# PURPOSE

* 1. This policy establishes the definitions followed by the human research protection program. This is a non-exhaustive list and regulatory agencies should be referenced for complete definitions where applicable.

# REVISIONS FROM PREVIOUS VERSION

* 1. Toolkit 5.1 release and other administrative updates.

# POLICY

* 1. **Administrative Hold**: A voluntary action initiated by the Investigator, or a directive of the Food and Drug Administration (FDA), the sponsor, the facility at which the research is being conducted, or a Data and Safety Monitoring Board to temporarily stop some or all research activities pending a specified action. An administrative hold is not a suspension or termination; the protocol remains in an “active” status and requires continuing review.
  2. **Adult**: An individual who has achieved the legal age to consent to participate in research (individuals aged eighteen (18) years or older in the state of Florida).
  3. **Adverse Event (AE):** 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. AEs can encompass both physical and psychological harms.
     1. For Veterans Administration (VA) research, any untoward physical or psychological occurrence in a human subject participating in research, whether or not considered related to the subject’s participation in research.
        1. Adverse events are untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers.
  4. **Affiliate:** An entity other than the Masgutova Graduate School of Neurodevelopmental Science (MGS) with which MGS has a contractual relationship.
  5. **Agent:** Any employee, contractor, student, or individual, whether full-time, part-time, visiting, consulting, with or without compensation, who acts on behalf of MGS (or MGS Affiliate) or in conjunction with MGS (or MGS Affiliate).
  6. **Allegation of Non-Compliance**: An unproved assertion of non-compliance.
  7. **Approval Date**: The date on which the IRB committee or IRB Chair approves a submission. If modifications are required to secure approval, the approval date is the date of the IRB meeting.
  8. **Assent**: A child’s affirmative agreement to participate in research. The child must actively show his or her willingness to participate in the research. Failure of a child to object does not constitute assent. Assent may also be used to denote the agreement of subjects with impaired decision making capacity to participate in research.
  9. **Assurance of Compliance (Human Subjects) or Federalwide Assurance (FWA):** A legally binding written document that commits an institution to complying with the Federal Policy (Common Rule) and other applicable Federal and VA standards for the protection of human subjects.
  10. **Authorization Agreement**: Also called a Reliance Agreement, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating institution relying on the ethical review.
  11. **Capacity to Consent:** A legal distinction defined as the ability to provide legally effective informed consent to enroll in a research study.
  12. **Certification**: The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.
  13. **Children:** Persons who have not attained the legal age for consent to treatments or procedures involved in the research or clinical investigation, under the applicable law of the jurisdiction in which the research will be conducted. Florida Statute §39.01(12) defines “child” or “youth” as any unmarried person under the age of eighteen (18) years who has not been emancipated by order of the court. In research conducted in other states or territories, the legal definition of children will be determined by reference to the law of that state or territory.
  14. **Clinical Investigation:** Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA…or, the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
  15. **Clinical Trial:** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
  16. **Collaborating Individual Investigator:** The Office for Human Research Protections notes that some human subjects research conducted by an assured institution may involve the following two types of collaborating individual investigators:
      1. **Collaborating independent investigator:** not otherwise an employee or agent of the assured institution; conducting collaborative research activities outside the facilities of the assured institution; and not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the assured institution.
      2. **Collaborating institutional investigator**: not otherwise an employee or agent of the assured institution; conducting collaborative research activities outside the facilities of the assured institution; acting as an employee or agent of a non-assured institution with respect to his or her involvement in the research being conducted by the assured institution; and employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.
  17. **Collaborative Study:** A study in which two or more institutions coordinate, with each institution completing a portion of the research activities outlined in a specific protocol.
      1. For Veterans Administration (VA) research, Collaborative (Study) Research involves human subjects research activities involving investigators from VA and at least one non-VA institution. Collaborative Research includes VA and non-VA institutions.
  18. **Conflict of Interest**: Situations in which financial or non-financial considerations may compromise, or have the appearance of compromising, a researcher’s objectivity in meeting duties or responsibilities (including those associated with research activities).
  19. **Confidentiality:** The treatment of information/records/data that one has disclosed in a relationship of trust with the expectation that it will not be divulged in ways that are inconsistent with the understanding of the original disclosure to anyone without permission.
  20. **Continuing Non-Compliance**: A pattern of non-compliance which continues after initial discovery.
      1. For VA research, continuing non-compliance means repeated instances of non-compliance with applicable laws, regulations, policies, agreements, or determinations of a research review committee or the prolonged persistence of non-compliance occurring after its identification, awareness, or implementation of a corrective action intended to effectively resolve the non-compliance.
