Office of Research Protections (ORP) Overview
Information for Mission Partners

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US Army Medical Research and Materiel Command
25 March 2015

The views expressed in this presentation are those of the author(s) and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.

At this point in the Conference, you….

- Have an awareness of USAMRMC structure and function
- Understand the DoD's need to partner with academia and industry to conduct medical research, development and acquisition in support of the Warfighter
- Appreciate the mechanisms available to serve as our mission partner
- Can see your institution contributing to the efforts of one or more of our Research Program Areas
- Are ready to respond to one of the many USAMRMC solicitations
- Want to know how to be successful in partnering with USAMRMC

Purpose

- To increase attendees understanding of DoD and USAMRMC requirements for the conduct of research, development, test and evaluation activities involving human subjects, animals and/or cadaver specimens.
- Human Research Protections
  - Background
  - DoD/USAMRMC Requirements
  - HRPO Processes for Review, Approval and Life Cycle Oversight
  - Challenges and Strategies for Success
- Animal Care and Use Review
  - DoD/USAMRMC Requirements
  - ACURO processes for review and approval
- Cadaver Specimen use

Office of Research Protections - Mission

Oversees USAMRMC supported research and Army Medical Department clinical investigations involving human subjects, human anatomical substances, cadavers, or animals, to assure they are conducted IAW Federal, DoD, Army, USAMRMC, and international regulatory requirements

ORP's Support Role in USAMRMC-Supported Extramural Research

Executional Management Activity

Science Officer (SO)
Contracting Officer's (Technical) Representative (COR/COTR)

Common Goal

Support the Investigators'/Institutions' Efforts to Complete High Quality, Regulatory Compliant DoD-Supported Research

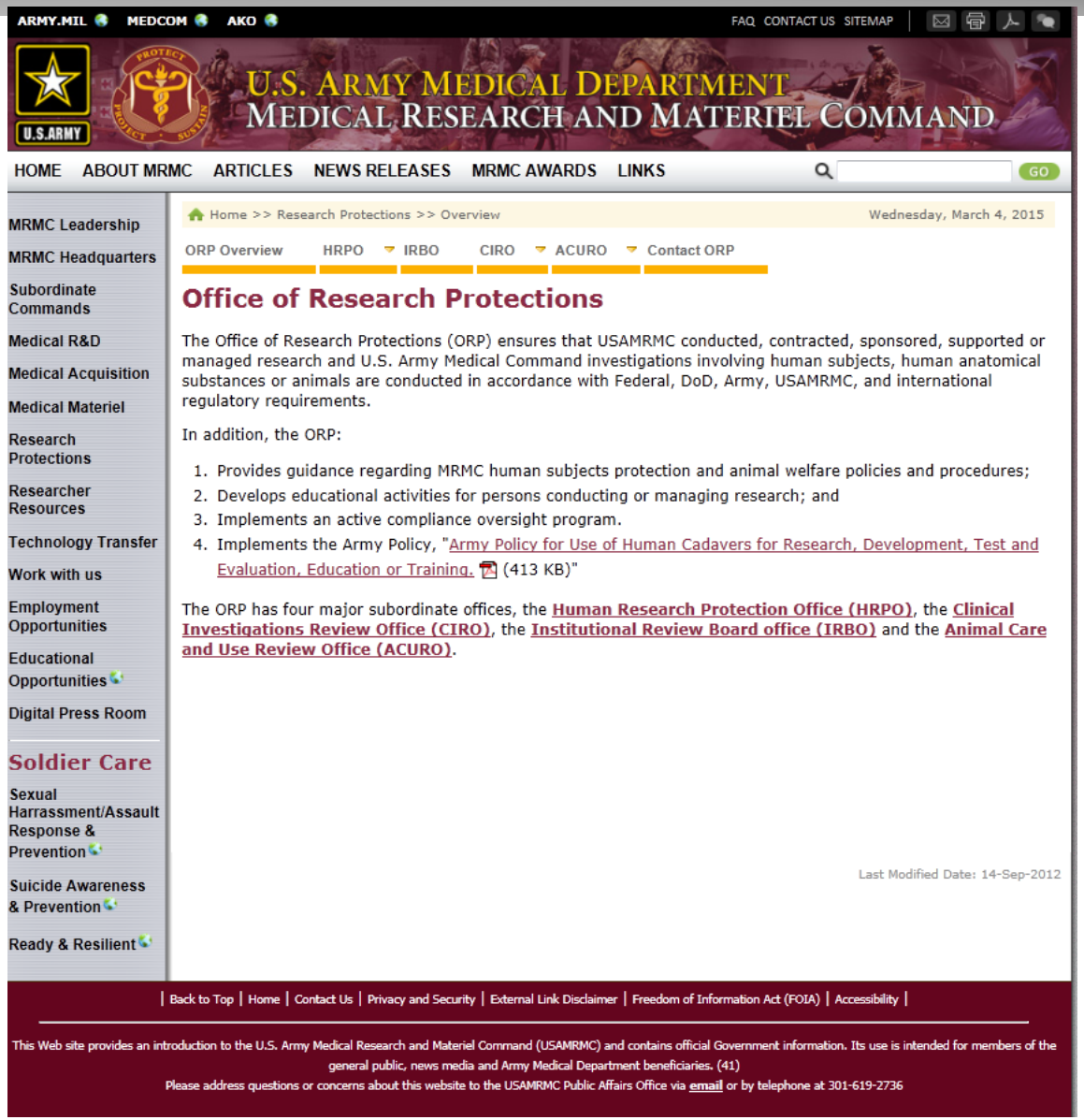
Office of Research Protections

Human Subjects Protection Scientist
Animal Use Specialist

US Army Medical Research Acquisition Activity

Contracting Officer
Contract Specialist

ORP Website



ARMY.MIL MEDCOM AKO FAQ CONTACT US SITEMAP

U.S. ARMY MEDICAL DEPARTMENT
MEDICAL RESEARCH AND MATERIEL COMMAND

HOME ABOUT MRMC ARTICLES NEWS RELEASES MRMC AWARDS LINKS GO

MRMC Leadership
MRMC Headquarters
Subordinate Commands
Medical R&D
Medical Acquisition
Medical Materiel
Research Protections
Researcher Resources
Technology Transfer
Work with us
Employment Opportunities
Educational Opportunities
Digital Press Room

Soldier Care

Sexual Harrassment/Assault Response & Prevention
Suicide Awareness & Prevention
Ready & Resilient

Home >> Research Protections >> Overview Wednesday, March 4, 2015

ORP Overview HRPO IRBO CIRO ACURO Contact ORP

Office of Research Protections

The Office of Research Protections (ORP) ensures that USAMRMC conducted, contracted, sponsored, supported or managed research and U.S. Army Medical Command investigations involving human subjects, human anatomical substances or animals are conducted in accordance with Federal, DoD, Army, USAMRMC, and international regulatory requirements.

