Common Acronyms used by the WVU ORIC & IRB

Office of Research Integrity & Compliance | Version 2
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This document contains a list of acronyms that is commonly used by the WVU Office of Research Integrity & Compliance, along with the IRB. If further clarification is needed, please contact the ORIC at 304-293-7073 or by email at IRB@mail.wvu.edu.

Acronyms

21 CFR – Code of Federal Regulations from the FDA. It only applies to drugs and devices.

45 CFR – Code of Federal Regulations from OHRP (see below). It applies to all human subjects research.

AAHRPP – The accreditation agency for IRBs. We have just renewed our accreditation for the next five years.

AE – Adverse Events

AER - Advancing Ethical research (conference)

BRAAN – was WVU's electronic protocol system before KC

CFR – Code of Federal Regulations

CIRB – Central IRB. These are usually commercial IRBs that review studies for compensation. We have an agreement with two. One is from NCI (see below) for cancer studies – Phases II, III, and IV. This is free and includes various cancer cooperative groups formed by NCI. The other is an agreement with Chesapeake who charges for their review. All of these are tracked by our office.

CITI – Collaborative Institutional Training Initiative

COC – Certificate of Confidentiality, which is issued by NIH and is used by investigators to protect their data from being subpoenaed.

COIR – Conflict of Interest in Research

Common Rule - a rule of ethics regarding biomedical and behavioral research involving human subject in U.S.—heavily influenced by the Belmont Report; currently must be followed by trials that are federally funded but may extend to any trials done by institution that accepts federal funds

CORE – Center for Organ Recovery and Education

CR – Continuing Review or Continuing Renewal

CRH – Chestnut Ridge Hospital

CRO – contract research organization

CT – Computed Tomography

CTA – Clinical Trial Agreements

CTRU – Clinical Trials Research Unit. This is the group that develops and administers most of the clinical trials that are submitted. All of the cancer trial studies come through this unit.

CTSI – Clinical and Translational Science Institute. This is an acronym for a grant supported group at WVU that helps research with funds to conduct research studies. The CTSI is a group at WVU that funds various projects. WVU has a grant from the feds to support research in WV. The CTWG is a committee that reviews these protocols before the CTSI will fund them.

CTWG - The CTSI reviews all studies that they agree to fund in a scientific review committee. The CTWG is a committee that reviews these protocols before the CTSI will fund them.

CV – Curriculum Vitae

DHHS – Department of Health and Human Services

DMC – Data Monitoring Committee – same purpose as a DSMB

DNA – Deoxyribonucleic Acid

DSMB - Data Safety Monitoring Board – This is a Board that reviews all the reports of adverse events or side effects from all of the sites conducting clinical trial studies. They review all of these reports to see if whether the study should be stopped or can continue. Usually this Board meets every 3 – 6 months and each clinical trial will receive a copy of their determination.

DSMP – Data Safety Monitoring Plan. The plan would involve either a DSMB or some other method of reviewing side effects.

ERA – Electronic Research Administration

FDA – Food and Drug Administration

FWA – Federal Wide Assurance with OHRP (see below). WVU's Federal wide Assurance number is FWA00005078.

GCP – Good Clinical Practice

HDE – Humanitarian Use Device Exemption

HIPAA – Health Insurance Portability and Accountability Act. Came into being in 1996 and protects a person's health information to keep it private. WVU has given the overview of conforming to the HIPAA rules to the IRB.

HIV – Human Immunodeficiency Virus

HR&E – Human Resources and Education

HRPP – Human Research Protections Program

HSC – Health Sciences Center

HUD – Humanitarian Use Device. These are protocols using a device that has been approved by the FDA but there are less than 2000 uses a year in the nation. They have been given a special status by the FDA and are not considered research, but they require review by the IRB. There is no consent form with them, rather they use a cover letter of information to the patient. The cover letter description is on our website oric.research.wvu.edu. Basically, patients are told what the device is and why the PI recommends this device.

IAA – Interinstitutional Authorization Agreement. An agreement between two institutions to waive review of a protocol if the other IRB has already reviewed and approved the protocol. One IRB cedes review to the other IRB.

IBC – Institutional Biohazards Committee. Any protocol that includes biohazards, infectious agents, etc. must go through this Committee before it is submitted to the IRB. This is done automatically by the system when the investigator responds to the biohazards question in the Questionnaire of the application with a yes. The IBC approval letter must be attached in the attachments of the study.

ICD - Informed consent document (form). More often ICF is used. There are elements that must be included in a consent form. You can see these in our SOPs on our website oric.research.wvu.edu.

ICF – Informed consent form. There are elements that must be included in a consent form. You can see these in our SOPs on our website oric.research.wvu.edu.

IDE - Investigational Device Exemption – A number given by the FDA for new devices. We will not approve a new device without this number. The Board must determine if the device is NSR (not significant risk) or SR (significant risk) at the meeting.

IF – Incidental Finding

IND – Investigational New Drug – A number given by the FDA for new drugs. We will not approve a study where there is no IND from the FDA or unless it is already an FDA approved drug for commercial use.

IO – Institutional Official

IRB – Institutional Review Board for the Protection of Human Research Subjects

ISO - International Organization for Standardization

IT – Informational Technology. We rely heavily on their support with the KC system.

KC – Kuali Coeus – this is our electronic system for submitting and approving IRB protocols

LAR – Legally Authorized Representative

MMR – more than minimal risk

MOU – Memorandum of Understanding

MRI- Magnetic Resonance Imaging. This type of imaging does not involve radiation.

