COURSE TOPIC OUTLINES and LEARNING OBJECTIVES

RCR Topics

The first 9 topics are the traditional priorities of the Public Health Service (PHS) and its Office of Research Integrity (ORI), sometimes called the "ORI 9." The remainder of the list includes 5 common additions, for a total of 14. An introduction of "overarching objectives" brings the total to 15. Assuming 8 contact hours, in 2 4-hour sessions, each topic "slot" can be allocated approximately 30 minutes.

TEACHING TIPS

Consider your own goals for conveying knowledge, problem-solving skills, attitudes and/or behavioral change in the context of the RCR course.

Cover the important learning objectives, but leave time for your own additional materials (e.g., cases that you believe are particularly relevant, recent events and historical examples of RCR issues).

Avoid over-emphasis on rules ("do not falsify data") that are simple extrapolations of moral precepts most persons learned in childhood. Spend time emphasizing the reasons for rules. Cases can help.

SOURCES

The outline that follows is based in part on J M DuBois and J M Dueker, "Teaching and Assessing the Responsible Conduct of Research: A Delphi Consensus Panel Report" *Journal of Research Administration* (vol. XL, no. 1, 2009). DuBois's and Dueker's topic lists were adapted and expanded by UM RCR teaching faculty in 2009-2010.

For additional information about this document or RCR efforts at the University of Miami: contact Reid Cushman, UM Ethics Programs' RCR Program Director, at rcushman@med.miami.edu. Or visit the RCR Program web site at www.miami.edu/rcr.

OVERARCHING OBJECTIVES OF RCR

- Understand the importance of RCR
    - Learn some of the history of research, in both the U.S. and globally, including historical and recent examples of unethical conduct in research
    - Understand the social context of research: especially, consequences of unethical conduct in research for self, institution, science and society
- Identify sources of RCR regulations and policy
    - Federal laws, regulations and guidelines
    - State laws, regulations and guidelines
    - Professional organizations, certification bodies
    - Institutional policies
- Examine limitations of formal RCR guidance (laws, regulations, policies), variations in standards across fields, institutions, departments, labs
    - Understand that formal guidance still permits – and sometimes requires – discretion and creative problem solving
    - Understand that formal guidance does not cover all ethical responsibilities
- Understand the key distinctions within the field of RCR
    - Distinctions between ethical and legal/regulatory/policy duties
    - Distinctions within ethics, such as ethically obligatory, prohibited, and praiseworthy actions, and nuances in formal standards (must, should, may, etc.)
    - Distinction between "research misconduct" as regulations narrowly define it, and questionable regulatory practices ("researchers behaving badly")
- Importance of fostering "research integrity" or "professional character"
    - Motivating morally good action
    - Inculcating professional values such as pursuit of truth, honesty, intellectual humility
- Foster ethical sensitivity: the ability to identify ethical issues in the conduct of research
    - Identify common ethical issues such as those addressed within core RCR topics
    - Identify common threats, including pressures inherent in the research enterprise as it exists today and the perennial issues of personal bias
    - Distinguish between ethical responsibilities in research versus other activities
- Develop ethical problem-solving skills
    - Knowledge of relevant ethical frameworks, theories or principles
    - Ability to identify key elements of an ethical situation, including stakeholders (and their interests), relevant ethical and legal/regulatory/policy norms, relevant facts, and available options
    - Ability to reason critically using ethical principles or values
    - Ability to identify ethical and legal/regulatory/policy resources, such as peers, mentors, institutional officers, educational resources, consultation services and government agencies
- Examine ways of preventing ethical problems in research
- Provide an open forum for discussion of individual RCR concerns and challenges

RESEARCH MISCONDUCT (AND QUESTIONABLE RESEARCH CONDUCT)

