AAP PAL Course - 2018

Compliance Issues in PM&R Research

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Disclosures

- Director, American Board of PM&R
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The Central Issue

Protection of Human Subjects

Overview

A. History & General Principles
B. Good Clinical Practice
C. The Role of the IRB
D. Informed Consent
E. HIPAA issues in Research
F. Research Compliance
G. Animal Research
H. Case Studies

A. History & General Principles

- Nazi Germany → *The Nuremberg Code*
- World Medical Association → *Declaration of Helsinki* (`64, `75, `83, `89, '96, '00, '08)
- "Ethics & Clinical Research" (Henry Beecher)
  → U.S. Policies (`66)
- Tuskeegee Syphilis Study (`30s-`72)
  → U.S. Regulations (`74)
- *The Belmont Report* (`74-`78)
  → Revised U.S. Regulations (`81, `83, `91)

Basic Principles of the Belmont Report

- The Belmont Report contains the ethical principles upon which the federal regulations for protection of human subjects are based:
  1) **Respect for persons**
  2) **Beneficence**
  3) **Justice**

1 - Respect for Persons

- Autonomy
- Increased protection for those with diminished autonomy
- Addressed through informed consent process:
  - Information
  - Comprehension
  - Voluntariness

1 - Respect for Persons

- Vulnerable Populations
  - Prisoners
  - Children
  - Fetuses & *in vitro* fertilization
  - Pregnant & lactating women
  - Decisionally impaired
  - Emergency & terminally-ill patients
  - Subordinates
- Special Protections
  - Independent advocate review of study/consent
  - Witnesses to consent process
  - Periodic re-consent
  - Checks of comprehension

2 - Beneficence

- Do no harm
- Maximize possible benefits & minimize risks

- Addressed by performing risk/benefit assessments
  - Risk / Minimal Risk / No Risk
  - Significant Risk / Non-Significant Risk

2 - Beneficence

- Risks
  - Physical
  - Psychological
  - Social
  - Economic
  - Legal
- Benefits
  - To subjects
  - To society
- Remuneration
  - Not a “benefit”
  - Must be reasonable
  - Prorating appropriate

3 - Justice

- Fairness in distribution of research benefits and burdens
  - Balancing act -- Diversity in subject selection is required…
  - …but don't unduly involve persons from groups unlikely to be eventual beneficiaries
  - Don't systematically draw subjects from certain classes
  - Protections for certain groups may be appropriate
- Addressed through research subject selection process (inclusion/exclusion criteria)

Current Environment

- The **Common Rule** (1991) + FDA Regulations
  - IRB (& FDA) Review
  - Informed Consent
  - Assurances of Compliance
- Standardization of Clinical Trials
  - Good Clinical Practice (GCP) = SOP for a Clinical Trial
  - GCP Carry-over into Clinical Research in general
- Federal & Local Oversight
- A Constantly Evolving Environment

Who's Watching You & How Are They Watching?

- Federal review & oversight of research (funding level, compliance level)
  - Funding Agencies
  - Office for Human Research Protections
  - Food and Drug Administration
- Local/Institutional review & oversight of research
  - Institutional Review Boards (IRB's)

Why Are They Watching & What Are They Watching For?

- Research Subjects' Health, Safety & Welfare
- Good Science
- Compliance with Regulations
- Protection of Human Subjects

B. Good Clinical Practice (GCP)

- GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects.
- Compliance with this standard ensures that the rights, safety and well-being of trial subjects are protected, and that data are generated using sound scientific principles.
- The primary objectives of GCP are to:
  - Protect the safety, rights and welfare of subjects participating in clinical trials.
  - Ensure quality, integrity, & credibility of research data and resulting reports.

GCP Origins/Evolution

- GCP requirements were originally developed by the FDA and other regulatory authorities to guide the development of pharmaceutical products.
- Principles embodied in GCP are generally applicable to all research involving human subjects.
- Thus, GCP has been widely endorsed by Sponsors of clinical research, even trials not involving drugs and devices.
- International Conference on Harmonization (ICH) issued the main GCP guidance document in 1996: "**Good Clinical Practice: Consolidated Guidance** (ICH-E6)".

