

Definitions

1. *AAHRPP* is the Association for the Accreditation of Human Research Protection Programs.
2. *AE* is an Adverse Event.
3. *Associate Dean* is the Medical School Associate Dean for Regulatory Affairs.
4. *BEU* refers to the Hospital Biomedical Engineering Unit.
5. *CareWeb* is a web-based clinical patient record that provides rapid access to patient data from a wide variety of clinical systems, including lab, radiology, medical records and others.
6. *CDC* is the Centers for Disease Control
7. *CFR* is the United States Code of Federal Regulations.
8. *Chair(s)* are the IRBMED Chair, Co-Chair(s), and Vice-Chair(s) of the Board.
9. *CIRB* is the Central Institutional Review Board.
10. *COI* refers to a conflict of interest, and may consist of a financial conflict of interest or a conflict of commitment; it includes both actual and perceived conflicts of interest.
11. *Co-I* is a Co-Investigator. See also Sub-I (Sub-Investigator)
12. *Common Rule* is the Federal Policy for the Protection of Human Subjects, as set forth in 45 C.F.R. part 46, subpart A, and parallel regulations promulgated by agencies such as the Food and Drug Administration (FDA).
13. *Compliance Committee* is the committee charged with reviewing and approving compliance matters for the Medical School and Health System.
14. *CRCRAO* is the Clinical Research Calendar Review Analysis Office, formerly the Clinical Research Billing Unit (CRBU).
15. *CTSA* is the Clinical and Translational Science Award.
16. *Dean* is the Dean of the Medical School.
17. *DHHS* is the Federal Department of Health and Human Services.
18. *DSMB* is the Data and Safety Monitoring Board.
19. *EFIC* means an Exception from Informed Consent concerning FDA-regulated activity as set forth in 21 CFR 50.24.
20. *eRRM* is the eResearch Regulatory Management, the web-based system that centralizes the review and approval process for Human Subjects Research Applications and IBC Biosafety Registrations.
21. *eRPM* is the eResearch Proposal Management, used to accommodate the electronic routing, approval, and submission of funding proposals to external sponsors, including Grants.gov.
22. *eThORITY* is a tool to assist researchers with one point of data entry for building a clinical research budget and billing calendar and tracking your subject enrollment.
23. *EVPMA* is the Executive Vice President for Medical Affairs.
24. *FDA* is the Food and Drug Administration.
25. *FWA* refers to a Federal-Wide Assurance.

- 26.** *GCP* is Good Clinical Practice
- 27.** *GINA* is the Genetic Information Nondiscrimination Act of 2008
- 28.** *GWAS* is the Genome-Wide Association Studies
- 29.** *HDE* is a Humanitarian Device Exemption.
- 30.** *HHS* is the U.S. Health and Human Services.
- 31.** *HIPAA* is the Health Insurance Portability and Accountability Act of 1996, as amended, and privacy regulations promulgated pursuant to the Act.
- 32.** *HITECH* is the Health Information Technology for Economic & Clinical Health
- 33.** *hPSCRO* is the Human Pluripotent Stem Cell Research Oversight Committee.
- 34.** *HRPP* is the University of Michigan's Human Research Protection Program.
- 35.** *HUD* is a Humanitarian Use Device.
- 36.** *Human Subject means:*
 - OHRP: "A living individual about whom an investigation conducting research obtains (1) Data through intervention or interaction with the individual or (2) identifiable private information." 45 CFR 46.102 (f).
 - FDA: "An individual who is or becomes a participant 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." 21 CFR 50.3 (g) and 21 CFR 56.102 (e).
- 37.** *IAA* is the IRB (Institutional) Authorization Agreement
- 38.** *IB* is the Investigators Brochure.
- 39.** *IBC* is the Institutional Biosafety Committee.
- 40.** *ICD* is a Informed Consent Document
- 41.** *IDE* means an approved Investigational Device Exemption.
- 42.** *IDS* refers to the Investigational Drug Service, which is part of the University of Michigan Hospital and Health Centers.
- 43.** *IIA* is a Individual Investigator Agreement
- 44.** *IND* means an Investigational New Drug application.
- 45.** *Individual* means a current or former patient of UMHHC or the Medical School's Faculty Group Practice; or a member of M-CARE, M-CAID, or other health plans issued, administered, or serviced by the Health System.
- 46.** *IO* is an Institutional Official.
- 47.** *IRB* refers to a University of Michigan Institutional Review Board.
- 48.** *IRB-HSBS* is the Institutional Review Board for Health Sciences and Behavioral Science.
- 49.** *IRBMED* refers collectively to the University of Michigan Medical School Institutional Review Boards (A1, A2, B1, B2, and C1) for Human Subjects Research.
- 50.** *ITS* is the Information and Technology Services
- 51.** *LAR* is a Legally Authorized Representative, who is an individual, judicial body, or other party authorized under applicable law to consent on behalf of an individual to his/her enrollment and continued participation as a subject in a research project.

