# CRA Study Guide

Most of the information and material are provided by Kristy Ford from Research Costing Compliance

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## Acts

**Animal Welfare Act, 1966** – the only federal law in the US that regulates the treatment of animals in research, exhibition, transport, commerce, and by dealers

* All other laws, policies and guidelines may include additional species but they all refer to the Animal Welfare Act as the minimum acceptable standard

**Bayh-Dole Act (Patent and Trademark Amendment Act of 1980) (P.L. 96-517) (37 CFR 401)**-permits a university, small business, or non-profit institution to elect to pursue ownership of an invention in preference to the government

* Federal government was the obligated inventions owner on federally sponsored research before the amendment was enacted
* Government retain march-in rights (right to grant other entities licenses or give licenses to itself)
* Technology Transfer – transfer of research results from governments or universities to the commercial marketplace for the public benefit or for further development

**Byrd Amendment** – Anti-lobbying certification required on all agreements exceeding $100,000

* Colleges or universities must certify that they have not made or agreed to make payment with nonfederal funds for the purpose of influencing a specific award over $100,000 (disclosure)
* Applies to all agreements

**Civil Rights of Institutionalized Persons Act (CRIPA), 1980** – federal protecting the rights of people in state or local correctional facilities, nursing homes, mental health families and institutions for people with intellectual and developmental disabilities

* Does not apply to private institutions

**Clean Air Act (CAA) of 1970 –** regulates air emissions from stationary and mobile sources to protect public health and welfare

**Clean Water Act** – Applies to all government agreements and sub-awards in excess of $100,000

* Facilities listed by the EPA as violating the Clean Water Act may not be used as a location for conducting applicable government agreements
* Institution must certify compliance

**Copeland Act (“Anti-Kickback” Section)** – Applies to all contractors and subcontractors performing on a federally funded contract for the construction, prosecution, completion or repair of any public building or public work

* Each contractor or subcontractor must provide weekly statement of compliance regarding wages paid to employees during previous week

**Cooperative Research and Technology Enhancement Act (CREATE Act)** – allows invention to be patented when it is found to have “prior art” as long as the required conditions are met

* Prior art – not novel and obvious
* Before CREATE was enacted, communication between academic researcher and collaborator was deemed “prior art”; therefor un-patentable
* Conditions for patent
	1. Invention must be made by parties to joint research agreement that was in effect on or before the date the invention was made
	2. Invention was the result of activities completed within the scope of the agreement
	3. Application for patent must disclose the names of the parties of the joint research agreement

**Davis-Bacon Act of 1931 –** established requirement for paying the local prevailing wages in public works projects or laborers and mechanics

* Applies to contractors and subcontractors performing on federally funded contracts in excess of $2,000 for construction, alteration, or repair of public buildings or public works

**Drug-Free Schools and Communities Act (P.L. 101-226)** – Requires schools, colleges and universities to implement and enforce strict drug prevention programs and policies to be eligible to receive federal funds

* No flow-down required
* Certification must be submitted to Secretary of the Department of Education in order to receive federal funds
* Drug prevention program must include:
	+ Annual distribution in writing to employees and students
	+ Biennial (every 2 years) review of its program

**Fair Labor Standards Act (FLSA) of 1938** - Establishes minimum wage, overtime pay, record keeping and youth employment standards affecting full-time and part-time workers in the private section in Federal, State, and local governments.

**Federal Financial Assistance Improvement Management Act (P.L. 106-107)**–to improve the effectiveness and performance of Federal financial assistance programs, simplify Federal financial assistance and reporting requirements, and improve the delivery of services to the public

* [www.grants.gov](http://www.grants.gov) created as central system that provides centralized location for grant seeker to find and apply for federal funding opportunities

**Federal Funding Accountability and Transparency Act of 2006 (FFATA)**–Ensures that the public can access information on all entities and organizations receiving federal funds

* [www.usaspending.gov](http://www.usaspending.gov) was the result of this law and is a publicly available website containing information on Federal grants and contracts over $25,000
* [www.FSRS.gov](http://www.FSRS.gov) created for reporting on Federally funded first-tier sub-awards and executive compensation

**Federal Grant and Cooperative Agreement Act (P.L. 95-224) (USC 6301) –**

* Procurement Contract – the legal instrument used whenever the principal purpose of the agreement is the acquisition by purchase, lease or barter for property or services for the direct benefit or use of the federal government
* Grant Agreement – the legal instrument used when no substantial involvement is anticipated between the agency and the recipient whenever the principal purpose of the relationship is the transfer of a thing of value to the recipient to carry out to a public purpose of support (often referred to as an “assistance award”)
* Cooperative Agreement – the legal instrument used when substantial involvement is expected between the agency and the recipient when the principal purpose is to transfer something of value to carry out a public purpose

**Federal Information Security Management Act of 2002 - FISMA (P.L. 107-347**) –Requires each Federal agency to implement an information security program for information systems that support the operations and assets of the agency

* Risk level determines the controls put in place to protect the data and information systems that are part of that contract
* Applies only to contracts

**Flood Disaster Protection Act of 1973**– Requires flood insurance to be purchased when federal funds provide assistance to acquire or improve and or facilities located in identified flood-prone areas

**Fly America Act (49 USC 40118)** – travelers using federal funding must use US flag airline (not to be confused with US flag carriers) for all air travel and cargo transportation services. One exception to this requirement is transportation provided under a bilateral or multilateral air transport agreement, to which the US Government and the government of the foreign country are parties, and which the Department of Transportation has determined meets the requirements of the Fly America Act.

* Currently 4 bilateral/multilateral “Open Skies Agreements” in effect:
	+ US Government and the European Union (EU) including non EU members Norway and Iceland
	+ US and Australia
	+ US and Switzerland
	+ US and Japan
* For foreign travel, US flag carriers or foreign air carriers that code share with a US flag carrier may be used
* lower cost and personal convenience are not acceptable criteria for justifying the non-availability of a U.S. flag air carrier.
* Travelers using Department of Defense (DOD) are not permitted to take advantage of the Open Sky Agreements unless they qualify for exemption as noted in FTR 301-10.135

**Freedom of Information Act - *FOIA* (5 USC 552)** – Federal agencies have 20 working days to respond to FOIA request and information should be made available to the public by:

* Publication in Federal Register
* Providing the opportunity to read and copy records convenient locations
* Upon request, providing a copy of reasonably described record

**Hatch Act** – Prohibits State and local government employees from running for partisan office if their salaries are paid for completely by federal loans and grants