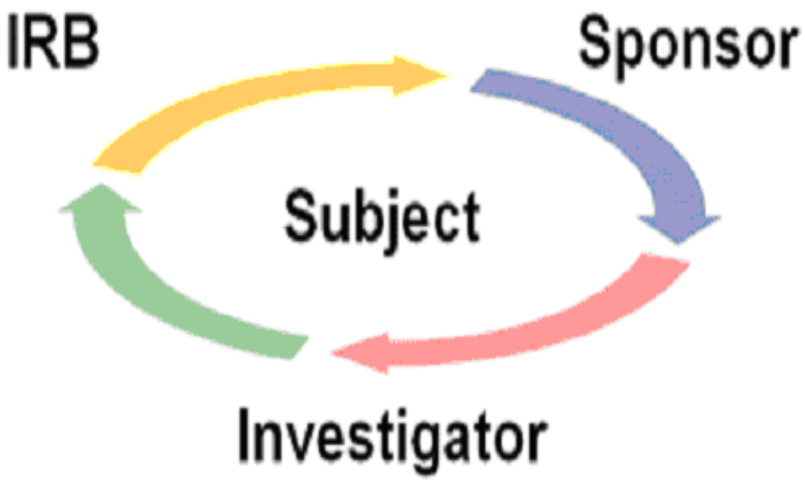
GCP Issues

- Regulatory compliance
- Study design, management & compliance
- Investigator qualifications
- Adequate resources
- Investigational product issues & QA/QC
- Safety issues & assessments
- Adverse Event monitoring & reporting
- Efficacy assessments
- Data handling & monitoring
- Statistics
- Subject selection, informed consent & medical care
- Privacy issues
- Randomization
- Blinding & Unblinding
- Communications
- Documentation
- Records & Reports
- Monitoring & Audits
- Compensation, insurance & other financial issues
- Publication policy
- Ethics

GCP "Partners"

- GCP identifies and focuses on three groups that cooperate in the conduct of a clinical trial:

  Sponsors, Investigators, IRBs



GCP - Sponsor

- Sponsor: An individual, company, institution or organization that takes responsibility for the initiation, management and/or financing of a clinical trial.
- Sponsor responsibilities include:
  - Those specified in federal regulations.
  - Trial design, management, record keeping.
  - Selecting Investigators.
  - Confirming IRB approval.
  - Manufacturing, labeling, and supplying investigational products.
  - Monitoring and auditing for quality assurance.
  - Other responsibilities as mandated.

GCP - Investigator

- Investigator: The person responsible for conducting a research project at the clinical site.
- If research involves a team of individuals, the Investigator is the responsible leader of the Study Team – the Principal Investigator (PI).
- The Investigator bears final responsibility for the safety and welfare of study subjects and the integrity and scientific merit of study findings.
- A PI may assemble a Study Team of researchers to conduct the trial.
- Study tasks may be delegated to team members qualified to perform those tasks.

GCP - Investigator

- Investigator responsibilities include:
  - Those specified in federal regulations.
  - Adhering to the study protocol.
  - Personally conducting and supervising the study.
  - Ensuring informed consent is obtained prior to participation.
  - Reporting adverse events as required by IRB and Sponsor.
  - Knowing the properties of the investigational product.
  - Ensuring that the Study Team is properly trained.
  - Maintaining adequate and accurate records.
  - Ensuring the study receives appropriate IRB and R&D committee review.
  - Ensuring appropriate medical care is provided to subjects.
  - Other responsibilities as mandated.