- Significance of misconduct
  - What it is: "FFP" and lesser crimes
  - History of scientific misconduct
  - Incidence and prevalence of misconduct (estimates of various studies)
  - Consequences of misconduct for individuals, labs/research groups, research institutions, science, society
- Factors that contribute to misconduct
  - Effects of lab/group and institutional environment
  - Reward systems in academic and industry settings
- Fabrication and falsification
  - Definitions and examples
  - Consequences
- Plagiarism
  - Definitions and examples
  - Ghost-authorship and guest-authorship as forms of plagiarism?
  - Consequences
- Other serious deviations from best practices ("questionable practices")
  - Data/outcomes manipulation (short of F/F)
  - Sabotage
  - Hostile environments
  - Other types of questionable practices
  - Unintentional deviations vs. intentional ones
- Laws, regulations and policies addressing misconduct
  - Government: Office of Research Integrity (ORI), et al
  - Certification organizations
  - Institutional policies
- Responding to observed or suspected misconduct
  - Evidentiary standards
  - Whistle-blowing, including responsibilities of and protections for whistleblowers
  - Alternatives to whistle-blowing
- Current issues and cases
- Local policies and resources

CONFLICTS OF INTEREST AND COMMITMENT

- The significance of conflicts of interest
    - Human decision-making research and conflicts of interest – how conflicts of interest may cloud judgment or influence decisions
    - Historical examples that confirm the decision-making research
    - Consequences of conflicts of interest for researchers, institutions, students, and research participants
- Types, definitions, and examples of conflicts of interest
    - Conflicts of interest are pervasive in research, and not always bad
    - Conflicts of interest are objective relationships (not "apparent"), but do not imply actual or intended wrong doing
    - Financial conflicts of interest (gifts and honoraria, patents and other IP, spin-off companies, SBIR/STTRs, personal/family investments, funding contracts, etc.)
    - Non-financial conflicts of interest (recognition, publications, promotions, etc.)
    - Role conflicts (e.g., physician-researcher or teacher-researcher) and conflicting duties to self, clients, institutions and society
- Conflicts of commitment (dividing one's efforts within and outside one's research)
    - Effort reporting rules
    - Balancing sponsored research, consulting, and other remunerative activities with other duties
    - The perils of becoming over-extended
    - Situations where the review of protocols or other committee duties would be inappropriate due to professional relationships
    - Personal relationships (good or bad) that might influence decisions
- Conflicts of conscience or belief
    - Situations where religious or philosophical beliefs could bias decisions or evaluations (e.g., climate research, embryonic stem cell research)
- Institutional conflicts of interest
    - Conflicted oversight (e.g., IRB and IACUC members who review peers' work)
    - Institutional financial conflicts (e.g., investments and profits from research)
    - Institutional non-financial conflicts (e.g., reputational concerns)
- Managing conflicts of interest
    - Avoiding or eliminating conflicts of interest
    - Disclosing conflicts of interest (e.g., in informed consents, in publications)
    - Management plans (e.g., role separation, independent review)
- Conflicts of interest law, policy, and ethics
    - Laws and regulations
    - Institutional policies and procedures (e.g., institutional reporting systems)
    - Personal duties
- Current issues and cases
- Local policies and resources