In addition, the ORP:

1. Provides guidance regarding MRMC human subjects protection and animal welfare policies and procedures;
2. Develops educational activities for persons conducting or managing research; and
3. Implements an active compliance oversight program.
4. Implements the Army Policy, "Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation, Education or Training. (413 KB)"

The ORP has four major subordinate offices, the **Human Research Protection Office (HRPO)**, the **Clinical Investigations Review Office (CIRO)**, the **Institutional Review Board office (IRBO)** and the **Animal Care and Use Review Office (ACURO)**.

Last Modified Date: 14-Sep-2012

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This Web site provides an introduction to the U.S. Army Medical Research and Materiel Command (USAMRMC) and contains official Government information. Its use is intended for members of the general public, news media and Army Medical Department beneficiaries. (41)
Please address questions or concerns about this website to the USAMRMC Public Affairs Office via email or by telephone at 301-619-2736

Office of Research Protections

Supports the *HQ USAMRMC Institutional Review Board* and the *Research Ethics Advisory Panel*

Human Research Protection Office (HRPO)

- USAMRMC policy and compliance oversight for USAMRMC labs and institutes
- Compliance oversight for all USAMRMC-supported intramural and extramural research
- Under agreements provide intramural and extramural oversight to other Army and DoD organizations
- Consults the USAMRMC Research Ethics Advisory Panel

Clinical Investigation Regulatory Office (CIRO)

- Compliance oversight for all human research at all Army Medical Treatment Facilities
- Pre-approval of studies involving medical products/devices to ensure FDA regulatory compliance
- Instrumental staff assistance via education series, Staff Assistance Visits, and real time resource for problem solving

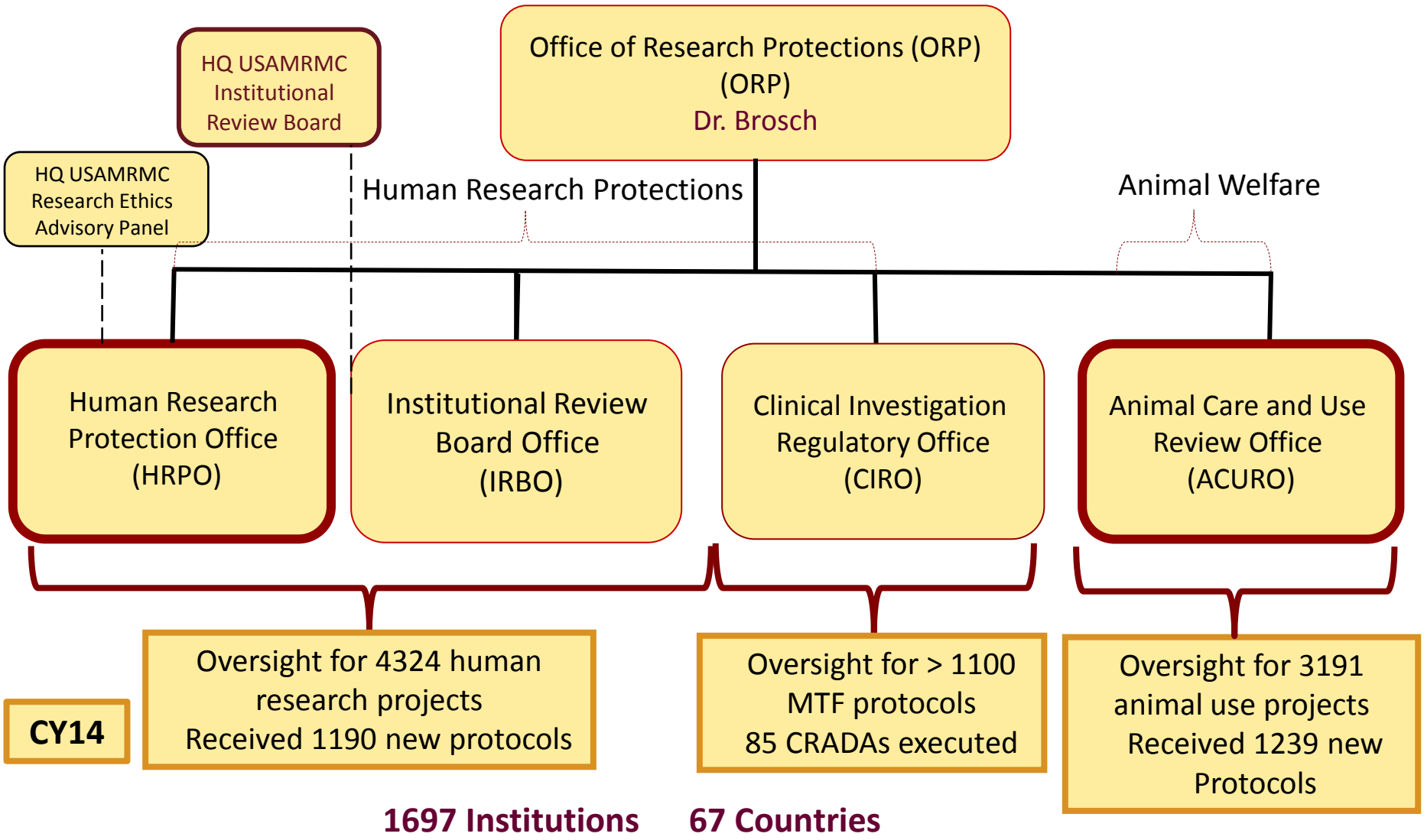
Institutional Review Board Office (IRBO)

- Supports HQ USAMRMC IRB - the primary IRB for several USAMRMC labs/institutes
- Supports many Army/DoD institutions without their own IRBs
- Can serve as a Central IRB for DoD studies conducted at multiple sites

Animal Care and Use Review Office (ACURO)

- Animal care and use review oversight for all Army-supported research involving animals
- Oversight for Army Combat Trauma Training involving live animals
- Under agreements provide intramural and extramural oversight to other DoD organizations
- Lab Animal Residency Program