  21. **Corrective and Preventative Action**: An action required of the Investigator that is necessary to reduce the risk to the subjects and/or prevent a recurrence of a protocol deviation or noncompliance.
  22. **Data and Safety Monitoring Board (DSMB):** An independent group of individuals with pertinent expertise that reviews, on a regular basis, accumulating unblinded data from protocols involving human subjects research to assure the continuing safety of research subjects, relevance of the study question, appropriateness of the study, and integrity of the accumulating data.
  23. **Data and Safety Monitoring Plans (DSMPs):** Plans designed to ensure that studies involving human subjects have a system for appropriate oversight and monitoring of the conduct of the research. This oversight can include reviewing data at specific points in time, after a specific number of subjects have been enrolled, or upon recognition of harm.
  24. **Deception:** Misleading subjects as to the true nature of the study procedures. Deception includes both active deception and deceptive incomplete disclosure.
      1. **Active Deception:** A situation where an individual is provided false or misleading information regarding the true purpose of the study, which may include incomplete disclosure, and may be used to avoid study bias or test a hypothesis that requires the subject’s misdirection.
      2. **Deceptive Incomplete Disclosure**: A situation in which an investigator withholds information about the specific purpose, nature, or other aspect of research; and 1) that information, if provided during initial consent may have affected subjects decision to participate and/or 2) when subjects learn of the information withheld, they would likely feel deceived.
  25. **De-identified:** The identities of data subjects cannot be readily ascertained, the eighteen (18) identifiers enumerated in the HIPAA Privacy rule are removed, and the study team has no actual knowledge that the remaining information could be used alone or in combination with other information to identify the subject of the data.
  26. **Deviations:** A departure or inadvertent action in study activity from the currently approved protocol, practices, or procedures
  27. **Effective Date:** The date on which modifications required to secure approval are accepted by the IRB Chair.
  28. **Engagement in Human Subjects Research:** An institution engaged in human subjects research when its employees or agents for the purposes of the research project obtain:
      1. Data about the subject of the research through intervention or interaction with them;
      2. Identifiable private information about the subjects of the research; or
      3. The informed consent of the subjects for the research.
  29. **Enrolled:** All subjects who have signed the consent document, agreed to participate verbally or online pursuant to a waiver of documentation of consent, and the number of subjects whose records/charts/data have been collected/reviewed pursuant to a waiver of consent process.
  30. **Experimental Subject**: For Department of Defense (DOD) research, research involving an “experimental subject” is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving “experimental subjects” is a subset of research involving human participants.
  31. **Expiration Date:** The first date that the protocol is no longer approved. The date after the end date of the approval period.
  32. **Human Subjects Research:** Any activity that either:[[1]](#footnote-2)
      1. Is Research as Defined by DHHS and involves human subjects as Defined by DHHS; or
      2. Is Research as Defined by FDA and involves human subjects as Defined by FDA.
  33. **Human Subject as Defined by DHHS**: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. For the purpose of this definition:
      1. **Intervention**: Physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
      2. **Interaction**: Communication or interpersonal contact between Investigator and subject.
      3. **Private Information**: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
      4. **Sensitive Personally Identifiable Information (SPII):** Information that if lost, compromised or disclosed could result in substantial harm, embarrassment, inconvenience, or unfairness to an individual.
      5. **Identifiable Private Information**: Private Information for which the identity of the subject is or may readily be ascertained by the Investigator or associated with the information. The MGS IRB utilizes the eighteen (18) identifiers in the HIPAA Privacy Rule to determine whether data or biospecimens are identifiable.
      6. **Identifiable Biospecimen**: A biospecimen for which the identity of the subject is or may be readily ascertained by the Investigator or associated with the biospecimen. The MGS IRB utilizes the 18 identifiers in the HIPAA Privacy Rule to determine whether data or biospecimens are identifiable.
  34. **Human Subject as Defined by FDA:** An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.
  35. **Immediate Family:** Spouse, domestic partner, and dependent children.
  36. **Individual Investigator Agreement**: a permissible mechanism under which an institution holding an Office for Human Research Protections (OHRP)-approved Federal wide Assurance (FWA) may extend – for one or more research protocols – the applicability of its FWA to cover two types of collaborating individual investigators: collaborating independent investigators and collaborating institutional investigators employed by a non-assured institution.
  37. **Informed Consent:** An individual’s voluntary agreement, based upon adequate knowledge and understanding of relevant information and the potential risks and benefits to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. Informed consent is an ongoing process throughout the duration of the research; the IRB approved consent form document is the written record that contains information communicated to the subject and documents their signature.
  38. **Institutional Official/ Organizational Official (IO/OO):** 
      1. Institutional Official (IO): Term utilized by DHHS.
