1 PURPOSE
1.1 This policy establishes the definitions followed by the human research protection program at the University of New Mexico Health Sciences Center.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Removed requirements of VA that are no longer in VA handbook

3 POLICY
3.1 Adverse Event: For Veterans Administration (VA) research any untoward physical or psychological occurrence in a human subject participating in research. It can be any unfavorable and/or unintended event, including an abnormal laboratory finding, symptom, or disease associated with the research or the use of a medical investigational test article. It does not necessarily have a causal relationship to the research.

3.2 Allegation of Non-Compliance: An unproven assertion of Non-Compliance.

3.3 Child(ren): Persons who have not attained the legal age for consent to treatments or procedures involved in research, under the law of the jurisdiction in which the research will be conducted.

3.4 Clinical Trial: A biomedical or behavioral research study involving human subjects designed to answer specific questions about diagnostic procedures or therapeutic interventions (drugs, biologic products, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are designed to determine whether new diagnostic procedures or therapeutic interventions are safe and efficacious.

3.5 Conflict of Interest: An individual involved in the design, conduct, reporting, or review of research is automatically considered to have a potential Conflict of Interest when the individual or the individual’s Immediate Family have any of the following interests that reasonably appear to be related to the individual’s Institutional Responsibilities, including but not limited to:

3.5.1 Ownership interest, stock options, or other ownership interest of any value in a publicly or non-publicly traded entity, exclusive of interests in publicly-traded, diversified mutual funds and retirement accounts.

3.5.2 Compensation of any amount in the past year in a publicly or non-publicly-traded entity, excluding compensation for costs directly related to conducting research.
3.5.3 Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement other than through UNM or STC.UNM (formerly known as Science & Technology Corporation@ UNM).

3.5.4 A position as a director, board member, executive officer, advisory or review panel member, partner, trustee, manager, or employee of an outside entity, regardless of compensation.

3.5.5 Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.

3.5.6 Any income from seminars, lectures, teaching engagements, or participation in a speaker’s bureau, for non-profit or for-profit entities that are not a federal, state, or local government agency or associated with an institution of higher education.

3.5.7 Any other situation not described above that the individual believes may be potential or actual conflict of interest.

3.5.8 Any other potential conflict of interest which is covered by 42CFR50, subpart F and 45CFR94 and UNM COI Policy (UNM Policy E110), the UNM HSC Supplemental Policy, and the Additional Reporting Requirements for HSC Investigators.

3.6 Continuing Non-Compliance: A pattern of Non-Compliance that suggests the likelihood that, without intervention, instances of Non-Compliance will recur, a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply.

3.6.1 For Veterans Administration (VA) research Continuing Non-Compliance includes a persistent failure to adhere to the laws, regulations, or policies governing Human Research.

3.7 Designated Reviewer: The HRRC chair or an Experienced HRRC Member designated by the HRRC chair to conduct Non-Committee Reviews.

3.8 Emergency Use: the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)]. The emergency use provision in the FDA regulations [21 CFR 56.104(c)] is an exemption from prior review and approval by the IRB. Life-threatening, for the purposes of section 56.102(d), includes the scope of both life-threatening and severely debilitating, as defined below.

3.8.1 Life-threatening means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival. The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened meeting of the HRRC is feasible.

3.8.2 Severely debilitating means diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis or stroke.

3.9 Experienced HRRC Member: An HRRC member is considered experienced if the HRRC chair considers the HRRC member to have sufficient experience in and knowledge of conducting HRRC reviews.

3.10 Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.
3.11 Finding of Non-Compliance: Non-Compliance in fact.

3.12 Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. The role of a guardian in the context of research involving a child who is a ward is to provide permission, in lieu of a child's biological or adoptive parents, for the ward to participate in the research.

3.13 Human Research: Any activity that either:
   3.13.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or
   3.13.2 Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.

3.14 Human Research Review Committee (HRRC): Nomenclature used for the institutional review board(s) at the University of New Mexico Health Science Center.

3.15 Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:
   3.15.1 Intervention: Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
   3.15.2 Interaction: Communication or interpersonal contact between investigator and subject.
   3.15.3 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 which the individual can reasonably expect will not be made public (for example, a medical record).
   3.15.4 Identifiable Information: Information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

3.16 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.

3.17 Humanitarian Use Device (HUD): A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. When used according to the FDA approved labeling and indication, the deployment of HUD does not constitute research.

3.18 Immediate Family: Spouse, domestic partner; and dependent children.


3.20 Institutional Responsibilities: An individual's professional responsibilities conducted on behalf of UNM such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

3.21 Legally Authorized representative: Individuals, judicial bodies, or other groups authorized under applicable New Mexico state law to consent on behalf of a

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1 The terms “Human Subject Research,” “Research Involving Human Subjects,” “Clinical Research,” “Clinical Investigation,” “Clinical Study” and similar phrases are considered to be synonyms for the term Human Research.
prospective participant to his or her participation in the procedures involved in the research.

3.22 **Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research that 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.\(^2\)

3.22.1 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.