HQ USAMRMC ORP Organization



Human Research Protections

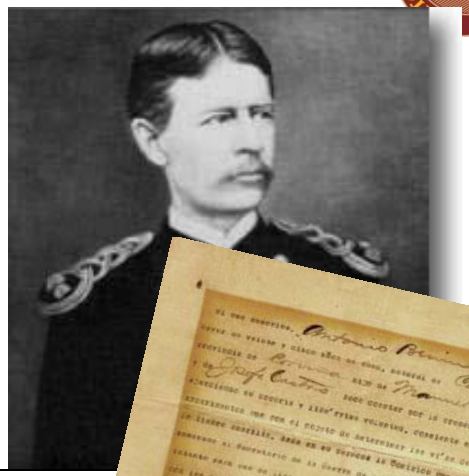
UNCLASSIFIED

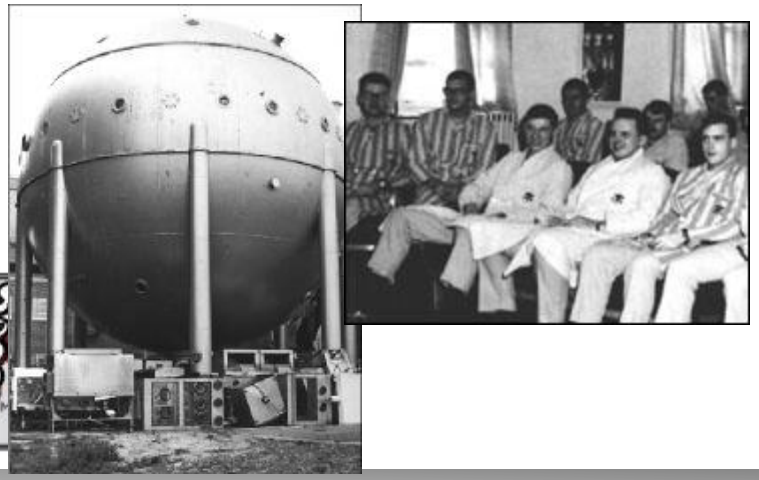
HRPO Website

Human Research Protections in the DoD

Important DoD contributions

- Walter Reed
  - Informed Consent
- Wilson Memorandum 1953
  - Implemented Nuremburg Code
- Operation Whitecoat





Human Research Protections in the DoD

Checkered past -

"Atomic Soldiers"

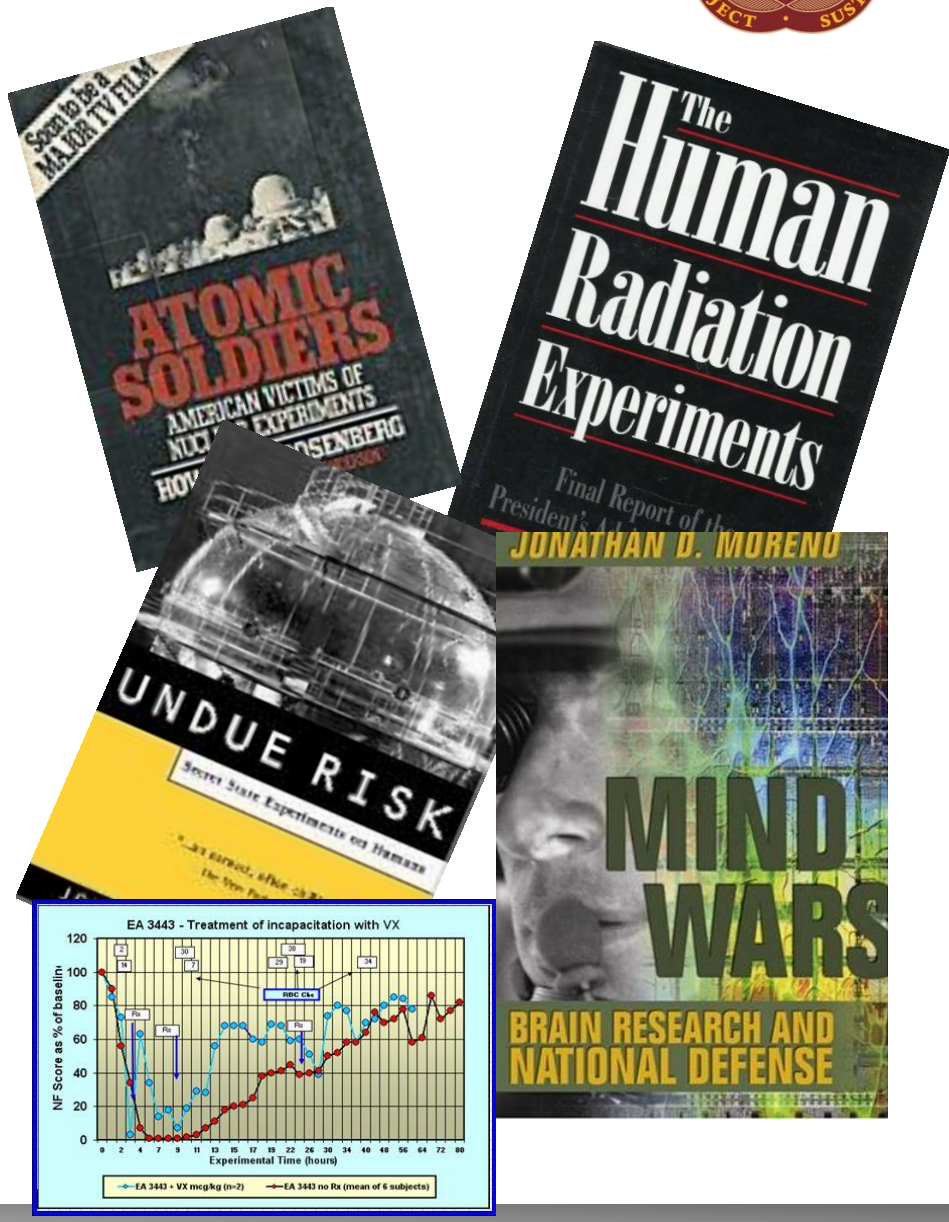
- injurious exposures
- absences of controls
- no informed consent
- poor record-keeping

LSD experiments

- CIA at Fort Detrick
- Army at Edgewood

Incapacitating Agents

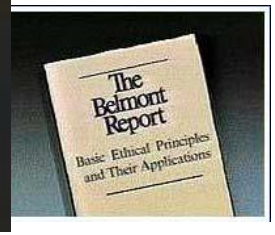
- Army Chemical Center
- Volunteer participants

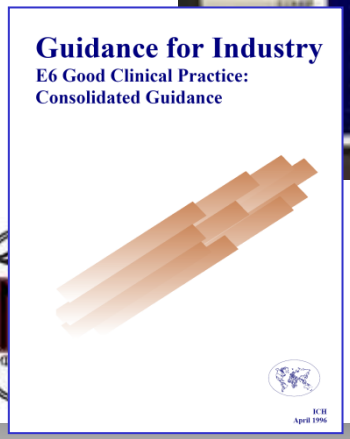


Human Subjects Research Regulations

DHHS

- 45 CFR 46 Subparts A,B,C,D
- 21 CFR 50,56,812
- FDA Guidances
- OHRP Guidances
- HIPAA
- State laws