         1. The Institutional Official (IO) is the individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. The IO is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federal wide Assurance (FWA)[[2]](#footnote-3). At MGS, the IO is the Senior Vice President for Research, Innovation & Knowledge Enterprise.
         2. For Veteran’s Administration (VA) research, the Institutional Official (IO) is the individual legally authorized as Signatory Official to commit an institution to an FWA. The Signatory Official assures that human subjects’ research to which the FWA applies is conducted in accordance with the terms of the assurance (see VHA Handbook 1058.03). The Principal Deputy Under Secretary for Health or designee is the IO for VHA Central Office, and VA facility Directors are the IOs for local VA facilities.
      2. **Organizational Official (OO):** Term utilized by AAHRPP.
         1. An identified, knowledgeable leader of the HRPP who is responsible for the program and has the authority to implement the program. This individual may rely on others for the interpretation of laws, regulations, codes, and guidance and the day-to-day operations of the HRPP, and should have a basic understanding of the relevant laws, codes, regulations and guidance that govern research involving human subjects, the responsibilities of an organizational official, and the responsibilities of the IRB or EC and researchers and research staff in protecting research subjects. This individual should be directly involved in the allocation of resources to the HRPP. In some circumstances, more than one individual serves in this capacity[[3]](#footnote-4).
  39. **Institutional Profile:** A record of information an institution keeps about another collaborating institution/organization for one or more collaborative studies or multi-site studies.
  40. **Investigator:** Collective term denoting the Investigator, sub-investigator or co-investigator (including faculty, staff, students or agents) who are responsible for the design, conduct, implementation, evaluation, subject safety, and/or reporting of the proposed or ongoing research project. Investigators include individuals employed by MGS or MGS Affiliates and those who fall under a contractual agreement (including an Individual Investigator Agreement) or IRB Authorization Agreement with the MGS IRB.
  41. **Legally Authorized Representative (LAR):** An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures(s) involved in the research.
      1. If there is no applicable law addressing this issue, then this individual is recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research.
      2. See HRP-013 - SOP - LARs, Children, and Guardians for who may serve as a Legally Authorized Representative at this institution.
  42. **Minimal Risk**: The probability and magnitude of harm or discomfort anticipated in the 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.[[4]](#footnote-5)
      1. For research involving prisoners, minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
      2. When following Department of Defense (DOD) regulations, the definition of minimal risk in 32 CFR 219 does not include the inherent occupational risks that certain participants face in their everyday life, such as those:
         1. Encountered by Service members, law enforcement, or first responders while on duty.
         2. Resulting from or associated with high-risk behaviors or pursuits.
         3. Experienced by individuals whose medical conditions involve frequent tests or constant pain.
  43. **Multi-Site Study:** A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.
  44. **Non-Committee Review:** Any of the following:
      1. Determination of whether an activity is human subjects research.
      2. Determination of whether human subjects research is exempt from regulation.
      3. Reviews of non-exempt research using the expedited procedure.
      4. Determinations of which subjects can continue in expired research.
      5. Concurrence of IRB Chair or Vice Chair for non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) or non-emergency individual patient expanded access IND with request for authorization to use alternative IRB review procedures.
  45. **Non-Compliance**: Failure to follow the regulations, state or local laws, or the requirements or determinations of the IRB.
      1. In the case of research funded or conducted by the DOD, Non-Compliance includes failure of a person, group, or institution to act in accordance with DOD instruction 3216.02, its references, or applicable requirements.
      2. In the case of VA research, non-compliance is any failure to adhere to the requirements for overseeing, reviewing, approving, or conducting VA research set forth in law, regulation, policy, or study agreements (such as reliance agreement, memoranda of understanding, data use agreements), including any failure to conduct research in accordance with a VA study protocol approved by a research review committee.
  46. **Participating Site (pSite):** An institution that participates in a Single IRB (sIRB) Study.
  47. **Prisoner**: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
      1. Per OHRP guidance, an institution is considered engaged in a particular human subjects research proposal involving prisoners when its employees or agents, for the purposes of the research proposal, obtain: 1.) data about the prisoner subjects through intervention or interaction with them; or 2.) identifiable private information about the prisoner subjects.
      2. For DOD research the term includes military personnel in either civilian or military custody.
  48. **Protocol Exception**: A one-time, intentional action or process that departs from the approved protocol. Protocol exceptions are generally for a single subject (e.g., the subjects does not meet eligibility criteria or is allergic to one of the medications provided as supportive care). IRB approval of the protocol exception is required prior to implementation by the study team.
  49. **Research as Defined by DHHS:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
      1. **Generalizable Knowledge**: Information that is produced for the purposes of dissemination to a scientific audience outside of the population served by the institution.
  50. **Research as Defined by FDA:** Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:
      1. Must meet the requirements for prior submission to the FDA under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