DATA ACQUISITION, MANAGEMENT, SHARING AND OWNERSHIP

- Ethical values behind the scientific standards for DAMSO
    - Confidentiality, privacy, and respect for persons
    - Trustworthiness, honesty, and transparency
    - Right to property or to prosper from work
    - Scientific collegiality and virtue of sharing
- Variations in lab/organization practices – legitimate and illegitimate variations
    - Value of having regulations and standards
    - Value of thorough documentation
- Data acquisition issues
    - Informed consent or permission to gather/use data
    - Methodological concerns: sampling and data selection (validity); verifying and cleaning data (reliability)
- Data management issues – storage, protection, and archiving
    - Competence to enter, store, and archive safely
    - Knowing how long to save data and in what format (legal, regulatory and policy)
    - Data protection and backup – confidentiality, integrity, availability (CIA)
    - Unique issues related to special types of data – e.g., tissues vs. bits
- Data sharing issues
    - How and when data should be shared, advantages and disadvantages
    - Transferring data (CIA concerns)
    - Acceptable and unacceptable uses for shared data
- Data ownership, rights and governance
    - Ownership of data, patents, copyrights, and intellectual property
    - Institutional vs. research/researcher rights to own and use data
    - Commercially useful data
    - Negotiating contracts
- Data protection laws and regulations
    - Federal (HIPAA et al), state, institutional
    - Legal “reasonableness” standards, notification rules
- Scientific methodology issues
    - Importance of research design
    - Elements of good scientific design and methodology
    - Proper use vs. abuse of statistics and data presentation techniques
    - Challenges to maintaining objectivity in designing research, analyzing results
- Data reporting
    - Ethical issues when reporting data in publications or presentations
    - Responsibility to interpret findings appropriately to diverse audiences
- Special issues related to scientific roles (PI-mentor vs. student-trainee)
- Current issues and cases
- Local policies and resources

PUBLICATION PRACTICES AND RESPONSIBLE AUTHORSHIP

- The significance of authorship
    - The benefits of publishing (promotion, tenure, fame, fortune)
    - The problems of inappropriate authorship for legitimate authors, illegitimate authors, and science
- Authorship assignment
    - Authorship criteria
        - Substantial intellectual contribution to study or text
        - Familiarity with and approval of the final text
    - Ideal of "transparent contributions"
    - Multiple authors: how to determine first author, and order of any authors after that
    - Appropriateness of discussing authorship at outset of a project
    - Acknowledgements: purpose and examples (including faculty contributions to students' work, and vice-versa)
    - Variations of standards and norms across cultures, disciplines, and institutions
- Inappropriate authorship practices
    - Ghost authorship (who was excluded that really did the writing/work?)
    - "Guest" authorship – who was included that perhaps did not deserve it (e.g., when one is asked to add authors for "political" or "courtesy" reasons)?
- Dealing with controversies that arise in authorship
    - Addressing authorship issues early and not after the work is complete
- Scientific responsibilities of authors
    - Disclosure of funding sources and other sources of potential bias
    - Specification of deviations from standard scientific practices
    - Full and accurate description of methods, procedures and analytic techniques that allows replication; citation of relevant literature without bias
    - Duty to report findings accurately and completely, including reporting critical or negative findings (even if they are contrary to own research agenda)
- Poor publication practices
    - Plagiarism versus proper citation or paraphrasing
    - Delay in reporting for commercial reasons
    - Publication bias (the unloved null hypothesis)
    - Text recycling , overlapping publication, duplicate and salami publications (LPUs and "self plagiarism")
    - Quality standards
- Protecting privacy in publication
- Addressing compliance with ethical standards, and legal/regulatory/policy standards, within articles (e.g., mentioning IRB/IACUC approval, and discussing ethically controversial aspects)
- Responsible disclosure of scientific information within the popular press
- Current issues and cases
- Local policies and resource

PEER REVIEW

- The significance of peer review
    - Peer review as mechanism for quality assurance in publication and funding
    - The need for peer reviewers to be competent and genuine peers
- Conflicts of interest and peer reviews
    - Identifying potential conflicts of interest reviewers may have
    - Managing conflicts of interest by excusing oneself from a review, or disclosing and managing the conflict with the assistance of those directing the review
    - Other sources of peer review bias
- Qualities of a good review/reviewer
    - Striving for fairness and objectivity
    - Providing timely, clear, scientifically competent, and complete reviews
    - Collegiality – conveying a respectful, professional tone while offering criticism
    - Respecting confidentiality and intellectual property (e.g., by avoiding use of information and destroying manuscripts after review)
- Logistics of peer reviewing
    - Format of and process for written review (single, double- and no-blind)
    - Selection of reviewers
    - "Delegating" review responsibilities
- Responding to reviewers
    - Responding to competent reviews: revision and resubmission process
    - Responding to questionable, biased or conflicted reviews: the roles of authors, editors, and scientific review chairs
    - Inappropriate responses to reviewers and inappropriate modifications to publications or proposals
- Editorial responsibilities
    - Selecting appropriate reviewers
    - Attending to matters of RCR (proper authorship, disclosures of bias and conflicts)
    - Respecting rights of rebuttal and mediating disputes
    - Maintaining confidentiality
- Reviewer roles in ensuring RCR
- Current issues and cases
- Local policies and resources