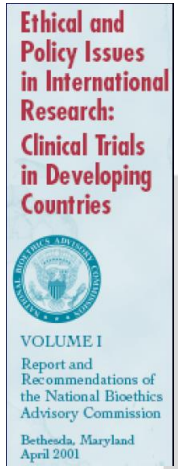


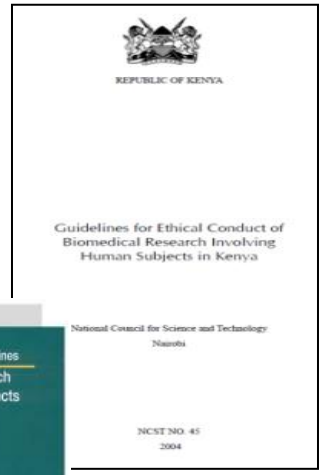
DoD

- 10 USC 980
- 32 CFR 219
- 45 CFR 46 Subparts B,C,D
- DoDI 3216.02
- DoDI 6200.02
- Component-specific regulations (e.g., Army, Navy, Air Force)
- State laws

International

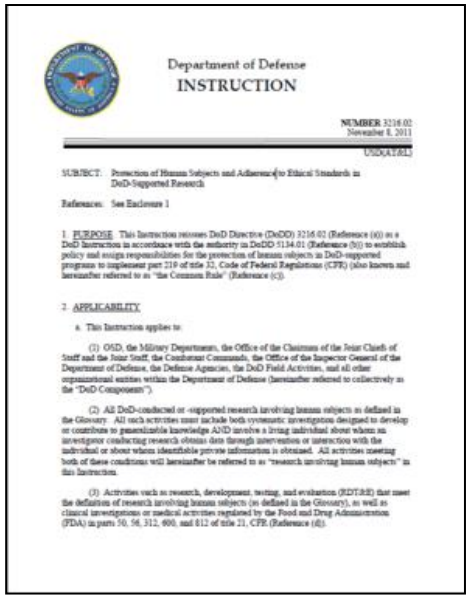
- Country-specific laws and regulations
- Declaration of Helsinki
- Council for International Organizations of Medical Sciences (CIOMS)





Human Subjects Protection Requirements for DoD-Supported Research

DoD Instruction (DoDI) 3216.02 (November 2011) = Common Rule + FDA + Local/Host National + DoD requirements



Department of Defense
INSTRUCTION

NUMBER 3216.02
November 8, 2011

USD(AT&L)

SUBJECT: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research

References: See Enclosure 1

1. PURPOSE. This Instruction reissues DoD Directive (DoDD) 3216.02 (Reference (a)) as a DoD Instruction in accordance with the authority in DoDD 5134.01 (Reference (b)) to establish policy and assign responsibilities for the protection of human subjects in DoD-supported programs to implement part 219 of title 32, Code of Federal Regulations (CFR) (also known and hereinafter referred to as "the Common Rule" (Reference (c)).

2. APPLICABILITY

a. This Instruction applies to:

(1) OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the Department of Defense (hereinafter referred to collectively as the "DoD Components").

(2) All DoD-conducted or -supported research involving human subjects as defined in the Glossary. All such activities must include both systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or about whom identifiable private information is obtained. All activities meeting both of these conditions will hereinafter be referred to as "research involving human subjects" in this Instruction.

(3) Activities such as research, development, testing, and evaluation (RDT&E) that meet the definition of research involving human subjects (as defined in the Glossary), as well as clinical investigations or medical activities regulated by the Food and Drug Administration (FDA) in parts 50, 56, 312, 600, and 812 of title 21, CFR (Reference (d)).

Defense Finance Acquisition Regulations System (DFARS) clause for contracted human subjects research or comparable clause for other mechanisms of DoD support for extramural research

DoD Instruction 3216.02

- DoDI 3216.02 requires:
  - IRB of Record review for non-exempt human subjects research
  - ***Human Research Protection Official (HRPO)*** administrative review for compliance with human subjects protection regulatory requirements for all extramural research and select categories of intramural research

- ***HRPO*** review consists of an assessment of the basic human subjects protection regulatory compliance (to include unique DoD requirements) of a USAMRMC supported protocol. ***HRPO review is not a second "DoD IRB review "***

- HRPO approval indicates that a protocol has been determined to be in compliance with regulatory requirements

"Protections of Human Subjects in Research" Clause

- 2009 clause for use in DoD contracts/agreements involving human subjects in research
- Identifies contractor responsibilities to oversee execution of the research to ensure regulatory compliance
- Describes the role of a DoD Human Research Protections Official (HRPO)
- Prohibits performance of the research activities involving human subjects until HRPO has reviewed and approved the protocol, accepts the Federal Assurance(s) and IRB documentation from the institution

"Protections of Human Subjects in Research" Clause

- Contractor must include similar language in subcontracts that support research involving human subjects.
- Allows DoD review and inspection of contractor records
- Allows DoD representatives to prohibit research that is determined to present unacceptable hazards or is non-compliant with DoD regulatory requirements

HRPO Administrative Review, Approval and Compliance Oversight

- The ORP HRPO has designated approval authorities to meet the DoDI 3216.02 and DFARs *HRPO* requirement
- We conduct criteria-based reviews to assure studies are in compliance with DoD, Army and other applicable human subjects regulatory requirements
- ***Work directly with Principal Investigator and Site Principal Investigators (with few exceptions)*** to ensure all human subjects regulatory requirements are met and DoD-required language is in the protocol and consent form
- Continuing compliance oversight - initial approval to final report or for ***duration of award***

Appointment of a Research Monitor

- Required for all ***greater than minimal risk research studies***
- Must be independent of research team
- Different from a Sponsor's "Medical Monitor"
- IRB must approve *by name* and include description of duties, authorities and responsibilities
- One research monitor is required, but more than one may be needed based on specific circumstances of the research
- May be an ombudsman or member of Data Safety Monitoring Board
- Duties should be based on specific risks and concerns of the research. Should have independent authority to take steps to protect individual subjects

DoD Unique Human Subject Protections

10 USC 980 Restriction on use of DoD funds

DoD Funds may not be used for research involving human being as ***an experimental subject***

> ***Unless***: informed consent of subject is obtained in advance; or if research is intended to be beneficial to the subject, informed consent is obtained from legally authorized representative

Implications

If protocol meets DoDI 3216.02 definition of ***experimental subject*** and includes persons who cannot consent for themselves, protocols must include description of how the research is intended to benefit ***each subject*** in the protocol (placebo and treatment arms)

CAN BE WAIVED BY THE SECRETARY OF THE ARMY

DoD Unique Human Subject Protections

- Special considerations for recruitment of military personnel in selected types of studies
  - No Chain of Command involvement in recruitment
  - Ombudsperson
- Negotiating access – required military approvals
- Limitations in compensation for research participation
- Considerations for risk of breach in subject confidentiality
- Feasibility and operational constraints-deployability considerations

DoD Unique Human Subject Protections

- A statement that DoD is funding the study
- A statement that representatives of the DoD are authorized to review research records
- Representatives of the DoD are an entity to whom protected health information (PHI) can be disclosed in HIPAA Authorization

HRPO Administrative Review Timeline

- HRPO Recommendations provided to Principal Investigator by HSP Scientist within 15 working days of complete protocol submission. ***Studies can go "straight to approval" if all requirements are met!***

- Principal Investigator provides response and revised documents (if needed) to HSP Scientist.