3.23 **Non-Committee Review:** Any of the following:

3.23.1 Determination of whether an activity is Human Research.
3.23.2 Determination of whether Human Research is exempt from regulation.
3.23.3 Reviews of non-exempt research using the expedited procedure.
3.23.4 Determinations of which subjects can continue in expired research.

3.24 **Non-Compliance:** Failure to follow the regulations, or the requirements or determinations of the HRRC.

3.24.1 In the case of research funded or conducted by the Department of Defense (DOD), Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements
3.24.2 In the case of Veterans Administration (VA) research, Non-Compliance includes failure to follow the requirements of VHA Handbook.

3.25 **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.

3.25.1 For Department of Defense (DOD) research the term includes military personnel in either civilian or military custody.

3.26 **Related to the Research:** A financial interest is **Related to the Research** when the interest is in:

3.26.1 A sponsor of the research;
3.26.2 A competitor of the sponsor of the research;
3.26.3 A product or service being tested; or
3.26.4 A competitor of the product or service being tested.

3.27 **Research as Defined by DHHS:** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

3.28 **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:

\(^2\) 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).
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3.28.1 Must meet the requirements for prior submission to the Food and Drug Administration 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;

3.28.2 Must meet the requirements for prior submission to the Food and Drug Administration 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

3.28.3 Any activity, the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

3.29 Resticted: Applies to investigators who are delinquent in meeting HRRC requirements.

3.30 Remuneration: Includes salary and any payment for services not otherwise identified as salary (e.g. consulting fees, honoraria, paid authorship).

3.31 Serious Non-Compliance: Non-Compliance that adversely affects the rights or welfare of subjects.

3.31.1 For Department of Defense (DOD) research Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (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.

3.31.2 For Veterans Administration (VA) research Serious Non-Compliance includes a failure to adhere to the laws, regulations, or policies governing Human Research that might reasonably be regarded as:

3.31.2.1 Involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others; or

3.31.2.2 Substantively compromising the effectiveness of a Veterans Administration (VA) facility’s human research protection or human research oversight programs.

3.31.3 For Veterans Administration (VA) research the unfounded classification of a serious adverse event as “anticipated” constitutes Serious Non-Compliance.

3.32 Sponsor Company: Any company that is (a) the sponsor of research at UNMHSC; or (b) a supplier of services to UNMHSC; or (c) the manufacturer of a product to be evaluated or used in research at, or under the auspices of, UNMHSC.

3.33 Suspension of HRRC Approval: An action of the HRRC, HRRC designee, Institutional Official, or designee of the Institutional Official, as appropriate to temporarily or permanently withdraw HRRC approval of some or all research procedures short of a Termination of HRRC Approval. Suspended studies remain open and are subject to continuing review.

3.34 Termination of HRRC Approval: An action of the HRRC, HRRC designee, Institutional Official, or designee, as appropriate to permanently withdraw HRRC approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.
3.35 Unanticipated Problem Involving Risks to Subjects or Others: Any information that is (1) unanticipated and (2) indicates that subjects or others are at increased risk of harm.

3.35.1 For Department of Defense (DOD) research the term Unanticipated Problem Involving Risks to Subjects or Others includes any incident, experience, or outcome that meets ALL three of the following conditions:

3.35.1.1 Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the HRRC-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.

3.35.1.2 Is related or possibly related to participation in the research (in this 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).

3.35.1.3 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.

3.35.2 For Veterans Administration (VA) research:

3.35.2.1 The terms “unanticipated” and “unexpected” refer to an event or problem 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.

3.35.2.2 The term Unanticipated Problem Involving Risks to Subjects or Others includes any event or problem that is serious, unexpected, and related to the research, where “related” means the event or problem might reasonably be regarded as caused by, or probably caused by, the research.

3.35.2.3 Serious Unanticipated Problems Involving Risks to Subjects or Others includes:

3.35.2.3.1 Interruptions of subject enrollments or other research activities due to concerns about the safety, rights, or welfare of human research subjects, research staff, or others.

3.35.2.3.2 Any work-related injury to personnel involved in human research, or any research-related injury to any other person, that requires more than minor medical intervention (i.e., basic first aid), requires extended surveillance of the affected individual, or leads to serious complications or death.

3.35.2.3.3 Any VA National Pharmacy Benefits Management (PBM) Bulletins or Communications (sometimes referred to as PBM Safety Alerts) relevant to one or more of the VA facility’s research projects.

3.35.2.3.4 Any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee report describing a safety problem.
3.35.2.3.5 Any sponsor analysis describing a safety problem for which action at the VA facility level might be warranted.

3.35.2.3.6 Any unanticipated problem involving substantive harm, or a genuine risk of substantive harm, to the safety, rights, or welfare of human research subjects, research staff, or others;

3.35.2.3.7 Any problem reflecting a deficiency that substantively compromises the effectiveness of a VA facility’s human research protection or human research oversight programs.

4 RESPONSIBILITIES

4.1 Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline

4.2 Individuals using policies and procedures are to consult this policy for the definitions of double underlined terms.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 None

7 REFERENCES

7.1 45 CFR §46.102.

7.2 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR §812.3(p), 45 CFR 46.402(e), 45 CFR 46.402(c)