* Excludes:
	+ Individual with no function in connection with activity
	+ Individual employed by an educational or research institution
* Covered employee may not:
	+ Be a candidate for elective office
	+ Financially contribute to a party, person, agency, etc for political purposes
	+ Use official authority for purpose of affecting result of election or nomination

**Health Research Extension Act, 1985 (P.L. 99-158)**–guidelines for use of animals in DHHS-funded research must be established

* Defines establishment of Institutional Animal Care and Use Committees (IACUC)

**National Research Act, 1974** – created the National Commission for the Projection of Human Subjects of Biomedical and Behavioral Research to develop guidelines for human subject research and oversee and regulate the use of human experimentation in medicine

**Occupational Safety and Health Act (29 CFR 1910)** – Performance of a federally funded award will not take place under conditions that are unsanitary or hazardous to the health and safety of employees

* Requires employers to provide a workplace that is free from recognized hazards that could cause death or serious harm
* Applicable to agreements over $2,500
* Enforcement of
	+ Standards for emergency plans
	+ Environmental and occupational health
	+ Hazardous material
	+ Personal protective equipment
	+ Fire protection

**PATRIOT Act** – Restricts possession, transportation, shipment, or receipt of select agents and toxins regulated by the CDC or APHIS

* Prohibits “restricted persons” form possessing, transporting or shipping, or receiving select agents or toxins
	+ “restricted person” – convict, fugitive, controlled substance user, illegal alien, mentally ill, a national of sanctioned countries such as Cuba, Iran, North Korea, Iraq, Libya, Sudan, Syria or dishonorably discharged from Armed Services veteran
* Individuals and institutions must comply

**Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188)** – prevent, prepare and respond to bioterrorism and other public health emergencies

* All persons processing OR transporting select biological agents or toxins deemed a threat to public health, animal or plant health or anima or plant products must register with the appropriate federal agency

**Safe Drinking Water Act (SDWA) of 1974 –** ensures the quality in American’s drinking water

**Shelby Amendment (Data Access Act)** – amends Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through procedures established under the Freedom of Information Act

**Solomon Amendment** – allows the Secretary of Defense to deny federal grants (including research grants) to institutions of higher education if they prohibit or prevent ROTC or military recruitment on campus

**Stevens Amendment (Disclosure of Federal Participation)** – requires acknowledgement of sponsorship in publications

**Uniform Relocation Act of 1970** – establishes minimum standards for federally funded programs and projects that require the acquisition of real property or displace persons from their homes, businesses or farms

* Provides uniform, fair and equitable treatment of persons whose real property is acquired or who are displaced in connection with federally funded projects

**Walsh-Healy Public Contracts Act (P.L. 74-8456)**–contractor must comply with the government’s minimum wage and hour requirements, child and convict labor restrictions, and work safety provisions

* Applies to any contract for manufacture or furnishing of materials, supplies, articles and equipment in any amount exceeding $10,000 (flowdown to subcontractors is required)

## Executive Orders

**Coordinated Review Process (EO 12372)** – states may choose to participate

* Procedures can vary by state
* State chooses which programs to review
* Typically programs which non-federal sources provide some of the funding or when the state would be affected by the federal award
* Programs selected require submission of proposal to State Single Point of Contact (SPOC) prior to submission to the federal agency

**Debarment and Suspension (EO 12549 supplemented by EO 12689)** – Applies to all grants and cooperative agreements and contracts in excess of simplified acquisition threshold

* Flow-down required
* Institution must certify in proposal that they (nor their researchers) are:
	+ Not debarred, suspended, proposed for debarment, ineligible
	+ Not convicted of fraud, embezzlement, or in violation of federal or state antitrust statues (within 3 years)
	+ Not indicted or criminally or civilly charged by government of above offenses
	+ Have not had public transactions terminated for cause or default (within 3 years)

**Equal Employment Opportunity (EO 11246)** – Requires awardees to provide equal opportunity

**Utilization of Women-Owned Small Businesses (EO 12138)** – clause used in federal contracts when it exceeds the simplified acquisition threshold of $150,000

* Contractor must agree to use its best efforts to give women-owned small business the maximum practicable opportunity to participate in subcontracts that it awards

## Research Guidelines/Code

**Misconduct in Science** – No direct statutory requirement

* Federal agencies required to implement the definition in their own policies
	+ Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results
* Requirements of institutions
	+ Develop policies/procedures for an impartial process for reviewing allegations
	+ Notification of funding agency
	+ Protect integrity of the research, research subject and the public
	+ Observe legal requirements and responsibilities
	+ Protect the person brining the allegations
	+ Maintain records

**Nuremburg Code 1947** – The 10 points are, (all from United States National Institutes of Health)

1. The voluntary [consent](http://en.wikipedia.org/wiki/Consent) of the human subject is absolutely [essential](http://en.wikipedia.org/wiki/Essence). This means that the person involved should have [legal](http://en.wikipedia.org/wiki/Legal) capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not [random](http://en.wikipedia.org/wiki/Random) and unnecessary in nature.
3. The experiment should be so designed and based on the results of [animal experimentation](http://en.wikipedia.org/wiki/Animal_experimentation) and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary [physical](http://en.wikipedia.org/wiki/Physical_property) and [mental](http://en.wikipedia.org/wiki/Mind) suffering and injury.
5. No experiment should be conducted where there is a prior reason to believe that death or disabling [injury](http://en.wikipedia.org/wiki/Injury) will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the [humanitarian](http://en.wikipedia.org/wiki/Humanitarian) importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conductedonly by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at [liberty](http://en.wikipedia.org/wiki/Liberty) to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has [probable cause](http://en.wikipedia.org/wiki/Probable_cause) to believe, in the exercise of the good faith, superior skill and careful [judgment](http://en.wikipedia.org/wiki/Judgment) required of him that a continuation of the experiment is likely to result in injury, [disability](http://en.wikipedia.org/wiki/Disability), or [death](http://en.wikipedia.org/wiki/Death) to the [experimental subject](http://en.wikipedia.org/wiki/Experimental_subject).