- HSP Scientist reviews and makes recommendation to HRPO Approval Authority whether all revisions have been adequately addressed.

- HRPO Approval Authority approves study if all requirements met.

HRPO Reporting /Life Cycle Requirements

- Human research ***will not be initiated*** until HRPO approval memo sent to each site (memo specifies reporting requirements):
- Life Cycle Actions – PI must promptly report to HRPO (per DoDI 3216.02)
  - Substantive Amendments to the Protocol (and Statement of Work)
  - Continuing Review Reports Provided to IRB
  - Related Serious Adverse Events & DSMB Reports
  - Unanticipated Problems Involving Risks to Subjects or Others
  - Final Study Report Provided to IRB
  - Any suspensions, terminations and serious or continuing non-compliance regarding the DoD-supported research

HRPO Closure of Protocol

- HRPO tracks each protocol to closure due to completion or withdrawal, termination, and end of award – whichever comes first.

- HRPO ***must know*** whether a project will continue beyond the end date of the period of performance (e.g., EWOF, continuation award, other)

Special Circumstances: Research with other DoD Components /Federal Agencies

- **Survey Research**
  - Component requirements (Army, Navy, Air Force) – research that crosses Commands requires additional review by a Component Survey Office
  - Research that crosses Components – review by Defense Manpower Data Center and Washington Headquarters Service
- **Deferral of Oversight**

  HRPO can defer oversight to Navy, Air Force, or USD P&R (e.g., for USUHS) or a federal agency that is a “Common Rule” Signatory (e.g. VA, DHHS) (Case by case basis)

Efficiencies for Multi-Site Studies

Consider centralized protocol coordination

"Coordinating Center" approves core protocol and submits IRB approved documents to HRPO; HRPO approved protocol distributed to sites to submit to IRBs; Site specific documents submitted to HRPO for approval of each site

Consider time for regulatory reviews and reporting

When planning the protocol, consider time for IRB and DoD human subjects protection reviews, additional DoD regulatory reporting responsibilities across sites

Ensure adequate resources (e.g. study coordinator) are available

Coordination and management of regulatory documentation, communication, and reporting across sites

Challenges that can Cause Delays

- Unclear/undetermined/incorrect regulatory pathways for FDA-regulated research.
- Lack of adequate personnel to address IRB and regulatory processes (e.g. study coordinator).
- Inadequate PI or coordinating center oversight for multi-center studies.
- Difficulty in identifying the scope of DoD funded work.
- Determining what is DoD-funded work when it is added as an amendment to an ongoing protocol.
- Tracking continuation of work previously reviewed by HRPO, when protocols cross awards or funding agencies.
- SBIR awards for human research involving institutions without Federal Wide Assurances (FWAs)

Formula for Success

Program Announcement

Program Announcement
for the
Defense Health Program
Defense Medical Research and Development Program
Department of Defense
Congressionally Directed Medical Research Programs
Peer Reviewed Orthopaedic Research Program
Clinical Trial Award

Funding Opportunity Number: W81XWH-14-PRORP-CTA
Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), June 27, 2014
- **Invitation to Submit an Application:** August 2014
- **Application Submission Deadline:** 11:59 p.m. ET, October 24, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, October 29, 2014
- **Peer Review:** December 2014
- **Programmatic Review:** February 2015

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"The Congressionally Directed Medical Research Program Award Guide for Funded Investigators "

CDMRP
Department of Defense

THE CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS AWARD GUIDE FOR FUNDED INVESTIGATORS

March 2014 revision

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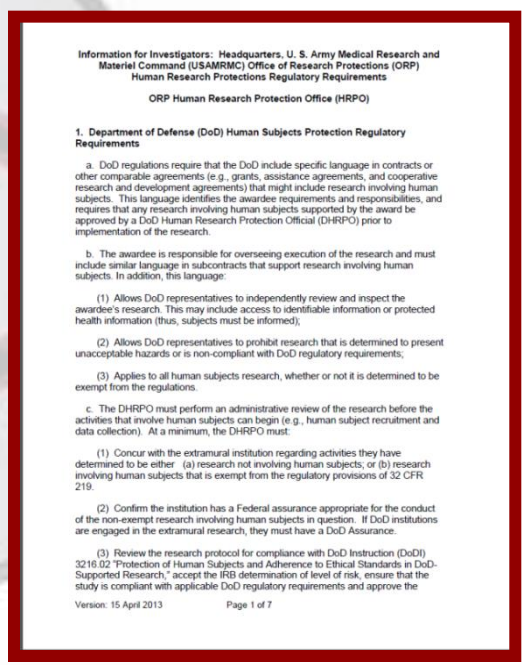
"HRPO Information for Investigators"
"Protocol Submission Forms"



Information for Investigators: Headquarters, U. S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Human Research Protections Regulatory Requirements

ORP Human Research Protection Office (HRPO)

1. Department of Defense (DoD) Human Subjects Protection Regulatory Requirements

a. DoD regulations require that the DoD include specific language in contracts or other comparable agreements (e.g., grants, assistance agreements, and cooperative research and development agreements) that might include research involving human subjects. This language identifies the awardee requirements and responsibilities, and requires that any research involving human subjects supported by the award be approved by a DoD Human Research Protection Official (DHRPO) prior to implementation of the research.

b. The awardee is responsible for overseeing execution of the research and must include similar language in subcontracts that support research involving human subjects. In addition, this language:

(1) Allows DoD representatives to independently review and inspect the awardee's research. This may include access to identifiable information or protected health information (thus, subjects must be informed);

(2) Allows DoD representatives to prohibit research that is determined to present unacceptable hazards or is non-compliant with DoD regulatory requirements;

(3) Applies to all human subjects research, whether or not it is determined to be exempt from the regulations.

c. The DHRPO must perform an administrative review of the research before the activities that involve human subjects can begin (e.g., human subject recruitment and data collection). At a minimum, the DHRPO must:

(1) Concur with the extramural institution regarding activities they have determined to be either (a) research not involving human subjects; or (b) research involving human subjects that is exempt from the regulatory provisions of 32 CFR 219.