The Role of the Institutional Review Board

- **Primary Focus: Protection of Human Subjects**
- **Ethical Review of Research**
- Compliance with Federal, State & Local Regulations
- Establish Additional Safeguards for Vulnerable Populations
- Scientific Peer Review
- Administrative Review of Proposals, Contracts, Grants
- Establish COI Policies
- Educate Researchers on Scientific Integrity & Misconduct

Key Definitions

- **"Human Subject"** means 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 individual or a patient.
- **"Institutional Review Board (IRB)"** means any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, and to approve the initiation of and conduct periodic review of such research.
- **"Informed consent"** means a voluntary agreement by an individual to participate in research, based upon adequate knowledge and understanding of relevant information.
- **"Assent"** means a voluntary agreement by an individual, not competent to give legally valid informed consent, to participate in research.
- **"Legally authorized representative"** means an individual or judicial or other body authorized under applicable law to "give permission" on behalf of a prospective subject for the subject's participation in research.
- An **"adverse effect" or "adverse event"** is an undesirable and unintended, although not necessarily unexpected, result of an intervention/investigation.

Levels of Risk

- **"Minimal risk"** means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Expedited Review may be appropriate.
- **Note: "minimal risk" is not synonymous with "non-significant risk".**
- A **"significant risk"** device is one that:
  - Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
  - Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
  - Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
  - Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- A **"non-significant risk"** device is one that does not pose a significant risk.

"Minimal Risk" Examples

- General physical exams
- Routine blood draws (in adults)
- Hair, nail or other biological specimen collection (via non-invasive & non-disfiguring means)
- Non-invasive data collection (w/o sedation or anesthesia) using procedures routinely employed in clinical practice
- Some drug and device studies (if test article does not require IND or IDE and is used in accordance with labeling)
- Research involving materials collected for non-research purposes
- Research involving data from voice, video, digital, or image recordings

NSR & SR Device Examples

- Non-Significant Risk (NSR) Device Examples
  - Surface Stimulators
  - Daily Wear Contact Lenses
  - Some Conventional Scopes & Catheters
  - Traditional Dental Filling Materials
  - Menstrual Pads & Tampons (cotton or rayon)
  - EEG
- Significant Risk (SR) Device Examples
  - Percutaneous & Implant Stimulators
  - Extended Wear Contact Lenses
  - Some Scopes & Catheters
  - Dental Endosseous Implants
  - Cervical Caps, Diaphragms, IUDs, Sponges
  - Implanted Intracranial Pressure Monitor

IRB Review of Research

- An IRB's purpose is to protect the rights and welfare of human subjects involved in clinical investigations.
- An IRB shall review and have authority to approve, require modifications to, disapprove, suspend or terminate all research activities covered by the IRB regulations, as well as to conduct continuing reviews.
- An IRB shall report to appropriate authorities:
  - adverse events,
  - serious or continuing noncompliance, and
  - suspension or termination of IRB approval.
- Some research (minimal risk or less; minor protocol changes) may be reviewed through an expedited review procedure (but can not be disapproved).
- Research reviews take place at convened meetings at which a majority of the members are present, including at least one whose primary concerns are in nonscientific areas. For research to be approved, it must receive the approval of a majority of the members present at the meeting.

Requirements for Research Protocol (CWRU/MHMC)

- Educational Requirements for Key Personnel
  - Continuing Research Education Compliance
    - Core Certification + Continuing Certification
- Departmental Review
  - Chair reviews and signs off, vouching for:
    - Scientific Merit
    - Investigator Qualifications & Privileges
    - Departmental Resources (Budget)
- Clinical Research Unit (CRU), Nursing Review
- Clinical Engineering Review of Equipment
- IRB Review

IRB Protocol Content

- Basic Information
- Description & Rationale
  - Background – Review of Literature
  - Specific Aims & Hypotheses
- Subject Population & Rationale for Special Groups
  - Number / Description
  - Source / Recruitment Method (inc. Advertising)
  - Inclusion / Exclusion Criteria
  - Special Considerations for special groups
- Methods
  - General Study Design
  - Specific Procedures
  - Special Procedures (e.g., INDs, IDEs)
  - Time Schedule
  - Data Analysis