## Human Research History

**Tuskegee Syphilis Experiment 1932-1972** – The 40 year study was funded by the U.S Public Health Service to study the natural progression of untreated syphilis in rural African American men who thought they were receiving free health care from the U.S. government

* Subjects were not told they had syphilis nor received treatment
* Penicillin was widely available to treat syphilis by 1947
* Led to the National Research Act, 1974
* Led to 1979 Belmont Report and establishment of the Office for Human Research Protections (OHRP)
* Federal laws and regulation developed requiring Institutional Review Board (IRB) for protection of human subjects in research

**Nazi Experiments 1940s**–a series of medical experiments on prisoners who were coerced into participating

* Experiments typically resulted in death, disfigurement or permanent disability and are considered examples of medical torture
* Crimes related to these experiments were tried during the Doctor’s Trial
* Nuremburg Code 1947 was developed as a result

**Universal Declaration of Human Rights (UDHR), 1948** – Adopted by the United Nations General Assembly as a result of the World War II (especially the Nazi Experiments) and represents the first global expression of rights to which all human beings are inherently entitled

* The beginning of the IRB system and implements review of research by noninvolved individuals

**Human Radiation Experiments 1940s-1970s**–Experiments conducted by the Atomic Energy Commission (AEC) under the banner of “national security” which enabled researchers to secretly test radiation theories or effects on human subjects without their consent or knowledge

**The Thalidomide Tragedy, late 1950s** – Originally prescribe to pregnant women to alleviate nausea and morning sickness and became an over the counter drug in Germany

* 5,000 – 7,000 infants in Germany were born with malformation of limbs (phocomelia), and only 40% of those children survived
	+ Other effects include eyes, hearts, alimentary, and urinary tracts, and blindness and deafness
* 10,000 cases worldwide linked to thalidomide and infants born with phocomelia with 50% survival rate
* Kefauver-Harris Amendment developed requiring drugs to show proof-of-efficacy

**Milgram Study (Experiment), 1961** – series of psychological experiments conducted to measure the willingness of study participants to obey an authority figure who instructed them to perform acts conflicting with their personal conscience

* Some scientists considered experiments unethical and physically or psychologically abusive

**Kefauver-Harris Amendment (Drug Efficacy Amendment) to Federal Food, Drug, and Cosmetic Act, 1962** – Introduced requirement for drug manufacturers to provide proof of the effectiveness and safety of their drugs before approval

* Required drug advertising to disclose accurate information about side effects
* Stopped generic drugs being marketed as expensive drugs under new trade names as new “breakthrough” medications

**Jewish Chronic Disease Hospital Study, 1963**–22 elderly patients were injected with live cancer cells by Chester M. Southam to research how healthy bodies fight against malignant cells

* Southam was placed on probation for 1 year and then elected as Vice President of American Cancer Society two years later

**Willowbrook Hepatitis Experiments, 1963-1966** – mentally disabled children were given hepatitis at the Willowbrook State School for study

* Public outcry led to the school’s closure in 1987
* Led to the creation of the Civil Rights of Institutionalized Persons Act (CRIPA), 1980

**Declaration of Helsinki, 1964** – A set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association (WMA)

**The Beecher Article, 1966** – helped implement federal rules on human experimentation and informed consent

**Public Health Service (PHS) Policy, 1966** - support new policy requiring institutional review to assure ethical acceptability of research with human subjects

* Institutional committee (IRB) would have to review the rights and welfare of the research subject, appropriateness of informed consent method, and the balance of risks and benefits
* Director James Shannon was instrumental in developing this first PHS policy

**The Belmont Report, 1979** – a cornerstone document of ethical principles and guidelines for research involving human subjects

* The 3 core principles are respect for persons, beneficence, and justice
	+ Three areas of application in: informed consent, assessment of risk and benefits, and equitable selection of subjects
* Created in part by the Tuskegee Syphilis Study

**Council for International Organizations of Medical Sciences (CIOMS) Guidelines, 1982** – established by the World Health Organization (WHO) to promulgate guidelines for the ethical conduct of research for human experimentation such as informed consent, standards for external review, recruitment of participants and others

* 21 guidelines (15 in original report)

**The Common Rule, 1991(45 CFR 46)** – a rule of ethics regarding biomedical and behavioral research involving human subjects in the United States

* These regulations govern IRB for oversight of human research
* Governed by Office for Human Research Protections (OHRP) under Public Health Service (PHS)
* Subpart A – basic HHS policy for protection of human research subjects (“Common Rule”)
* Subpart B – additional protection for pregnant women, human fetuses, and neonates
* Subpart C – additional protection pertaining to biomedical and behavioral research involving prisoners as subjects
* Subpart D – additional protections for children involved as subjects in research
* Subpart E – registration of institutional review board

**National Bioethics Advisory Commission, 2000s** – provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities regarding:

1. Bioethical issues arising from research on human biology and behavior; and
2. Applications, including clinical applications of that research

## OMB Circulars

(see actual Circulars for more details)

***Cost principles***

**A-21 (2 CFR 220)** – educational institutions

**A-87 (2 CFR 225)** – state, local and Indian Tribe Governments

**A-122 (2 CFR 230)** – non-profit organizations

***Administrative requirements***

**A-110 (2 CFR 215)** – grants and agreements with institutions of higher education, hospital and other non-profit organizations

**A-102**– state and local governments

***Audits***

**A-133** – states, local governments and non-profit organizations

* Non-Federal entity expending more than $500,000 or more in a year after December 31, 2013 in Federal awards is required to have a single or program-specific audit annually

***Not covered by OMB Circulars***

* 45 CFR Part 74, Appendix E – Hospitals
* FAR 48 Subpart 31.2 – for-profits

## Uniform Guidance (2 CFR 200) Released December 26, 2013

(See actual UG for more detail)

* Objective to reduce administrative burden and the risk of waste, fraud and abuse
* Federal awarding agencies must implement Uniform Guidance to federal awards by December 26, 2014
* Subpart F: Audit Requirements will apply t audits of fiscal years beginning on or after December 26, 2014

Subpart A – Acronyms and Definitions (200.1 – 200.99)

Subpart B – General Provisions (200.100 – 200.113)

Subpart C – Pre-Award Requirements (200.200 – 200.211)

Subpart D – Post-Award Requirements (200.300 – 200.345)

Subpart E – Cost Principles (200.400 – 200.475)

Subpart F – Audit Requirements (200.500 – 200.521)

* Audit Threshold change to Non-Federal entities that expend $750,000 or more in Federal awards during their fiscal year
* Threshold for reportable questions cost increased to $25,000
* Type A/B Threshold
	+ Type A programs are those above the threshold
	+ Type B programs are those below the threshold
	+ Minimum increases to $750,000

Appendix I – Full Text of Notice of Funding Opportunity

Appendix II – Contract Provisions for Non-Federal Entity Contracts Under Federal Awards

Appendix III – Indirect (F&A) Cost Identification and Assignment, and Rate Determination for Institutions of Higher Education

Appendix IV – Indirect (F&A) Cost Identification and Assignment, and Rate Determination for Nonprofit Organization

Appendix V – State/Local Governmentwide Central Service Cost Allocation Plans

Appendix VI – Public Assistance Cost Allocation Plans

Appendix VII – State and Local Government and Indian Tribe Indirect Costs Proposals

Appendix VIII – Nonprofit Organizations Exempted from Subpart E – Cost Principles

Appendix IX – Hospital Cost Principles

Appendix X – Data Collection Form

Appendix XI – Compliance Supplement

## Public Laws (see Acts section)

Contains 51 titles and are codified (published) every 6 years.