COLLABORATIVE SCIENCE

- The nature and advantages of successful collaborations
    - Benefits and risks of collaboration
    - Identifying a good collaborator
- Types of collaboration
    - Collaboration within an institution, between US institutions, and internationally
    - Collaboration involving data or tissue sharing
    - Collaboration involving shared resources or work (beyond data or tissue)
    - Collaboration involving controlled technologies or materials
- Working well with others
    - Identifying the authority and procedures for establishing collaborative relationships
    - Defining and clarifying roles, responsibilities and expectations in a collaboration
    - Identifying mechanisms for ongoing decision-making
    - Understanding when written agreement are necessary, and what should be addressed in contracts, MOUs, et al
    - Knowing how and when to end collaborative relationships
- Dealing with challenges in collaborative relationships
    - Addressing failures in RCR or research integrity
    - Dealing with competition, and allocating rewards such as funding, credit, authorship, ownership, and rights of use
    - Addressing power discrepancies between/among collaborators at different professional levels
- The role of institutions in collaborative science
    - Knowledge of institutional policies
    - Working with appropriate institutional officers
- Current issues and cases
- Local policies and resources

HUMAN SUBJECTS

- History
  - Exigencies of wartime
    - Nazi medical war crimes (1930s-1945)
    - Japanese medical war crimes (1930s-1945)
    - Cold War human radiation experiments (1940s-1970s)
  - Imperatives outside of wartime
    - Syphilis study at Tuskegee (1932-1972)
    - Willowbrook study (1963-1966)
    - Jewish Chronic Disease Hospital study (1963)
    - Guatemala syphilis study (1946-1948)
  - Major documents of human subjects protection
    - Nuremburg Code Directives for Human Experimentation (1947)
    - UN Universal Declaration of Human Rights (1948)
    - Declaration of Helsinki (1964)
    - US federal protections for human subjects (1974, 1980-81, 1991)
    - National Commission for the Protection of Human Subjects and Belmont Report (1974-1979)
    - CIOMS Guidelines (1982)
- Codes and regulations
  - Belmont Report
    - The "big three" ethical principles: respect for persons, beneficence (with nonmaleficence), justice
    - Guidelines for conducting research
  - HHS Protections (45 CFR 46), equivalent FDA Protections (21 CFR)
    - Basic policies for all ("Common Rule") plus additional protections for vulnerable (pregnant women, human fetuses, neonates, children, prisoners)
    - Evaluation of risk to the subjects, adequacy of risk protections, potential benefits to the subjects and others, importance of knowledge to be gained
    - International research can be subject to other protective standards, but must receive at least equivalent protection to U.S. standards
    - Federalwide Assurance (FWA)
    - Institutional Review Board (IRB) review, full or expedited
    - Data and Safety Monitoring plans and Boards (DSMB)
    - Exempt research, minimal risk research, and research that is not human subjects research (e.g., secondary use of unidentifiable "coded" data)
- Respect for persons
  - Individuals treated as autonomous agents, persons with diminished autonomy entitled to additional protection
  - "Informed consent" – voluntariness, comprehension, disclosure, non-coercion