NCI – National Cancer Institute

NDA – Non-Disclosure Agreement

NHSR – Not Human Subjects Research – this is a level of protocol review that is conducted by office staff. Protocols submitted at this letter are not considered to be human subject's research but need a letter from us confirming that in order to get published. These would be program evaluations, needs assessments, case reports or histories where the researcher is only recording the events that took place, or they would be a second review of a data set that has no identifiers.

NIH – National Institutes of Health

NPRM -notice of proposed rule-making (by HHS/OHRP)

NSR - Not significant risk - usually referring to device studies

OHRP – Office for Human Research Protections

OMR – Only minimal risk

ORD – Office of Research and Development

ORIC – Office of Research Integrity and Compliance

ORO – Office of Research Oversight

OSP – Office of Sponsored Programs

PET scans – Positron Emission Test – this is another type of imaging test

PHI- Personal Health Information -This is information about a subject that contains health information, about that person such as blood pressure, doctor's visits, the subject's diseases, types of drug the subject is taking, etc.

PHS – Public Health Service

PI – Principal Investigator (must be a faculty or staff person at WVU)

PRMC – Protocol Review Monitoring Committee - A committee that conducts a review of protocols before they are submitted to the IRB. This is a scientific review by this committee. Usually they review all the cancer studies. They may also review other studies that use the CTRU for administration purposes.

PRIM&R – Public Responsibility in Medicine and Research

OHRP – Office for Human Research Protections - This is the federal regulatory agency under DHHS that oversees all of the IRBs in the US. The code from the OHRP is what we follow as well as the code from the FDA.

QA/QI - QA ensures compliance, QI improves best practice and increases efficiency of IRB operations

QIP – Quality Improvement Program

R&D – Research and Development

RFF – Reviewer feedback form - the checklists that you fill out on the Online Review page

Reliance Agreements - are for multi-site studies—general umbrella that one institution will use for all studies. Legal has to be involved.

SABR – Social and Behavioral Research

SAE – Severe Adverse Event

SBR – Social/Behavioral Research

SOPs – Standard Operating Procedures - Ours are on our website oric.research.wvu.edu

SR – Significant Risk –usually referring to device studies

UAP - Unanticipated Problems

UE – Unanticipated Event (may or may not involve risk to the subjects)

UPIRTSO – Unanticipated Problems Involving Risks - To Subjects or Others

URL – Uniform Resource Locator (website address)

VA – Veteran Administration

VAMC – Veteran Administration Medical Center

VHA – Veterans Health Administration

WVRHP – West Virginia Rural Health Education Partnership

WVU – West Virginia University

WVUH – West Virginia University Hospitals, Inc.

WVURC – West Virginia University Research Corporation

Additional Information

Clinical trials are conducted in 'phases.' Each phase has a different purpose and helps researchers answer different questions. The National Comprehensive Cancer Network[1] provides a summary of each phase of a clinical trials.

Overview of the Phases of Clinical Trials[2]

	Purpose	Study Population	Length of Study	General Results
Phase I	Safety and dosage	~20-100 healthy volunteers or people with disease	Several months	~70% of drugs move to the next phase
Phase II	Efficacy and side effects	Several hundred people with disease	Several months to 2 years	~33% of drugs move to next phase
Phase III	Efficacy and adverse reaction monitoring	300-3,000 people with disease	1-4 years	~25-33% of drugs move to next phase
Phase IV	Safety and efficacy for post-marketing	Several thousand with disease		

Phase I – aim to find the best dose of a new drug with the fewest side effects. The drug will be tested in a small group of 15 to 30 patients. Doctors start by giving very low doses of the drug to a few patients. Higher doses are given to other patients until side effects become too severe or the desired effect is seen. The drug may help patients, but Phase I trials are to test a drug's safety. If a drug is found to be safe enough, it can be tested in a phase II clinical trial.

Phase II – further assess safety as well as if a drug works. The drug is often tested among patients with a specific type of cancer. Phase I trials are done in larger groups of patients compared to Phase I trials. Often, new combinations of drugs are tested. Patients are closely watched to see if the drug works. However, the new drug is rarely compared to the current (standard-of-care) drug that is used. If a drug is found to work, it can be tested in a phase III clinical trial.

Phase III – compare a new drug to the standard-of-care drug. These trials assess the side effects of each drug and which drug works better. Phase III trials enroll 100 or more patients.

Often, these trials are randomized. This means that patients are put into a treatment group, called trial arms, by chance. Randomization is needed to make sure that the people in all trial arms are alike. This lets scientists know that the results of the clinical trial are due to the treatment and not differences between the groups. A computer program is often used to randomly assign people to the trial arms.

There can be more than two treatment groups in phase III trials. The control group gets the standard-of-care treatment. The other groups get a new treatment. Neither you nor your doctor can choose your group. You will also not know which group you're in until the trial is over.

Every patient in a phase III study is watched closely. The study will be stopped early if the side effects of the new drug are too severe or if one group has much better results. Phase III clinical trials are often needed before the FDA will approve the use of a new drug for the general public.

Phase IV – test new drugs approved by the FDA. The drug is tested in several hundreds or thousands of patients. This allows for better research on short-lived and long-lasting side effects and safety. For instance, some rare side effects may only be found in large groups of people. Doctors can also learn more about how well the drug works and if it's helpful when used with other treatments.

Sources: [1]National Comprehensive Cancer Network. Retrieved June 29, 2017, from https://www.nccn.org/patients/resources/clinical_trials/phases.aspx [2] The Drug Development Process - Step 3: Clinical Research. Retrieved June 29, 2017, from https://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm#Clinical_Research_Phase_Studies