P.L. 101-226 Drug-Free Schools and Communities Act

P.L. 106-107 Federal Financial Assistance Management Improvement Act

P.L. 107-188 Public Health Security and Bioterrorism Preparedness and Response Act of 2002

P.L. 107-347 Federal Information Security Management Act of 2002 (FISMA)

P.L. 74-8456 Walsh-Healy Public Contracts Act

P.L. 95-224 Federal Grant and Cooperative Agreement Act (USC 6301)

P.L. 96-517 Bayh-Dole Act (Patent and Trademark Amendment Act of 1980) (37 CFR 401)

P.L. 99-158 Health Research Extension Act

## Institutional Boards/Committees

**Institutional Review Board (IRB)**–independent board charged with ensuring that human experimentation is conducted according to ethical principles

* Reviews and approves protocols for the conduct of research that intervenes or interacts with human subjects or their identifiable private information, organs, fluids and tissues
	+ Protocol approval expires in 1 year
* IRB review required if definition of human subject and research are met
	+ *Human Subject* – living individual about whom an investigator conducting research obtains data through intervention/interaction with individual or identifiable private information
	+ *Research* – systematic investigation designed or developed to contribute to generalizable knowledge
* Requires 5 members and at least one member:
	+ Whose primary concerns are scientific
	+ Whose primary concerns are non-scientific
	+ Who is not affiliated with the institution
* Review types
	+ Initial – determined by level of risk
		- Exempt – no risk (no harm or discomfort anticipated to participant
			* IRB must make this determination
		- Expedited - minimal risk (probability and magnitude of harm or discomfort anticipated to participants is no greater than what might be encountered in daily life)
			* review conducted by chairperson or designated reviewer
		- Full board – high risk (probability and/or magnitude of harm, whether physical, psychological, social or economic, is more than minimal)
			* review conducted by full IRB at convened meeting
	+ Continuation
	+ Amendment/Modification
	+ Adverse Event
	+ Non-compliance
* Human subjects protection: exemptions (45 CFR 46.101.b)
	+ Common educational practices
	+ Unidentifiable data
	+ Elected or appointed officials or candidates
	+ Existing data
	+ Public benefit or service programs
	+ Taste and food quality evaluations and consumer acceptance studies
* Informed consent – process by which permission or consent is obtained by subject or a subject’s representative, based the following requirements
	+ Purpose of research
	+ Foreseeable risks
	+ Benefits to subject or others
	+ Disclosure of alternative treatments or procedures
	+ Confidentiality statement
	+ Availability of medical treatment or compensation in the event that it is necessary
	+ Contact information for questions or occurrence of adverse event
	+ Statement of voluntary participation
	+ *Can be waived if informed consent form is the only thing linking the subject to the research and risk would be potentially harmful if confidentiality is breached*
* Assent – a child’s consent to participate
	+ If participants are minors, the parent or guardian must first provide informed consent for their child
	+ Child’s assent can be obtained after parent’s consent is obtained
	+ Both child and parent must provide assent and consent before participation
* Record retention
	+ Copies of all protocols reviewed, scientific evaluations, approved sample consent documents, PI progress reports, and subject injury reports
	+ Meeting minutes
	+ Records of continuing review activities
	+ IRB-PI correspondence
	+ Listing of IRB members
	+ Written procedures
	+ *Maintain records for 3 years after research completion*
* Federal-wide Assurance (FWA) – a document submitted by the institution stating that it will comply with OHRP regulations set forth in 45 CFR 46 regarding the protection of human research participants
	+ Must be renewed every 5 years
	+ Covers all non-exempt human subjects research at the submitting institution that is funded by federal departments or agencies that adopted the Common Rule and relies on the FWA
		- Domestic institutions may voluntarily apply FWA to cover all human subjects research regardless of funding source

**Institutional Animal Care and Use Committee (IACUC)**

* See Animal Welfare Act in Acts section
* See Health Research Extension Act in Acts section
	+ IACUC developed under this Act
* Animal care and use program required of an institution if it has PHS supported activities involving vertebrate animals or activities subject to Animal Welfare Regulations (research, teaching, testing, experimentation, or exhibition purposes, or as a pet)
* Meets at least once every six months and consists of:
	+ One Doctor of Veterinary Medicine (PHS/USDA)
	+ One practicing scientist experienced in research involving animals (PHS)
	+ One non-scientific member (PHS)
	+ One member not affiliated in any way with the institutions (PHS)
	+ One public member to represent community interest in proper care and use of animals (PHS/USDA)
	+ No more than 3 members from the same administrative unit of an institution (USDA)
* Semi-annual review of programs
* Semi-annual inspection of facilities
* Review of each protocol for approval (approved protocols must be re-submitted for review every 3 years)
	+ Full or designated member review
	+ Full reviews only when quorum is present (>50%)
	+ When designated member review, all members may request full committee review of any protocol on list provided to them
	+ Designated members have authority to approve, require modifications or request full review
* Suspend animal use activities if there is a violation of policies
* Voluntary certifications for facilities
	+ AAALACI – Association for Assessment and Accreditation of Laboratory Animal Care International; Re-accreditation every 3 years
	+ AALAS – American Association for Laboratory Animal Science
* *Office of Laboratory Animal Welfare (OLAW)*–responsible for laboratory animal welfare
	+ Governs Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals
		- Applies to all vertebrate animals used or intended for use in research, research training, experimentation, or biological testing for related purposes
	+ Negotiates Animal Welfare Assurances
	+ Evaluates compliance with PHS Policy
	+ Educate institutions and investigators receiving PHS support
* *Animal and Plant Health Inspection Service (APHIS)*–division of United States Department of Agriculture (USDA) that governs the Animal Welfare Regulations (9 CFR 1 & 2)
	+ Applies to alive or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or any other warm-blooded animal, which is being used, or is intended for use for research, teaching, testing, experimentation, or exhibition purposes, or as a pet (excludes birds, rats, mice bred for research)
	+ Requires registration of research facilities
	+ Registration required when animals covered by USDA Regulations are held or used for regulated purposes (research, testing, experiments or teaching on premises)
	+ Continuing review of activities no less than annually

|  |  |
| --- | --- |
| **OLAW – Office of Laboratory Animal Welfare** | **APHIS – Animal & Plant Inspection Service** |
| PHS | USDA |
| PHS Policy on Human Care and Use of Laboratory Animals | Animal Welfare Regulations |
| Applies to live, vertebrate animals used in research, research training, experimentation or biological testing, or for related purposes | Applies to any live or dead dog, cat, nonhuman primate, guinea pig, hamster, rabbit, or other warm blooded animal which is used or intended for use for research, teaching, experimentation, or exhibitions or as a pet |
| 5 member minimum for IACUC | 3 member minimum for IACUC |
| Complete review of protocols every 3 years | Continuing review of protocols annually |
| Institutional Assurance approved up to 5 years | Research Facility or Transportation Registration updated every 3 years |
| Annual report at least every 12 months | Annual report on or before Dec 1 of each year |
|  | Dealers and exhibitors require license |
|  | If animals are maintained and exhibited (ie classroom) the facility may require USDA inspection and registration |
| 3 year record retention | 3 year record retention |