(2) Confirm the institution has a Federal assurance appropriate for the conduct of the non-exempt research involving human subjects in question. If DoD institutions are engaged in the extramural research, they must have a DoD Assurance.

(3) Review the research protocol for compliance with DoD Instruction (DoDI) 3216.02 "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," accept the IRB determination of level of risk, ensure that the study is compliant with applicable DoD regulatory requirements and approve the

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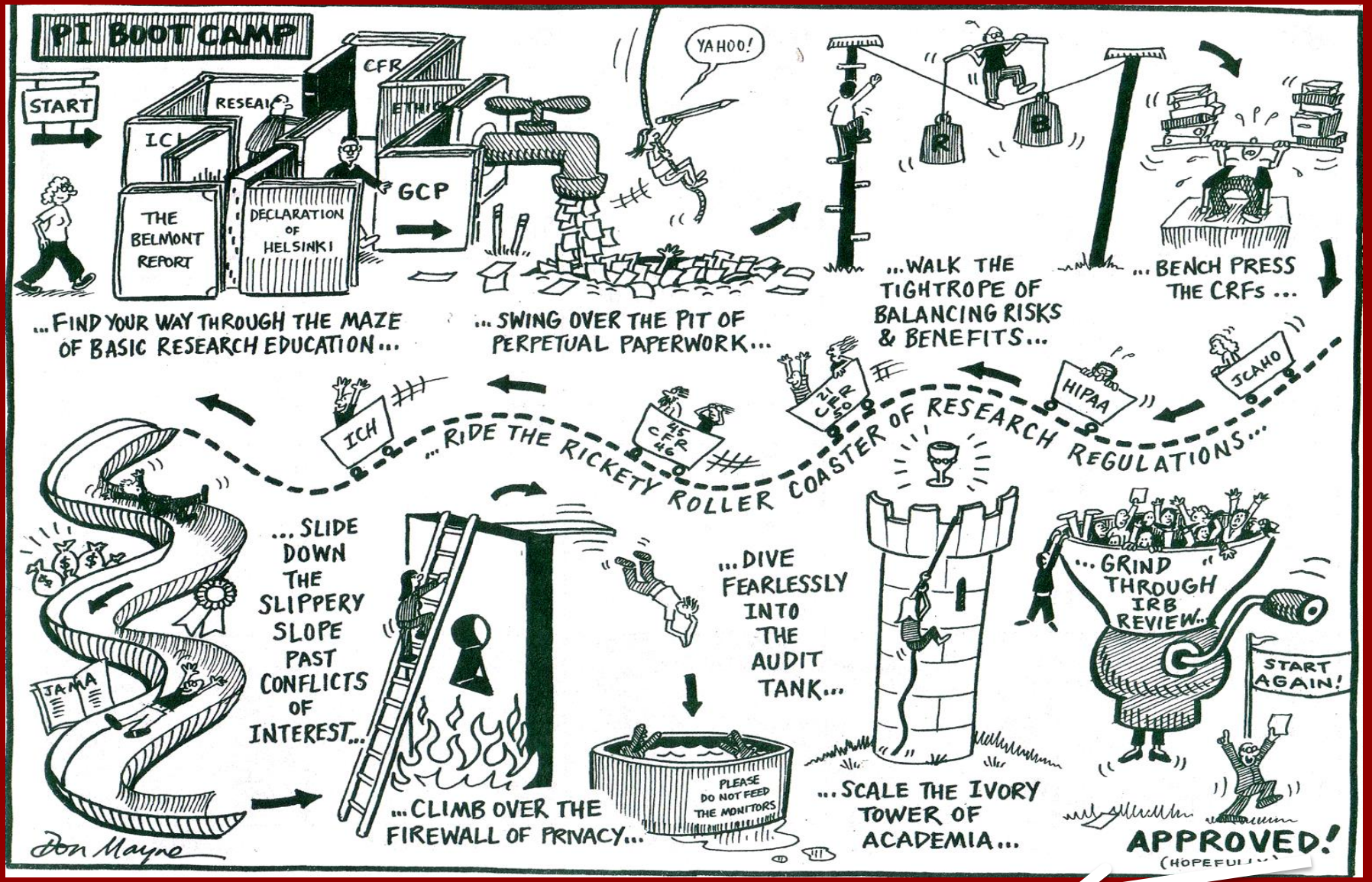
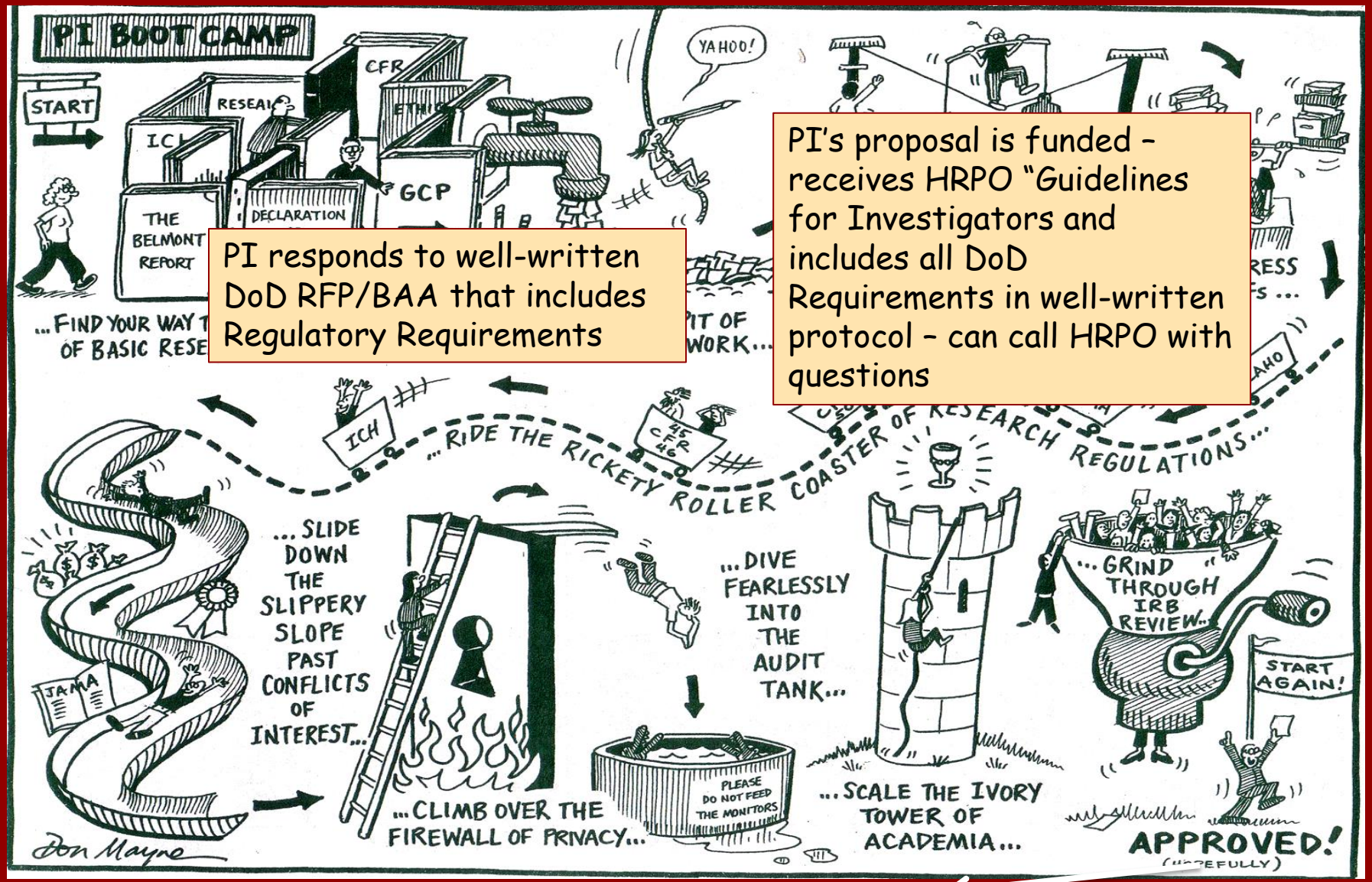
Investigator's Perception of the Regulatory Roadmap