        - Avoiding coercion, threats, undue influence, undue inducements, "therapeutic misconception"
        - Legitimate uses of incomplete disclosure, or deception (if any), and post-study debriefs
        - Comprehension of purpose, risks, benefits, alternatives (info + capacity)
        - Waivers and alterations for minimal risk protocols
        - An on-going process, not a one-time act
    - Special protections for vulnerable groups – pregnant women, fetuses, neonates, children, prisoners, mentally disabled, economic/educational disadvantaged
        - Decisions by legally-authorized representatives, assent plus permission (in case of children), limits on participation
    - Family, community consent as a supplement to individual consent
- Beneficence
    - Minimally, "do no harm" – to individuals, groups, society (nonmaleficence)
    - Maximize potential benefits, and minimize potential risks (harms)
    - Risks come in many forms: physical, psychological, social, legal, economic
        - Privacy/confidentiality protections address several types of risk
    - "Minimal risk" – what's ordinarily encountered in daily life, routine exams
    - Scope of benefits vs. scope of risks/harms – participant vs. larger community
    - Unavoidable risks justified
        - Maximum reasonable procedures taken to minimize risks
        - Remaining risks necessary for sound science, potential benefits to participant or society (importance of knowledge to be gained)
        - "Equipoise" – ending trials when genuine uncertainty ends
- Justice
    - Allocation of benefits and burdens
        - Fair procedures and outcomes in selection of individual research subjects (exposure to risks and burdens of participation)
        - Fair distribution of benefits and burdens to participating social populations
    - Exclusion and inclusion criteria for potential subjects
        - Exclusion of the (likely) vulnerable, unduly burdened
        - Proportional inclusion of persons from groups likely to benefit
        - Equity in selecting "easy" vs. "difficult" to recruit populations
        - Inclusion of women, minorities and children or other vulnerable groups
    - Issues to consider in international research
        - Preventing exploitation given scarce resources and/or other vulnerabilities
        - What is owed to the participants and the population, pre- and post-study
        - Negotiating cultural differences (individual, family, community consent)
- Institutional Review Boards' and Investigators' responsibilities
    - IRB initial review and on-going oversight
    - Minimum membership size, diversity, expertise

    - Investigators' initial commitment to good design and on-going oversight
- Vulnerable populations
    - Specifically protected by 45CFR 46 subparts B, C and D
    - Vulnerable populations who are not specifically protected (e.g., workers in the workplace, students, patients with terminal illness and cognitively impaired, etc.)
- Current issues and cases
- Local policies and resources

RESEARCH INVOLVING ANIMALS

- History
  - Animals' "moral status" through the ages
    - Aristotle, Descartes, Bentham and utilitarians, animal rights, "anti-vivisectionism"
  - Hall's principles (1856)
    - Lack of alternative approaches
    - Clearly stated objective to the experiment
    - Not unduly repetitious
    - Clear commitment to minimize pain and suffering
    - Clear and concise publication of results
  - Russell's and Burch's "Three Rs" (1959)
- Ethical aspects
  - The Three Rs of animal subject welfare
    - Replacement
      - Use non-animal alternatives when possible
      - Use animals with "lower ethical cost" otherwise
    - Reduction
      - Minimize the amount of animal use with improved study design
    - Refinement
      - Modify experiments and designs to minimize harm, pain, stress
      - Maximize care to reduce harm, pain, stress
  - Suffering and pain: "ethical cost" weighed against scientific justification
  - Animal rights vs. animal welfare (and balancing against human need)
  - Conscientious objection, reporting misuse, mistreatment or non-compliance
- Regulatory aspects
  - Federal agencies
    - PHS/HHS
      - Office of Laboratory Animal Welfare (OLAW)
      - Policies on Humane Care and Use of Laboratory Animals
      - Guide for the Care and Use of Laboratory Animals
    - USDA , per Animal Welfare Act
  - Private certification/accreditation/standards
    - Association for the Assessment and Accreditation of Laboratory Animal Care
    - Various professional guidelines
  - Internal institutional bodies and officials
    - Institutional Animal Care and Use Committee (IACUC)
      - Appointed by the Institutional Official (IO)
        - Includes community membership
      - Assures compliance with FDA, PHS regulations and other standards
      - Also many other duties