- 52.** *MCIT* is the Medical Center Information Technology
- 53.** *MCRU* is the Michigan Clinical Research Unit.
- 54.** *Medical School* is the University of Michigan Medical School.
- 55.** *Medical School Associate Deans for Research and Regulatory Affairs* refers to the Senior Associate Dean for Research and the Associate Dean for Regulatory Affairs.
- 56.** *MIAP* is the MICHR IND/IDE Investigator Assistance Program.
- 57.** *MICHR* is the Michigan Institute for Clinical and Health Research.
- 58.** *Minimal Risk* means that 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.
- 59.** *MSIS* is the Medical School Information Services
- 60.** *NCI* is the National Cancer Institute.
- 61.** *NCRC* refers to the North Campus Research Complex
- 62.** *NIAAA* refers to the National Institute on Alcohol Abuse and Alcoholism
- 63.** *NIDA* refers to the National Institute on Drug Abuse
- 64.** *NIH* is the National Institutes of Health.
- 65.** *NIMH* refers to the National Institute of Mental Health
- 66.** *NSR* is a Non-significant Risk Device:
- 67.** *Nonaffiliated Member* is a member of a IRB who has no ties to UM, its staff or faculty, usually from the local community (e.g., minister, business person, attorney, teacher, or homemaker).
- 68.** *OBA* is the Office of Biotechnology Activities.
- 69.** *OHRCR* is the Office of Human Research Compliance Review.
- 70.** *OHRP* is the Department of Health and Human Services Office for Human Research Protections.
- 71.** *OM* is the Operations Manual for the Office of the Vice President for Research.
- 72.** *OPRR* is the Office of Protection from Research Risks, now known as the OHRP.
- 73.** *ORIOs* are Other Reportable Information or Occurrences.
- 74.** *ORSP* (formerly DRDA) is the Office of Research and Sponsored Projects, a division of the University of Michigan Office of the Vice President for Research.
- 75.** *OVPR* is the Office of the Vice President for Research of the University of Michigan. The Vice President for Research is the “institutional official” named in the Single Project or Federal Wide Assurances.
- 76.** *PEERRS* is the Program for Education and Evaluation in Responsible Research and Scholarship.
- 77.** *PHI* means Protected Health Information (including demographic information) about a patient that (i) is created or received by a health care provider or health plan; (ii) relates to the past, present, or future physical or mental health of the patient; and (iii) identifies the patient or with respect to which there is a reasonable basis to believe it could be used to identify the patient.

- 78.** *PHS* refers to the Public Health Service
- 79.** *PI* is the Principal Investigator conducting research.
- 80.** *Privacy Board* is the subsection or subcommittee of the IRBMED charged with handling HIPAA matters referred to the IRBMED and in accordance with these Standard Operating Procedures (SOPs).
- 81.** *RDRC* is the Radioactive Drug Research Committee.
- 82.** *Research* is:
OHRP: "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge." 45 CFR 46.102 (d).
FDA: "[A]ny experiment that involves a test article and one or more human subjects [or specimen]...the results of which are intended to be submitted to...FDA... The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for this part." 21 CFR 56.102 (c).
- 83.** *RRERR* is a Routine Research Educational and Regulatory Review conducted by the Office of Human Research Compliance Review (OHRCR).
- 84.** *Senior Associate Dean* is the Medical School Senior Associate Dean for Research.
- 85.** *SHUR* is the University Subcommittee on the Human Use of Radioisotopes.
- 86.** *SOP* is a Standard Operating Procedure.
- 87.** *SPA* is a Single Project Assurance.
- 88.** *SPG* is the University of Michigan Standard Practice Guide.
- 89.** *SR* is a Significant Risk Device
- 90.** *STARS* refers to Speak to a Regulatory Specialist
- 91.** *Sub-I* is a Sub-Investigator. See also Co-I (Co-Investigator)
- 92.** *TPC* is the Tissue Procurement Core.
- 93.** *UMHHC* is the University of Michigan Hospitals and Health Centers.
- 94.** *UMHS* is the University of Michigan Health System.
- 95.** *UMMS* is the University of Michigan Medical School.
- 96.** *University* or *UM* is the University of Michigan.
- 97.** *UaP/UPIRSO* is a Unanticipated Problem Involving Risks to Subjects or Others
- 98.** *VPR* is the Vice President for Research.