IRB Protocol Content

- Safety / Risk-Benefit Status
  - Risks
  - Precautions to Minimize Risks
  - Benefits
  - Risk-Benefit Status
- Significance / Importance of Knowledge
- Informed Consent
  - Process
  - Informed Consent Form
  - HIPAA Addendum to Informed Consent Form
- Data & Safety Monitoring Plan (DSMP)

D. Informed Consent

- **8 Basic Elements + 6 Additional Elements**
- An education process, during which the investigator must ensure that all pertinent information is fully disclosed and understood.
- Investigator may delegate the consent process to properly qualified and trained individuals.
- Documented by the use of a written consent form approved by the IRB and signed by the subject.
- Subject shall be given a copy of the signed form.
- Provide prospective subjects with sufficient opportunity to consider whether or not to participate, permission to withdraw without penalty.
- Minimize coercion / undue influence.
- Language must be understandable to prospective subjects.
- No exculpatory language through which the subject is made to waive, or appear to waive, any legal rights.
- No exculpatory language that releases, or appears to release, the investigator, the sponsor, the institution, or their agents from liability for negligence.

8 Basic Elements of Informed Consent

1. Statement of research, Purposes, Expected duration of subject's participation, Procedures (identify which are experimental).
2. Risks or discomforts.
3. Benefits reasonably expected.
4. Alternative procedures / courses of treatment.
5. Statement of confidentiality of records. Identify those who may inspect records.
6. Explanation of compensation. Explanation of medical treatments that are available if injury occurs.
7. Contacts to answer questions about the research and research subjects' rights. Contacts for research-related injuries.
8. Statements that participation is voluntary and may be discontinued at any time, and that refusal/withdrawal will involve no penalty or loss of benefits.

6 Additional Elements of Informed Consent

1. Statement that there may be risks which are currently unforeseeable.
2. Anticipated circumstances under which participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs that may result from participation.
4. Consequences of a subject's decision to withdraw, and procedures for orderly termination of participation.
5. Statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be disclosed.
6. Approximate number of subjects involved in the study.

Informed Consent Form Recommendations

- Include a version number. (Version x.y)
- Date it. (Revised **/**/****)
- Paginate. (Page x of y)
- 12-point font minimum.
- Include Study Title on 1st page. Include title identifier on each page (e.g., in footer).
- Keep MASTER original that is returned from IRB and PHOTOCOPY from it for subjects.
- Don't change ANYTHING without having it reviewed and approved by the IRB, no matter how minor.

E. HIPAA Issues in Research

- Disclaimer
  - I am not a lawyer
  - I do not pretend to know everything about HIPAA
  - HIPAA's legal interpretations change frequently
- HIPAA = Health Insurance Portability and Accountability Act of 1996
- Key Definitions
  - PHI: Protected Health Information
  - CE: Covered Entity
  - Workforce: Has access to PHI

HIPAA Research Provisions

- DHHS Office of Civil Rights => IRB or Privacy Board and Risk Management as agents
- 2 of HIPAA's "Administrative Simplification" provisions apply to research:
  - **Privacy Rule – Concerns protecting privacy of all individually identifiable health information in hands of covered entities**
  - **Security Rule – Concerns confidentiality of electronic protected health information**

HIPAA Privacy & Security Rules

- Privacy Rule
  - Applies to all information that is not part of public record
  - Governs any use or disclosure of any form of PHI
  - Requires written Authorization to use or disclose PHI
  - Penalties for violations (civil, criminal, institutional)
- Security Rule
  - Storing & securing electronic PHI
  - Must be specific in IRB protocol
  - Institutions now pay MUCH more attention to this ($$$)
  - Computers/Laptops/PDA's/Jump Drives/Networks/Email
  - Penalties for violations (civil, criminal, institutional)