      2. Must meet the requirements for prior submission to the FDA under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
      3. Any activity the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
  51. **Restricted:** Applies to investigators who are delinquent in meeting IRB requirements.
  52. **Serious Adverse Event (SAE):** An adverse event (occurring at any dose or level of intervention) that results in any of the following outcomes: Death; Is life threatening (places subject at immediate risk of death from the event as it occurred - it does not include a reaction that, had it occurred in a more severe form, might have caused death); A required or prolonged hospitalization, persistent or significant disability/incapacity; congenital anomaly/birth defect; or may require medical, surgical, behavioral, social or other intervention to prevent one of the other outcomes listed in this definition.
  53. **Serious Non-Compliance**: Non-compliance such that the failure to comply could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject’s willingness to participate in research; or damage or compromise the scientific integrity of research data.
      1. For DOD research serious non-compliance includes failure of a person, group, or institution to act in accordance with DOD Instruction 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject’s willingness to participate in research; or damage or compromise the scientific integrity of research data.
      2. For VA research serious non-compliance is any failure to adhere to requirements for conducting human subjects research that may reasonably be regarded as:
         1. Presenting a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects or others, including their rights to privacy and confidentiality of identifiable private information;
         2. Presenting a genuine risk of substantive harm to the safety, rights, or welfare of research personnel who conduct research;
         3. Presenting a genuine risk of substantive reputational harm to the Veterans Administration (VA); or
         4. Substantively compromising a VA medical facility’s HRPP.
  54. **Significant Financial Interest:** A financial interest consisting of one or more of the following interests of the discloser (and those of the discloser’s spouse, domestic partner and dependent children):
      1. With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
      2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator’s spouse, domestic partner or dependent children) holds any equity interest (e.g. stock, stock option, or other ownership interest);
      3. A position as director, officer, partner, trustee or member of board of directors of any entity related to the research, whether or not remuneration is received for such service; or
      4. Intellectual property rights and interests (e.g. patents, copyrights). An intellectual property right or interest is considered to be present as soon as a patent is granted or an option or license agreement is executed.
  55. **Single IRB (sIRB) Study:** A study in which two or more institutions (participating sites, or pSites) coordinate to complete the research activities, but all institutions rely on a single institution’s/organization’s IRB for ethical review. The reviewing IRB may or may not be affiliated with any of the pSites.
  56. **Suspension of IRB Approval:** An action of the IRB, IRB Chair or Vice Chair, IO/OO, or designee of the IO/OO to temporarily or permanently withdraw IRB approval of some or all research procedures short of a termination of IRB approval. Suspended studies remain open and are subject to continuing review.
  57. **Systematic Investigation:** Refers to an activity that involves a prospective research plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question.
  58. **Termination of IRB Approval**: An action of the IRB or the IO/OO to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.
      1. For VA research, termination of IRB approval:
         1. Refers to a permanent halt in all research activities due to concerns about the safety, rights, or welfare of human subjects, research personnel, or others, regardless of whether the action was taken by an investigator, facility official, research review committee, or external entity.
         2. Does not refer to interruptions in research for other reasons, including the expiration of project approval periods.
  59. **Unanticipated Problem Involving Risks to Human Subjects or Others (UPIRHSO): [[5]](#footnote-6)**
      1. For FDA research, UPIRHSOs are defined as an event that is unexpected, serious, and has implications for the conduct of the study.
      2. For DHHS and DOD research, the term UPIRHSO includes any incident, experience, or outcome that meets ALL three of the following conditions:
         1. Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g. the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.
         2. Is related or possibly related to participation in the research (in the DOD Instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
         3. Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.
      3. For VA research:
         1. Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) is an incident, experience or outcome that is: unexpected; related or possibly related to participation in the research; and indicative of the research placing subjects or others at substantively greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized.
         2. The term “unexpected” refers to an incident, experience, or outcome that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population.
         3. The phrase “related to participation in the research” means a logical sequence of cause and effect shows that the study procedures were the reason for the incident, experience, or outcome. The phrase “possibly related to participation in the research” implies a lesser degree of certainty about causality and refers to an incident, experience, or outcome for which there is some evidence to reasonably suggest a causal relationship between study procedures and the incident, experience, or outcome.
         4. An unexpected SAE that is related or possibly related to participation in human subjects research constitutes a UPIRTSO.