        - Overall oversight of Animal Care and Use program
    - Attending Veterinarian (AV)
        - Hired by institution to promote animal research.
        - Resource for investigators, supervises care, participates in protocol planning (esp. where pain/suffering involved)
    - IACUC as manager/mediator
        - Reconciling social tensions and conflicts on use of animals in context of individual protocols
        - How comparable to IRB role
- Current issues and cases
- Local policies and resources

MENTOR / TRAINEE RESPONSIBILITIES

- Definitions and expectations of the mentor/trainee relationship
    - Who is who: Graduate advisors, thesis/dissertation advisors, department chairs, laboratory/project directors, mentors and trainees
    - Boundaries of the mentor/trainee relationship
- Power relationships and the potential problems they involve
    - Power structures and hierarchical relationships in an institution, vs. the mentor/trainee relationship
    - Friendships and mentoring relationships
    - Harassment, sexual and other types
- Responsibilities and roles of the mentor
    - Promoting professional research skills, including identifying research questions, writing proposals and designing research, conducting research, publishing research
    - Fostering research compliance (IRB, IACUC, etc.), RCR, and professional integrity
    - Finding funding or other kinds of support, negotiating grants and contracts
    - Sharing discipline-specific wisdom on how to operate in one's professional context
    - Career counseling, for trainees with science/academic or other career goals
    - Conflict resolution
    - Fostering trainee's independence and professional development while fulfilling the mentor's supervisory and other responsibilities
- Responsibilities of the trainee within the mentor-trainee relationship
    - Work with integrity
    - Willingness to "blow whistle" to challenge misconduct or questionable conduct
    - Respecting the mentor's time and other commitments
    - Knowing when to move on
- Maximizing benefits and addressing challenges in a mentor-trainee relationship
    - Compatibility ("optimal characteristics") of mentors and trainees
    - Effective mentoring strategies for both parties
    - Clear communications about expectations ("contracting")
    - Dealing with diversity of cultures, races, and other personal traits
    - Conscientious refusal when appropriate, by both parties
- Current issues and cases
- Local policies and resources

LAB SAFETY, CHEM-BIO-SAFETY, RADIATION SAFETY, ETC.

- Overview of safety issues is the lab
- Laboratory-associated infections
- Biohazard risk assessment
- Medical surveillance
- Risk Management – work practices
    - Working Safely with Sharp Instruments
    - Disinfection
    - Other
- Risk Management – personal protective equipment
    - Confining aerosols
    - Centrifuge precautions
    - Safe sharps devices
    - Other engineering controls
- Risk Management – laboratory design
- Risk Management – emergency procedures
- Risk Management – infection control
    - Bloodborne pathogens
    - Hepatitis B virus vaccination and exposure routes
    - Labels and engineering controls
    - Universal Precautions and work practices
    - Emergency Response procedures
- NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules
- Human gene transfer research
- Select agents
- Biosecurity and bioterrorism
- Shipping regulated biological materials
    - Overview
    - Classifications
    - Packaging requirements
    - Shipping papers
    - Permits for restricted shipments
    - Security awareness
    - Emergency Response
    - Refrigerants
- Animal biosafety
- Understanding nanotechnology
- Radiation safety
- Current issues and cases
- Local policies and resources