....Then the DoD process begins .... NOT!!!

Improved Version - Regulatory Roadmap



PI responds to well-written DoD RFP/BAA that includes Regulatory Requirements

PI's proposal is funded – receives HRPO "Guidelines for Investigators and includes all DoD Requirements in well-written protocol – can call HRPO with questions

….Submits IRB-approved protocol to HRPO for approval

….STARTS recruitment/enrollment/study

Human Research Points of Contact

https://mrmc-www.army.mil

Under Research Protections, Select HRPO (Human Research Protection Office)

For questions and electronic submissions:
usarmy.detrick.medcom.usamrmc.other.hrpo@mail.mil
Office Phone: (301) 619-2165 (DSN 343)

Animal Care and Use Review

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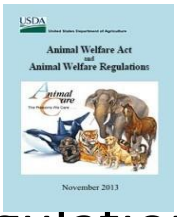
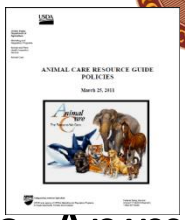
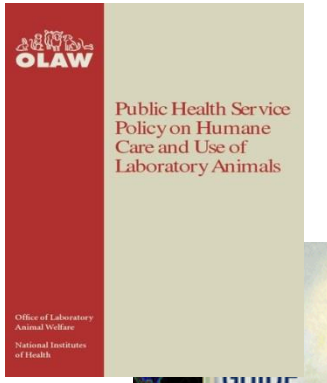
Regulations that Govern Animal Care and Use

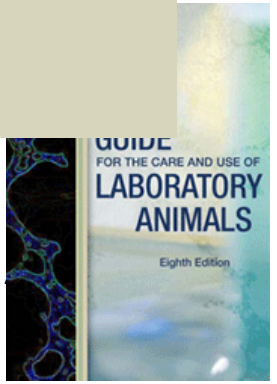




- USDA
  - Animal Welfare Act; Animal Welfare Regulations; Animal Welfare Policies
- DHHS (NIH)-Office of Laboratory Animal Welfare

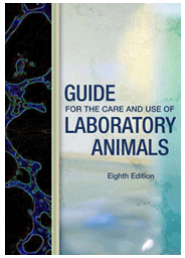
  -Animal Welfare Assurance
  - PHS Policy and “The Guide”
- Contract Clauses for extramural research
  - ACURO’s Prohibition Clause
    - Indicates that animals may not be used in any way without approval from , including amendments to existing protocols

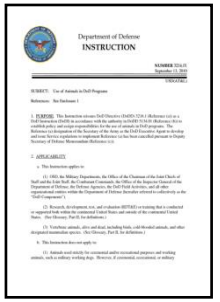




Regulations that Govern Animal Use Protection

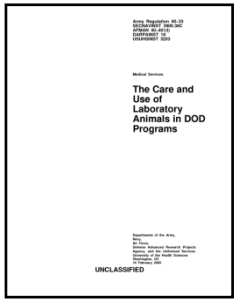
- Association for Assessment and Accreditation of Laboratory Animal Care, International
  - Best practices-The Guide




Department of Defense
INSTRUCTION

- DoD Instruction (DoDI) 3216.01 (13 Sep 2010) and the Joint Regulation
- Joint Regulation AR 40-33; SECNAVINST 900.38C;

AFMAN 40-401(I); DARPAINST 18; USUHSINSTR 3203


The Care and Use of Laboratory Animals in DOD Programs

UNCLASSIFIED

Documents Required for Review

- Institutional Animal Care and Use Committee (IACUC)-approved animal use protocol
  - ACURO only reviews protocols that have been approved by the research site's IACUC
- Documentation of IACUC approval
  - Original approval of the protocol, not just the most recent
  - Approval document may come in many forms
- Completed ACURO animal use appendix
  - Must use current version
  - Abbreviated or full version

Submission to ACURO

- Documents may be submitted to:
- Directly to ACURO via email from PI (Usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil)
  - Upon receipt, ACURO staff will confirm receipt of submission

All ACURO staff provide courtesy copies of ALL correspondence throughout the entire review process to: Funding agency POC (Science Officers, CORs, GORs, Grants Managers, etc.), Contract Specialist, Award PI, Protocol PI, other institutional contacts identified in submission or requested during review

ACURO Review Process

Step 1: Administrative Staff Processing-collection of ALL required documents

Step 2: Assigned to Review Specialist on a first come first served basis

Step 3: Veterinary Review

Step 4: Approval Letter

-***Must have approval prior to initiation of study!!!***

- Step 5: Site Visit (if applicable)
  - Non human primates, Dog, Cat, marine mammals OR other determining factor revealed during review (visibility)
  - MAY be waived IF AAALAC FULL Accreditation (clean record with USDA, OLAW, etc.)
  - Site visit is conducted AFTER ACURO approval not before
  - Timing is determined by veterinarian preference but generally is conducted when work begins

Reporting Requirements

ACURO's approval letter outlines all of the reporting requirements

-Life cycle reports: all modifications, triennial and de novo reviews

-serious or continuing noncompliance

-any serious deviation from "The Guide"

-any suspensions of protocols by the IACUC

-adverse events (animal welfare issues, disasters, animal rights issues, etc.)