# RESPONSIBILITIES

* 1. Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline.
  2. Individuals using policies and procedures are to consult this policy for the definitions of double underlined terms.

# PROCEDURE

* 1. None

# MATERIALS

* 1. HRP-013 - SOP - LARs, Children, and Guardians

# REFERENCES

* 1. 45 CFR §46.102.
  2. 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR §812.3(p)
  3. VHA Handbook 1058.01 dated October 22, 2020; VHA Directive 1004.08 dated October 31, 2018; VHA Directive 1200.05 dated January 7, 2019, amended January 8, 2021; VHA Directive 1058.03 dated September 17, 2020
  4. AAHRPP elements I.1.A, I.1.E, I.5.D, I.6.B, I.7.C, I-9, II.1.D, II.2.A, II.2.B, II.2.G, II.2.H, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.A, II.4.A, III.1.B, III.2.D

1. The terms “Human Subjects Research,” “Research Involving Human Subjects,” “Clinical Research,” “Clinical Investigation,” “Clinical Study” and similar phrases are considered to be synonyms for the term Human Subjects Research. [↑](#footnote-ref-2)
2. https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-september-18-letter-attachment/index.html [↑](#footnote-ref-3)
3. AAHRPP Evaluation Instrument (2018-10-15); http://www.aahrpp.org/apply/web-document-library/domain-i-organization [↑](#footnote-ref-4)
4. The phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” should not be interpreted to include the inherent risks certain categories of subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their environment (e.g. emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g. frequent medical tests or constant pain). [↑](#footnote-ref-5)
5. See OHRP guidance “Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance (2007)” at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html> [↑](#footnote-ref-6)