**Institutional Biosafety Committee (IBC)**

* Implements policies pertaining to
	+ Microorganisms
	+ Recombinant DNA (rDNA)
	+ Center for Disease Control (CDC) list of Select Agents
	+ Genetically Engineered Organisms and Products
	+ 5 person committee for review and approval
	+ Nature of the research defines the level of review and **containment** required
		- Containment is used in describing safe methods for managing biological materials in the environment where they are being handled or maintained
		- Purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous or detrimental materials
	+ Nonexempt research requires registration
	+ CDC and NIH established criteria for four levels of containment called Biosafety Levels (BSL)
		- These criteria consists of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities
		- BSL 1 – basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for hand washing
		- BSL 2 – practices, equipment, and facility design are applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with moderate-risk agents that are present in the community and associated with humans
			* Ex. Hepatitis B, HIV, salmonellae, and Toxoplasma spp
		- BSL 3 – applicable to clinical, diagnostic, teaching, research, or production facilities which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as result of exposure by the inhalation route.
			* All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate persona protective clothing and equipment
			* Lab has special engineering and design features
		- BSL 4 - Required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease
			* Agents with close or identical antigenic relationship to Biosafety Level 4 agents are handled at this level until sufficient data are obtained either to confirm continued work at this level or to work with them at a lower level
			* Access to the laboratory is strictly controlled by the lab Director
			* The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building
			* A specific facility operations manual is adopted
	+ 42 CFR 73: Select Agents and Toxins
		- Applies to all use of identified agents/toxins and is applicable both to individuals and entities
		- Entities must designate a Responsible Official (RO) and develop:
			* A safety plan and laboratory compliance program
			* An emergency response plan
			* A record management system
			* A theft, loss, or release notification procedure
		- Criminal and civil penalties for violation

**Radiation Safety Committee (RSC)**

* Implements institutional policies
	+ Only on licensed use of radiation sources, radioisotopes, radiolabeled compounds
	+ Regulated by the Nuclear Regulatory Commission (NRC)
	+ Reviews use and protocols
	+ Training required

**Occupational Safety & Health Administration (OSHA)**

* Ensure a safe and healthful workplace by setting and enforcing standards and providing training and outreach
* Enforce the Occupational Safety & Health Act (29 CFR 1910) – see Act Section

## Award Types

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Grant** | **Cooperative Agreement** | **Contract** |
| **Basic Purpose** | Provides assistance | Provides assistance with substantial sponsor involvement | Procure tangible goods and services - acquisition |
| **Solicitation Method** | PA\*, PAR\*, unsolicited | RFA\* | RFP\*, RFQ\*, BAA\* |
| **Award Instrument** | Refer to general terms and conditions | General terms; describes sponsor involvement, party relationship | Detailed specs, clauses, regulations and expected results and deliverables |
| **Involvement by Sponsor** | Generally none | Substantial | May be extensive |
| **Re-budgeting** | Flexible | Usually flexible | Varies |
| **Equipment Title** | Grantee | Varies | Varies |
| **Performance Period** | Specified in Grant | Specified in Cooperative Agreement | Specified in Contract |
| **Patent Rights** | Usually favor recipient | May be involved and complicated | Provision Contract |
| **Publication Restrictions** | May ask to be informed | May ask to be informed | May require prior review/approval |
| **Technical Reports** | Annual report summary | Frequent reports | Detailed and sometimes as frequent as monthly |
| **Export Controls** | Fundamental research | Fundamental research | Varies – may require license |

Contracts may be terminated for:

* Convenience – government may no longer require the services/supplies under the contract and may terminate for convenience
* Default – government exercises the right to completely or partially terminate a contract because of the contractor’s actual or anticipated failure to perform its contractual obligations

**NIH Modular Budgets** – Budget increments of $25,000 in direct costs up to a maximum of $250,000. Applies mainly to R type grants such as R01.

**Unilateral Award** - An award made by a funding agency to an organization without considering competitive proposals.  Unilateral awards are most often made when unsolicited proposals receive favorable treatment.

**Current NIH Salary Cap** – Executive Level II - $185,100 (Effective January 10, 2016)

\*Funding Opportunities

PA – Program Announcement

RFA – Request for Applications

FOA – Funding Opportunity Announcement

RFP – Request for Proposals

RFQ – Request for Quotation

RFB – Request for Bid

BAA – Broad Agency Announcement

## Patent, Copyright and Trademark

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Patent** | **Copyright ©**  | **Trademark ™** |
| **What is it?** | Protection of Intellectual Property (IP) | Protection of original works/art | Protection of recognizable sign, design or expression |
| **What does it protect?** | Grants exclusive rights to inventor that excludes others from making, taking, using and selling while patent is in effect | -literary works, musical & dramatic works-pantomimes & choreographic works-pictorial, graphic, & sculptural works-motion pictures & audiovisual works-architectural works-right to reproduce or copy, display to public or prepare derivative works | Distinct names, slogans, designs and other devices used to identify certain goods and services |
| **Requirement** | Useful, novel, non-obvious | Fixed tangible medium |  |
| **Not protected** | -Substitution of one material for another-Change in size or shape, more portable-Reversal of parts | -Nontangible form of expression-Titles, names, short phrases, slogans, symbols or designs-ideas, procedures, methods, discoveries-works of common property with no original authorship | Does not protect, symbol or sign from being used by others, only prevents others from using the mark as a way to “confuse consumers as to the source of the goods/services” |
| **Protection duration** | -Utility patents – 20 yr from filing-Plant patents – 20 yr term from filing-Design patents – 14 yr term from issue | Duration of artist’s life plus 70 years | Never expires, but must continue to use the mark and renew registration-can die if trademark becomes a common noun (Ex yo-yo, dry ice) |
| **Registration** | US Patent and Trademark Office (USPTO)-cannot sue for infringement w/o registration | US Patent and Trademark Office (USPTO)-cannot sue for infringement w/o registration-file with customs to prevent importation of infringing copies of work | US Patent and Trademark Office (USPTO)-cannot sue for infringement w/o registration-file with customs to prevent importation of infringing copies of work |
| **Exceptions** |  | “Work for hire” – employer is considered the author in work |  |

