is It Human Subjects Research?
Vers 08/26/2021

Occasionally a sponsor, agency, editor, or vendor wants verification from an impartial source that activities do not (or did not) require IRB approval. This decision is based on specific regulatory definitions and there is no regulatory requirement to have the determination made by an IRB. The questions on this form are intended to act as a guide through the decisions necessary to make such a determination.

If preferred, this form may be used to request a formal, written determination by THE IHMC IRB. To make such a request, complete and submit this form (*no blanks and pay attention to checkboxes and sections highlighted in green*), and provide the appropriate attachments. If a grant is involved, it must be attached. This is most common in evaluation studies and with secondary use of information or specimens.

A decision that an activity is not "human subjects research" means that it is not subject to the human subjects regulations. It does not relieve anyone from other ethical, moral or legal obligations.

Inclusion of the following items is always ***required*** for review. Check each that you have attached:

- ☐ This form, signed and dated
- ☐ Any associated grants or summaries (narrative sections only)
- ☐ Additional supporting documents, if any (e.g., sponsor/prime instructions or requests)

MAKE A COPY FOR YOUR STUDY CORRESPONDENCE FILE.
Send completed package to irb@ihmc.us

A. CONTACT INFORMATION

	Applicant/Lead Contact		
Name/Title		Phone	
Company / Business		E-mail	
Address			
City, State, Zip			

Project Title	
Date or Version #	
Funding Source(s)	(I.e., Sponsor (private) Funded, NIH, Dept of Education, DoD, etc.) Include source even if only partially funded, and include any agencies involved in conducting the study. ***If through the Dept of Defense or Dept of Justice (including Bureau of Prisons), contact irb@ihmc.us first.***
Assigned Number	
Regulations to apply	☐ Dept of Health & Human Services (45 CFR 46 is the default) ☐ Dept of Defense (Ref 3216.02 2018) ☐ Food and Drug Administration (Use Appendix B) ☐ Dept of Justice, Bureau of Prisons (**please contact *irb@ihmc.us* before submitting**) ☐ Other:

Appendix G

IRB Authorization Agreement (IAA)-external IRB cedes to IHMC IRB

Florida Institute for Human and Machine Cognition
Institutional Review Board (IRB) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution/Organization A):
Florida Institute for Human and Machine Cognition (IHMC)

IRB Registration #: IRB00011160 Federalwide Assurance (FWA) #: FWA00008325

Name of Institution Relying on the Designated IRB (Institution/Organization B):

_____

IRB Registration #:_____FWA #: _____

The Officials signing below agree that Institution B, _____, and its project researchers led by _____ may rely on the designated IRB for review and continuing oversight of its human participants research described below: (*check one*)

(___) This agreement applies to all human participants research covered by Institution B's FWA.
(X) This agreement is limited to the following specific protocol(s):

Name of Research Project:_____
Name of Principal Investigator:_____
Sponsor or Funding Agency:_____Award Number, if any: _____

(___) Other (*describe*):_____

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution/Organization A):

_____ Date: _____

Print Full Name: Anil Raj, M.D. Institutional Title: Chair, IHMC IRB

Signature of Signatory Official (Institution B):

_____ Date: _____

Print Full Name:_____ Institutional Title: _____

IRB Authorization Agreement (IAA)-IHMC IRB cedes to external IRB

Florida Institute for Human and Machine Cognition
Institutional Review Board (IRB) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution/Organization A):
Florida Institute for Human and Machine Cognition (IHMC)

IRB Registration #: IRB00011160 Federalwide Assurance (FWA) #: FWA00008325

Name of Institution Relying on the Designated IRB (Institution/Organization B):

IRB Registration #:_____FWA #: _____

The Officials signing below agree that Institution B, _____, and its project researchers led by _____ may rely on the designated IRB for review and continuing oversight of its human participants research described below: (*check one*)

(___) This agreement applies to all human participants research covered by Institution B's FWA.
(X) This agreement is limited to the following specific protocol(s):

Name of Research Project:_____
Name of Principal Investigator:_____
Sponsor or Funding Agency:_____Award Number, if any: _____

(___) Other (*describe*):_____

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution/Organization A):

_____ Date: _____

Print Full Name: Anil Raj, M.D. Institutional Title: Chair, IHMC IRB

Signature of Signatory Official (Institution B):

_____ Date: _____

Print Full Name*:*_____ Institutional Title*:* _____

Appendix H

IHMC Individual Investigator Agreement (IIA)

Individual Investigator Agreement (IIA)

Name of Institution with the Federalwide Assurance (FWA):

Florida Institute for Human and Machine Cognition (IHMC)

Applicable FWA #: FWA00008325

Individual Investigator's Name: _____

Specify Research Covered by this Agreement:

_____

(Name of Project/Study)

1. The above-named Individual Investigator has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.
2. The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.
3. The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.
4. The Investigator will abide by all determinations of the Institutional Review Board (IRB) designated under the above FWA and will accept the final authority and decisions of the IRB, including but not limited to directives to terminate participation in designated research activities.
5. The Investigator will complete any educational training required by the Institution and/or the IRB prior to initiating research covered under this Agreement.
6. The Investigator will report promptly to the IRB any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
7. The Investigator will report immediately to the IRB any unanticipated problems involving risks to subjects or others in research covered under this Agreement.
8. The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) and stipulated by the IRB.
9. The Investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the IRB in a timely fashion.