HIPAA: PHI Disclosure

- Authorization for Research Use & Disclosure of PHI
  - Required for any research activity (creating a database counts)
  - Must be specific to study, & contain "core elements" + "required statements"
  - Can be combined with Informed Consent Form
  - Subject must receive signed copy of the form
  - Requirement can be waived
- Authorization "core elements" and "required statements"
  - What PHI will be used/disclosed
  - Who will receive the PHI
  - Purpose for use/disclosure
  - When the authorization expires (including "None")
  - Right to revoke with process and exceptions for revoking
  - Ability/inability to condition treatment, payment, eligibility on giving Authorization
  - PHI may no longer be protected after initial disclosure

Adverse Events

- Internal vs. External
- Is the Adverse Event…
  - …Serious?
  - …Related or possibly related?
  - …Unexpected?
- Specific reporting requirements for Adverse Events and Deaths vary depending upon the above issues.
- Mandatory Monitoring Processes
- Refer to IRB Guidance for more details.

FDA-Regulated Research

- FDA approves new drugs, biologics & devices for marketing
- FDA requires evidence of Safety, Effectiveness, and Clinical Utility
- Clinical studies are performed under IND (Investigational New Drug) & IDE (Investigational Device Exemption) protocols, with SR/NSR determination
- Pre-clinical research is usually a prerequisite
- Clinical studies of *approved* products also may require an IND/IDE
  - *e.g.,* off-label application or patient population
  - *e.g.,* off-label dosage, duration, administration of a drug
  - *e.g.,* significant reformulation of a drug or redesign of a device

F. Research Compliance

- The effective management of public funds to maximize research outcomes
- The avoidance of fraud, institutional mismanagement, and poor management of Federal funds

What grantees are responsible for…..

- Safeguarding all assets
- Spending funds in accordance with the authorized purpose
- Developing and implementing systems to ensure proper stewardship of funds
  - Financial management systems
  - Procurement systems
  - Time & effort reporting systems
  - Monitoring activities
  - Adherence to terms & conditions of award

Grantee Compliance Requirements

Institutional Policies

- Organizational Structure
- Purchasing
- Accounting/Budgetary Controls
- Time and Effort Reporting
- Travel
- Consulting
- Property Management
- Ethics/Conflict of Interest

Federal Compliance Requirements

Code of Federal Regulations (CFR)

- 42 CFR Part 52 – Grants for Research Projects
  http://www.access.gpo.gov/nara/cfr/waisidx_03/42cfr52_03.html
- 45 CFR Parts 74 & 92 – Public Welfare/Administrative Requirements
  (74) http://www.access.gpo.gov/nara/cfr/waisidx_04/45cfr74_04.html
  (92) http://www.access.gpo.gov/nara/cfr/waisidx_04/45cfr92_04.html
- 45 CFR Part 46 – Public Welfare/Protection of Human Subjects
  http://www.access.gpo.gov/nara/cfr/waisidx_04/45cfr46_04.html

Federal Compliance Requirements

OMB Circulars - http://www.whitehouse.gov/omb/circulars/

Administrative Requirements or Standards:

- **A-102**: Uniform Administrative Requirements for Grants and Cooperative Agreements awarded to State and Local Governments and Indian Tribes
- **A-110**: Uniform Administrative Requirements for Grants and Agreements awarded to Universities, Hospitals, and Other Non-Profit Organizations

These include pre-award and post-award requirements

Federal Compliance Requirements

Cost Principles: Applicable OMB Circulars and CFRs

- **A-21**: Cost Principles for Educational Institutions
- **A-87**: Cost Principles for State and Local Governments and Indian Tribes
- **A-122**: Cost Principles for Non-Profit Organizations
- **45 CFR Part 74, Appendix E**: Principles for Determining Costs Applicable to Hospitals
- **48 CFR Subpart 31.2 (Federal Acquisition Regulation)** Applicable to For-profit organizations

Federal Compliance Requirements

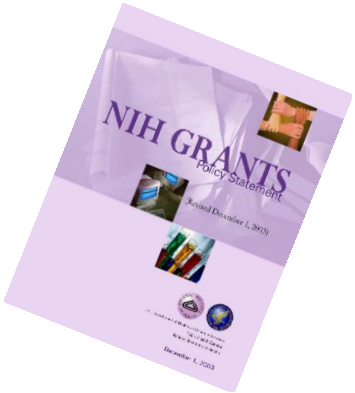
Audit Requirements: Applicable OMB Circular & CFR