## Export Control

Federal laws that prohibit the unlicensed export of certain commodities or information for reasons of national security or protections of trade

Export controls arise for the following reason(s):

* The nature of the export has actual or potential military application or economic protection issues
* Government concerns about the destination country, organization, or individual
* Government concerns about the declared or suspected end use of the end user of the export

An export is any oral, written, electronic or visual disclosure, shipment, transfer or transmission of commodities, technology, information, technical data, assistance or software codes to:

* Anyone outside the US including a US citizen
* A non-US individual wherever they are (deemed export)
* A foreign embassy or affiliate

Type of Exports

* Physical
	+ Equipment and supplies
* Technology/Software Exports
	+ E-mails/, speeches, phone call
* “Deemed Exports”
	+ Exposures, facility tours
	+ Deemed export is the disclosure of covered technology and software to a Foreign National (including Foreign Nationals in the US on a valid work visa or student visa) who is within the US (has the same effect as an export to the recipient’s county of citizenship or residence)
	+ Verbal, written, electronic, and/or visual disclosures of information to foreign nationals inside or outside US
		- Includes assisting or training foreign nationals, in US or abroad in connection with design, development, manufacture, testing, modification, processing, and use of covered items

A Foreign National is an individual who is not a US citizen, a permanent resident alien of the US or a protected individual as defined by 8 USC 1324b(a)(3).

Licenses to export controlled items/topics can be obtained from Department of Commerce or Department of State.

Department of Commerce enforces Export Administration Regulations (EAR)

* + EAR (15 CFR 730-774) covers dual use items (civilian and military applications)
	+ Covers goods and technology
	+ Re-exports – sending something overseas that is then sent to a third country; protect institution with End-User Certificate
	+ Commerce Control List (CCL) classified in into 10 groups with specific Export Control Classification Number (ECCN) and subdivided into 5 product groups:
		1. Nuclear materials, facilities and equipment
			- Systems, equipment and components
			- Test, inspection and production equipment

Applies to other 9 groups in CCL

* + - * Material
			* Software
			* Technology
		1. Materials, chemicals, microorganisms and toxins
		2. Materials processing
		3. Electronics
		4. Computers
		5. Telecommunications and information security
		6. Sensors and lasers
		7. Navigation avionics
		8. Marine
		9. Propulsion systems, space vehicles and related equipment
	+ Exceptions
		1. Fundamental research
			- Basic and applied research in science and engineering performed by colleges and universities
			- Must be carried out openly and without restrictions on publication
			- No restrictions on the access of research results (including foreign national restrictions or approvals)
			- Allows research to be conducted with the participation of foreign nationals and results may be disseminated inside or outside the US without the need for license
			- Not applicable to shipment or disclosure outside the borders of the US
		2. Teaching exemption
			- Authorizes the disclosure of educational information released by instruction in catalog courses or
			- General scientific, mathematical or engineering principles commonly taught in colleges and universities without a licenses
		3. EAR 99
			- “catch all” category
			- Technology or goods not covered by the 10 CCL categories
			- Licenses are not required under this category except in limited circumstances:
				* Exports to countries or individuals to whom exports are embargoes (OFAC)
				* End users who are defined as “denied persons”
		4. Public domain
			- Information is published
			- Generally accessible to the public
			- Unlimited and unrestricted distribution
			- Fundamental research at accredited institution of higher learning in the US
			- Results are published and shared with the scientific community
		5. No license required for:
			- Information arising during or resulting from fundamental research
			- Data released orally or visually at open conferences, lectures, trade shows or other media open to public
			- Publications that may be purchased without restrictions at nominal cost or are readily available at public libraries
			- Patents available at any patent office
			- Dissemination of educational information by instruction in catalogue course and associated laboratories in academic institutions
	+ Never qualify for fundamental research exemption
		1. Physical goods
		2. Encryption data and software
		3. Research when there is no intention to publish results
		4. Research conducted out of the US

Department of State enforces International Traffic in Arms Regulations (ITAR)

* + ITAR (22 CFR 120-130) covers military items or defense articles
	+ Regulates goods and technology designed to kill or defend against death in military setting
	+ Includes space related technology because of application to missile technology
	+ Includes technical data related to defense articles and services
	+ US Munitions List specifies the controlled items
	+ Fundamental research exemption
		1. Excludes information restricted for proprietary reasons from the definition of fundamental research
		2. University research will not be considered fundamental research if the university or its researchers accept other restrictions on the publication of scientific and technical information resulting from the project or activity, or the research is funded by US government and specific access and dissemination controls protecting information resulting from the research are applicable

Department of Treasury restricts exports and imports through economic sanctions against certain countries through Office of Foreign Asset Control (OFAC)

* + OFAC regulates transfer of items/services of value to embargoed nations
	+ Imposes trade sanctions, and trade and travel embargoes aimed at controlling terrorism, drug trafficking and other illicit activities
	+ Prohibits payments/providing value to nationals of sanctioned countries and some specified entities/individuals
	+ May prohibit travel and other activities with embargoed countries and individuals even when exclusions to EAR/ITAR apply

## Clinical Research

Clinical trials are research studies that test how well new medical approaches work in people. Each study answers scientific questions and tries to find better ways to prevent, screen for, diagnose or treat a disease. Clinical trials may also compare a new treatment to a treatment that is already available.

Every clinical trial has a protocol, or action plan, for conducting the trial. The plan describes what will be done in the study, how it will be conducted, and why each part of the study is necessary. Each study has its own rules about who can participate. Some studies need volunteers with a certain disease. Some need healthy people. Others want just men or just women.

Sponsors are responsible for registering clinical trials on ClinicalTrials.gov.

In the US, an independent committee of physicians, statisticians and members of the community must approve and monitor the protocol. They make sure that the risks are small and are worth the potential benefits.