-AAALAC, OLAW, USDA regulatory noncompliance of Program or Facility

If there's any question about whether an incident should be formally reported to ACURO, just contact us and ask. It's much better to err on the side of caution than to have an incident go unreported and have us discover it at a later time. (timely reporting-5 days)

Common Causes of Approval Delays

- Submission of incorrect documents. ACURO doesn't accept old versions of the appendix so it's important to download the current version for each submission. We must have the IACUC approval for the original protocol and any amendments; not just the most recent review.
- Communication issues: The time to approval of a protocol rests mainly on the PI's shoulders; timely responses are critical to an efficient review
- Failure to address issues raised. Protocol PIs frequently mistake the importance of addressing all issues raised. When all questions aren't answered, it means additional rounds of correspondence, adding time and frustration to the review.

Additional Considerations

- PIs MUST plan for up to 60 days for ACURO review and approval. Can be faster if packet is complete upon submission

- ACURO requires that every protocol amendment be submitted for review and approval prior to initiation
  - including administrative changes such as additional personnel, minor amendments like blood collection changes, as well as major amendments such as additional animals and procedure changes.
  - No retroactive approvals - all work performed **without** ACURO approval will be non-compliant with the terms of the award.

- International work- International work- Host national regulations apply in addition to DoD requirements (regulatory comparability review conducted by ACURO requires additional time- contact ACURO early)

Ongoing Requirements

Lifecycle Actions:

- Throughout the life of an award, all protocols must adhere to ACURO's review requirements. These include ACURO review of:
- The initial protocol
- All protocol amendments (even minor administrative changes)
- All protocol rewrites (either triennial or annual de novo review depending upon the site)
- All adverse events, protocol violations, etc as described above in reporting requirements
- USDA inspection reports for each research site (generally downloaded from USDA's web page)

Close-Out

- Protocols are closed out in several different ways.
  - Notification from PI that work on a protocol has been completed
  - Notification from PI that protocol is being terminated and replaced by a new protocol
  - Failure to respond to requests for documents

- Awards are only closed out when award period has ended and we've confirmed that no extensions will be granted or when we've been notified officially by the funding agency or USAMRAA

ACURO Website

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U.S. ARMY MEDICAL DEPARTMENT
MEDICAL RESEARCH AND MATERIEL COMMAND

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Animal Care and Use Review Office (ACURO)

The Animal Care and Use Review Office (ACURO), a component of the USAMRMC Office of Research Protections (ORP), implements the animal care and use policies of USAMRMC. While the ACURO is located organizationally at the USAMRMC in Fort Detrick, Maryland, ACURO's responsibility for laboratory animal welfare extends beyond Fort Detrick to a large number of recipients of USAMRMC managed contracts and grants involving animals.

Specific ACURO responsibilities include:

- Implementation of USAMRMC Animal Care and Use Policies
- Review of animal use proposals and protocols
- Evaluation for compliance with USAMRMC and DOD Policies and other applicable standards
- Reporting of USAMRMC animal use
- Site visits to institutions receiving USAMRMC support and funding

USAMRMC and the Department of Defense animal use policy applies to any live vertebrate animal, which is being used or is intended for use in a DOD animal care and use program or to any recipient of a USAMRMC managed contract or grant.

Regulations, Standards & Requirements

- Compliance with USAMRMC policy requires familiarity with each of these documents. This section briefly describes each one and includes a link to the full text.

Requirements for Contracts, Grants and Cooperative Research and Development Agreements

- Information in this section is relevant to the investigator submitting an animal use appendix to USAMRMC. As the ACURO office reviews the animal use appendix, there are common areas that frequently require additional information or clarification. We have tried to highlight those areas in this section.

Resources

- Regulations, Standards & Requirements
- Requirements for Contracts, Grants and Cooperative Research and Development Agreements
- Additional Information and Useful Guidelines
- View the Animal Use Appendix

Last Modified Date: 10-Nov-2011

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Contacts

- Website:

https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1

Army Requirements for Research, Development, Testing, Evaluation, Education or Training using Human Cadaveric Specimens

Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation, Education or Training

- "Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation, Education or Training" dtd 20 April 2012
- Policy Applicable to:
  - All DA-conducted or -supported research, development, test and evaluation, education or training activities involving human cadavers.
- Policy Does Not Apply to:
  - Therapeutic uses of cadavers
  - e.g., organ donation, tissue transplantation, etc., which are regulated by FDA & other federal laws/regulations
- Additional Requirements:
  - Policy has baseline requirements for all applicable activities.
  - Some additional requirements for activities involving "sensitive uses"
  - Sensitive Use is defined as activities that involve exposing cadavers to impacts, blasts, ballistics testing, crash testing and other destructive forces

Considerations for Approval

To approve an activity IAW Army policy, ORP reviews the following **at a minimum**:

- **Proposal** – what activities were funded?
- **Scientific review** – were the proposed tests found to be scientifically valid?
- **Protocol, test plan or other governing document** – what are the details (number of cadavers, location of tests, blast pressures, test environments, etc.)?
- **Review by performance institution** – were all institutional requirements for approval/oversight met (e.g., reviewed by the institutional anatomical substance review board, the IRB office, etc.)?
- **Vendor information** – are vendors licensed; what communicable disease testing occurs; cadavers are properly and legally procured; what state laws apply to procurement?
- **Sample body donation form** – what was donor's expectation about use of their donation (i.e., was the donation form and/or supplemental info written so that prospective donors would have had a reasonable expectation their bodies would be used for the proposed activity)?
- **Activity-specific procedures** – how are cadavers stored or transported to the activity site from procurement site; can personnel opt-out of taking part in the activity without prejudice; is psychological help available if sought?

"Sensitive Use" Approval

Additional considerations for ORP approval of "**sensitive uses**," i.e. exposure to impacts, blasts, ballistics testing, crash testing, and other destructive forces:

- **Donor Expectation Plus** – Based on the donation form, would donors have a reasonable expectation that their bodies could be used for such activities?
- **Designed for Maximum Respect** – Are the tests designed to limit access/visibility and ensure respectful handling and disposition?
- **Maximize Protections to Staff** – Are staff aware of the nature of the tests, able to seek mental health care if requested, and able to opt out of testing without prejudice?
- **Strategic Communication to TSG and other DA leaders** – ORP sends the STRATCOM via CG, USAMRMC, to TSG for a 15-day staffing period before issuing approval.

Questions?