- **A-133**: Audits of States, Local Governments, and Non-Profit Organizations
- **45 CFR Part 74.26**: Audits of For-Profit and Foreign Organizations

Federal Compliance Requirements

- NIH Grants Policy Statement
  http://grants.nih.gov/grants/policy/nihgps_2013/
- Notice of Grant Award
- NIH Guide to Grants and Contracts (for new requirements)
  http://grants.nih.gov/grants/guide/index.html

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



Grant Accounting Requires that:

- A separate account is established for each project
- Program Income is identified and accounted for by project
- Program Income is used in accordance with the appropriate alternative (Additive/Deductive/Combination/Matching)
- Expenses are charged in accordance with
  - NGA Terms and Conditions
  - NIH Grants Policy Statement
  - Salary Rate Limitation
  - Cost Accounting Standards
  - OMB Circulars
- ALL expenses are appropriately documented

Budget Monitoring requires that:

- Actual expenses are periodically (at least monthly) compared with budget to ensure:
  - Total funds on the grant have not been exceeded
  - Total funds are used appropriately
  - Total funds for any cost category have not been exceeded if restricted on the NGA
- Actual expenses are accurate, i.e., reasonable, allocable, allowable and consistently charged
- Mischarges are corrected in a timely manner (cost transfers)
- Prior approvals are obtained when required
- **Subrecipient** expenses are monitored - (pass through entity's {Grantee's} responsibility)

Effort Reporting

- Documenting the proportion of work time devoted to:
  - *Research,*
  - *Teaching,*
  - *Administration/service, and*
  - *Clinical activities*
- *as a percentage of total professional activity*.
- Activities that fall outside the terms of appointment:
  - Consulting
  - Service on advisory boards
  - Professional organizations
  - Speaking engagements

Why the current focus on effort reporting?

- High profile audits have resulted in fines at institutions such as Northwestern, Johns Hopkins and Harvard
- Fines resulted from findings that effort and salary records were incomplete and or inconsistent
- Inspector General (OIG) giving high priority to effort certification audits
- All institutions that receive a significant amount of sponsored research funds, must assure government and private sponsors that the effort charged to projects is fair, consistent and timely
- Institutions have to develop a more comprehensive effort reporting system to respond to such expectations.

Effort Reporting Guidelines

- Documents the proportion of work time devoted to various professional activities
- "Reasonable and supportable" (~ 40 – 80 hours/week)
- Allocations based on individual work week (non-standard)
  - 50% of 40 hour work week = 20 hours
  - 50% of 60 hour work week = 30 hours
- Cannot be more or less than 100%
- Cannot report 0% on sponsored projects, except:
  - Equipment/instrumentation grants
  - Institutional/individual training grants for faculty
  - Doctoral dissertation fellows/research assistants

Expectations in reporting effort

- *Reasonable* assessment of time devoted to different activities/duties; a precise assessment is usually not feasible nor is it expected
  - Activities for faculty members change over time and often overlap
    - *e.g.*, faculty member on a clinical service may have students (teaching) and may recruit patients to a clinical trial (research) during clinic hours
- Faculty members must distinguish between salary distribution vs. effort reporting, as the salary distribution may not represent how they spend their time

Who is responsible for the effort report?