EXPORT CONTROLS AND NATIONAL SECURITY

- Connection between export controls and national security
    - "Dual-use" technologies may have military as well as commercial applications
    - Purely commercial technologies without an obvious military use may be included
- What does it mean to "export"?
    - Sending/taking technical data or technology to another country (outside US states or territories), even if temporarily
    - "disclosing technical data to a foreign person, whether in the US or abroad"
    - "release of technology subject to [export control] to a foreign national in the US" – a "deemed export" the home country of the foreign national
- Federal regulations
    - Export Administration Regulations (EAR) – Commerce Department
        - Commerce Department's " dual-use" technology listing
        - More detailed, ~200 pages
        - "specific information necessary for the development, production or use of a product"
    - International Traffic in Arms Regulations (ITAR) – State Department
        - State Department's "munitions" (military technology) listing
        - Short, broad definitions, ~10 pages
        - "technical data or information … required for the design, development, manufacture … testing … or modification of a defense article"
    - Key "4W" variables: what , where, why and to whom
        - What is it – EAR Export Control Classification Number (ECCN)
        - Where are you exporting it – EAR ECCN cross-referenced to Country Chart
        - Why – Purpose (use) together with what and where determine control level
        - Who will receive it—Some persons and organizations are banned (list)
        - Result: "No license required" (NLR), License Exception, License, Ban
    - Excludes information or technology "in the public domain"
    - Excludes basic and applies research "ordinarily published and shared broadly"
- Resources
    - Departments of Commerce and State
    - Institution's export control official
- Current issues and cases
- Local policies and resources

WHISTLE-BLOWING (MANAGING ALLEGATIONS OF MISCONDUCT, INVESTIGATIONS OF MISCONDUCT, FORMS OF DISPUTE RESOLUTION)

- What is required when you suspect something is wrong?
    - Understanding the nature of the possible problem
        - Research misconduct ("FFP")
        - Questionable research practices
        - Other types of misconduct or questionable practices
    - Assessing your evidence
        - Getting a second opinion
    - Understanding the risks of involvement
- Making the decision to act informally or formally
    - Informal intervention, pro and con
    - Formal intervention, pro and con
- Protections against intimidation or retaliation for reporting
    - Federal protections
    - Institutional protections
- Current issues and cases
- Local policies and resources

INTELLECTUAL PROPERTY

- Ideas as property
  - Property justification (rights to fruits of creative work, including credit)
  - Economic justification (incentives, security for collaborations)
  - Types of IP: Patents, copyrights, trademarks, and trade secrets
- Conditions of creation and the effect on ownership
  - "Works for hire" in commercial, academic contexts
    - What is within the normal "scope of employment"
    - To what degree were employer resources used
  - Prior agreements clarifying ownership
  - Necessity of consulting with one's institutional officials
- Patents
  - Filing required
  - "Prior art" search for prior patent (current or expired)
  - Technical assessment: Novelty and Non-obviousness
  - Marketing and feasibility assessment
  - 20-, 17- and 14-year protection (depending on type and when filed)
- Copyrights
  - "Fixing in a tangible medium" whether or not perceived by human senses
  - Registration vs. use of mark ©
  - Permissions and fair use (especially on the Internet)
  - Transfer of copyright – selling and licensing particular rights
  - Violations: "substantial similarity" to an ordinary observer
  - "Independent creation" defense
  - 120-, 95-. 50-year protection (depending on type and when filed)
  - Copyright alternatives (e.g., "copyleft" efforts like Creative Commons)
- Trademarks, "branding" and goodwill
  - Signaling identity, guarding reputation
  - More than words: colors, typefaces, symbols, etc.
  - Trademarks (products) vs. service marks (services)
  - No deadline on protection
  - Registration © vs. common-law marks ™ ℠
- Trade secrets
  - Speed and secrecy compared to patents
  - No protection against reverse engineering or independent efforts
  - Non-disclosure and non-compete agreements
- Current issues and cases
- Local policies and resources

SOCIAL RESPONSIBILITIES OF RESEARCHERS AND RESEARCH INSTITUTIONS

- Research priorities
- Fiscal responsibilities
- Public service
- Public education
- Advocacy by researchers
- Environmental impact
- Forbidden knowledge
- Current issues and cases
- Local policies and resources