- Faculty member must certify effort
  - "Personal Knowledge"
  - Administrators may provide a draft report for the faculty member to review and modify as needed
- The faculty member must feel that the final report is reasonable and defensible
- Everyone who works on sponsored projects must report effort
  - Faculty members report for themselves
  - PI's certify effort for non-faculty personnel on sponsored projects for both key & non-key personnel

Compliance Pitfalls

- Unallowable costs
- Misallocation of costs
- Excessive cost transfers
- Inaccurate effort reporting
- Incomplete other support
- Inadequate subrecipient monitoring
- Administrative & Clerical costs
- Noncompliance with Assurances and special terms and conditions of award
- Delinquent closeout reporting

G. Animal Research Issues

- **"The three R's" from "The Principles of Humane Experimental Technique" by W.M.S. Russell and R.L. Burch**
  - **Replacement: Justify why vertebrate animals must be used. Why are other methods, e.g. in vitro or in silico methods, or invertebrate animal models, unsuitable?**
  - **Refinement: Justify the pain or distress that animals may experience as a result of the proposed work. A search must be performed for alternative or more refined procedures which would cause less pain or distress or would result in better animal welfare. If the procedures performed on animals are not the most refined procedures available (producing the least pain or distress or resulting in better animal welfare), a scientific justification for using the proposed procedures must be provided.**
  - **Reduction: Justify why the number(s) of animals cannot be reduced from those requested. A search showing that the proposed work does not unnecessarily duplicate previous work must be performed. Indicate if the animals can be reused for other purposes.**

H. Case Studies

- **Case Study 1…**

  A University employee transfers funds from one account to another and annotates the cost transfer "to correct an accounting error."

  Internal Audit takes exception. Why?

Case Study 2…

Dr. Micron has a U01 in the -03 year with some unexpected equipment needs. Dr. Micron notices a large amount of unobligated funds from the -02 year.

Can these funds be used to purchase the equipment?

Case Study 2 (Part 2)...

Moving forward a few years, Dr. Micron's grant is now in its final year and is not being renewed. There is an unobligated balance of $100,000. Dr. Micron decides to request a no-cost extension to complete the research.

Is this appropriate?

Case Study 3…

You heard that an employee who works at the University of Woe (UW) was charged with theft by submitting false vouchers. This concerns you because this person is the administrator for a subcontract that supports the research of a PI in your lab.

Your supervisor advises you to stay out of it, it's none of your business. What should you do?

Case Study 4…

You are asked by a PI to stop at an office supply store on your way to work and pick up a few items. The PI also asked you to get some donuts for a lab meeting that morning. When you arrive at work, the PI tells you that all of the items should be charged to the grant.

Your Departmental Administrator tells you that these purchases must come from Departmental funds. Why?

Case Study 5…

You recently learned that a PI did not disclose on his proposal sign-off form that he was debarred for defaulting on his college loan. Unfortunately, you determined that this situation has gone unreported for a period of three years and during that time the PI's salary has been paid by NIH grant funds.

Now what?

Case Study 6…

The Co-Investigator on an NIH grant receives a new NIH award on which he is PI. As a result, he needs to reduce his effort on the existing grant from the initial approved level of 6 person months (50%) to 4.8 person months (40%).

1. Does the grantee institution need to obtain NIH prior approval for this change?

2. What if the PI has similar circumstances and wants to reduce her effort? Is NIH prior approval required?

Case Study 7…

Dr. Miller purchases a much needed piece of specialized equipment for her research on hypertension. When preparing the purchase request, she realizes that the only account with enough money is her grant for research on sleep disorders. Because both grants are funded by NIH, she charges the equipment to the sleep disorder grant.

Is this appropriate?

Case Study 8…

Dr. Admins submits a research grant application. The PI seeks support for a half-time secretary, two laptops and an iPhone in a grant proposal.

Are these types of costs appropriate for a traditional "R01" grant application?

Useful Websites

NIH Guide for Grants and Contracts: http://grants.nih.gov/grants/

Grants Policy & Guidance: http://grants.nih.gov/grants/policy/policy.htm

NIH Conflict of Interest:
http://grants.nih.gov/grants/policy/coi/index.htm

Office of Management Assessment: http://oma.od.nih.gov

Office of the Inspector General: http://oig.hhs.gov

Office of Research Integrity: http://ori.dhhs.gov

Office for Human Research Protections:
http://ohrp.osophs.dhhs.gov/index.htm

Office of Laboratory Animal Welfare:
http://grants.nih.gov/grants/olaw/olaw.htm