* Types of Clinical Trials:
	+ Treatment
		- What new treatment approaches can help people who have a specific disease/condition?
		- What is the most effective treatment for these people?
		- Placebos are almost never used
			* Placebos are used only when no standard treatment exists
			* Patients are told of this possibility before deciding to take part
	+ Prevention
		- What approaches can prevent a specific type of disease/condition from developing in people who have not previously had this disease/condition
		- Enroll healthy people at high risk for developing that disease
		- Action studies (“doing something”)
		- Agent studies (“taking something”) - also called “chemoprevention studies”
	+ Early detection/screening
		- What are new ways of finding specific disease/condition in people before they have any symptoms?
	+ Diagnostic
		- How can new tests or procedures identify the disease/condition more accurately and at an earlier state?
	+ Quality of life/supportive care
		- What kind of new approaches can improve the comfort and quality of life of people who have the disease/condition?

Study Design

* Blinding treatments prevent bias from entering the study through investigator, subject or evaluator
* Open label (un-blinded)
* Single – one party does not know treatments assigned
* Double – two or more parties do not know the treatments assigned
* Double dummy – two forms of treatment (one active and one placebo) dissimilar in appearance are assigned to each subject
* Types of controls
* Uncontrolled – no group control
* Placebo – compares treatment to placebo
* Active – compares two or more treatments
* Historical – compares observations from current study with those from previous studies
* No treatment – compares treatment group to a group who received no treatment
* Treatment sequences
* Parallel – receive one treatment for specified period of time
* Crossover – receive more than one treatment, each for specified period of time with a washout period between treatments
* Factorial – receive one of multiple or combination treatment
* Survival – receive one or more treatment until event (death)
* Cohort – subjects receive treatment based on assigned cohort of similar subjects
* Adaptive – randomized to different treatment arms, then re-randomized to new treatments at end of each arm to find effective treatment
* Subject assignment
* Randomization – study subjects assigned to treatment by statistician (statistical means)
	+ Allows for more similarities among groups
	+ Provides the best way to prove effectiveness of a new agent or intervention
	+ Participants have equal chance to be assigned to one of two or more groups:
		- Control group – one gets widely accepted treatment (standard treatment)
		- Treatment group – gets new treatment being tested, which researchers believe will be better than the standard treatment
* Stratification – subjects assigned to treatment based on confounding variable, or variable that may affect the outcome (such as smoking status or disease status); allows for comparability

Clinical Trial Phases

1. Phase 1
	* Investigational New Drug (IND) application submitted to FDA before phase 1 trial can begin
	* Determine metabolism and pharmacologic actions of drugs in humans
	* How does the agent affect the human body?
	* What dosage is safe
	* What side effects are associated with increasing doses?
	* May include healthy subjects or patients
2. Phase 2
	* Evaluate efficacy on larger sample of subjects with the illness or disease
	* Does the agent or intervention have an effect on the disease?
3. Phase 3
	* Compare standard of care to new treatment to determine which better treats disease or illness
	* Evaluate risk vs benefit
	* Participants have an equal chance to be assigned to one of two or more groups or arms
	* Is the new agent or intervention (or new use of a treatment) better than the standard?
4. Phase 4
* Marketing of treatment/drug outcomes research after treatment has been approved for consumer sale
* Post-marketing studies to further determine long-term risks and benefits
* Pharmaceutical companies also determine cost-effectiveness

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Phase | 1 | 2 | 3 | 4 |
| # of participants | 15-30 | < 100 | 100+ | Several hundred to thousands |
| Purposes | -Find safe dosage-decide how agent should be given-observe how agent affects the human body | - determine if the agent or intervention has an effect on a particular illness-See how the agent or intervention affects the human body | -compare the new agent or intervention (or new use of a treatment) with the current standard | -to further evaluate the long-term safety and effectiveness of a new treatment |

How are Patients’ Rights Protected?

* Informed consent
* Scientific review
* Institutional Review Boards (IRB)
* Data Safety and Monitoring Boards (DSMB)
	+ Ensure that risks are minimized
	+ Ensure data integrity
	+ Stop a trial if safety concerns arise or objectives have been bet

Investigational New Drug Application

* IND Application - means through which an investigator gets approval from the FDA to transport or distribute investigational drugs
* Must wait 30 days after submission of IND application to begin clinical trials to allow the FDA time to review the application for safety
* Must include information about:
	+ Animal pharmacology and toxicology studies
	+ Manufacturing information
	+ Clinical protocols and investigator information
* Types
	+ Investigator IND – submitted by physician who both initiates and conducts investigation, under whose immediate direction the investigational drug is administered or dispensed
	+ Emergency Use IND – allows FDA to authorize use of experimental drug in emergency that doesn’t allow time for submission of an IND accordance with 21 CFR 312. Also used for patients who do not meet the criteria of the existing protocol or if approved protocol does not exist
	+ Treatment IND – submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place
* Must submit to FDA to obtain approval to market and sell a new drug in US
* Clinical trials must be completed for NDA

## National Science Foundation (NSF)

* Independent federal agency
* Reports to the National Science Board (NSB), a 24 member board that establishes policies for the NSF as set forth by the President and Congress
	+ appointed by the President for 6 year terms
* NSF funding opportunities are in the 47 series of the CFDA numbers:
	+ 47.041-engineering grants, 47.049-mathematical and physical sciences…
* Proposals and Award Policies and Procedures Guide (PAPPG)
	+ Revised PAPPG effective Feb 24, 2014
	+ Part 1: Grant Proposal Guide
		- Special programs for
			* Undergraduate students
			* Graduate students
			* Postdoctoral fellows
			* K-12 educators
			* Small business programs
		- Proposals must be submitted to NSF via FastLane or Grants.gov
		- Up to 6 months for programmatic review
		- Supplemental Funding
			* an additional 6 months can be requested to complete original scope of work
			* additional funding and time to expand research if the already completed work is highly successful and led to expansion of research with great benefits
			* not for defraying costs of salary increases or for additional Facilities and Administration (F&A)
		- Special Guidelines
			* Rapid Response Research (RAPID) – mechanism of support for high-urgency projects, such as natural disasters
			* EArly-Concept Grants for Exploratory Research (EAGER) – for exploratory work that is untested with potential to be transformative and considered to be “high risk-high payoff”
			* Proposals for Symposia, conferences and workshops – intended to share recent research and education findings by experts in science or engineering fields
		- Proposal Review Criteria
			* What is the intellectual merit of the proposed activity?
			* What are the broader impacts of the proposed activity?
	+ Part 2: Award & Administration Guide
		- Cost-Sharing
			* Voluntary cost sharing is prohibited
			* Can only include cost-share if required
			* All institutional resources used for project must be described in Facilities, Equipment and Other Resources section of proposal
		- Effort Requirements
			* Senior personnel allowed to charge no more than 2 months of their institutional base salary to all NSF awards
			* Amount charged to all NSF awards cannot exceed 2 months salary between awards

## Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR)

* SBIR
	+ A legislated set aside program for domestic small business companies to conduct Research/Research & Development that has the potential for commercialization and public benefit
	+ 11 federal agencies participate in the SBIR program
		- **DHHS**
		- **DOD**

Top 5 funders

* + - **DOE**
		- **NASA**
		- **NSF**
		- USDA
		- COMMERCE
		- DoED
		- Homeland Security
		- Transportation
		- EPA
* STTR
	+ Legislated set aside program that requires small business to collaborate with a research institution in Phase I and Phase II
	+ 5 federal agencies participate in the STTR program
		- **DHHS**
		- **DOD**
		- **DOE**
		- **NASA**
		- **NSF**

|  |  |
| --- | --- |
| **SBIR** | **STTR** |
| PI must be employed by small business at time of award and for duration of project | Primary PI employment not stipulated |
| No partnering equipment | Requires research partner with university or other nonprofit research institution-at least 40% of research to be conducted by small businessAt least 30% of work to be conducted by the “partnering” research institution |

* Who qualifies?
	+ Company principally located in US
	+ <500 employees
	+ Primarily (>50%) American or permanent resident alien owned
	+ Work must be done in US
	+ SBIR requires PI to work primarily for small business
* SBIR/STTR Program Structure
	+ Phase 1
		- To establish feasibility of project, potential commercialization and prove concept is worth the investment
		- Typically $100,000 in total costs not to exceed 6 months for SBIR or one year for STTR
	+ Phase 2
		- To continue research/research & development efforts started in Phase 1
		- Only receive if Phase 1 work showed technical and scientific merit, as well as commercial potential
		- Only Phase 1 awardees are eligible
		- Typically $750,000 in total costs not to exceed 2 years
	+ Phase 3
		- Objective is small business to pursue commercialization resulting from Phase 1 and 2 research/research & development activities
		- No funding from SBIR/STTR Program funds (exceptions may apply)
		- May obtain funding for Phase 3 from other non-Federal or Federal non-SBIR funds
	+ Intellectual Rights
		- Business retains intellectual property right
		- Government receives royalty free use
		- Can obtain patents or copyrights for new created inventions, designs, writings, software, etc

## NIH Construction Grants

* Awarded under the C06 activity code
* 42 CFR 52b and 45 CFR 74 or 92
* Only public or private non-profit entities are eligible
* Typically single award covering more than 1 year to apply to the entire construction project
* Matching is usually required of at least 50% of total allowable project costs
* Generally does not allow third-party in-kind contributions
* Unallowable costs
	+ Bonus payments to contractors
	+ Construction shell space designed for future completion
	+ Consultant fees not related to actual construction
	+ Damage judgment calls
	+ Equipment purchased through condition sales contract
	+ F&A costs
	+ Fund raising expense
	+ Land acquisition
	+ Legal services not related to site acquisition
	+ Movable equipment
	+ Off-site improvements
* Public policy requirements
	+ Grantees must require contractors/subcontractors to comply with Equal Employment Opportunity, Labor Standards, and Other Contract Requirements
	+ Review of environmental effects (National Environmental Policy Act of 1969)
	+ Required to publicly disclose project in newspaper or other public medium (NEPA and EO 11514)
	+ Cannot be in a flood-prone community, unless it participates in National Flood Insurance Program and flood insurance is purchased (Flood Disaster Protection Act of 1973)
	+ Requires intergovernmental review under EO 12372
	+ Must design using metric system (metric usage in federal government program)
	+ Comply with Uniform Relocation Act, requiring that displaced people be treated fairly and equitably
	+ Clean Air Act
	+ Safe Drinking Water Act
	+ Conservation of Petroleum and Natural Gas (EO 12185)
	+ Procurement requirements
	+ Labor standards
	+ Administrative Requirements (must obtain prior-approval under certain circumstances)
	+ Real Property Management Standards
	+ Facilities typically used for biomedical or behavioral research
	+ NIH defines extended usage requirement as 20 years from date of beneficial occupancy (unless another period is determined by statute
	+ NIH may require that funding be returned if no approval was granted to use facility for other purposes during this period

# Acronyms

**APHIS – Animal & Plant Health Inspection Service -** agency of the United States Department of Agriculture responsible for protecting animal health, animal welfare, and plant health

* protects and promotes US agricultural health, regulate genetically engineered organisms, administer the Animal Welfare Act and carry out wildlife damage management activities
* Association of University of Technology managers (AUTM) maintains UMBTA repository

**CBD – Commerce Business Daily –** list notices of proposed government procurement actions, contract awards, sales of government property, and other procurement information

**CDC – Center for Disease Control**–protects public health and safety through the control and prevention of disease, injury, and disability

**CFDA – Catalog of Federal Domestic Assistance** – provides full listing of all Federal programs available to State and local governments (includes District of Columbia); federally-recognized Indian tribal governments; Territories (and possessions) of the United States; domestic public, quasi-public, and private profit and nonprofit organizations and institutions; specialized groups; and individuals

**CFR – Code of Federal Regulations**– codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government

**COFAR - Council on Financial Assistance Reform –** Established by OMB Memorandum M-12-01

* Comprised of an interagency group of Execute Branch officials
* Provides recommendations to OMB on policies and actions necessary to effectively deliver, oversee and report on grants and cooperative agreements
* Best practices and innovative ideas for transforming the delivery of assistance
* Replaces to Federal boards: The Grant Policy Council and the Grants Executive Board
* Builds in part on grants streamlining activities under Public Law 106-107

**DS-2 – Disclosure Statement –** Universities receiving over $25,000,000 in federal funding must file a disclosure statement confirming their compliance with cost accounting standards.

**EDGAR – Education Department General Administration Regulation** - US Department of Education (DoED)

* Title 34, Code of Federal Regulations (CFR), Parts 75-79, 81 to 86 and 97-99 EDGAR is currently in transition. For awards made prior to 12/26/2014, EDGAR Parts 74 and 80 still apply. For awards made on or after 12/26/2014, 2 CFR Part 200, which includes the substance formerly in parts 74 and 80, applies.
* EDGAR is DoED policy manual
* Submission through grants.gov
* [www.g5.gov](http://www.g5.gov) replaced e-Grants and is the DoED’s grant management system

**EO – Executive Orders** – regulation by the President which has the effect of law (text appears in Federal Register)

* Exchange of materials with industry colleagues or academic colleagues outside home campus

**EUI – Energy Usage Index –** Ratio of a laboratory energy use index to the corresponding index for overall average college or university space

**FAC – Federal Audit Clearing house** – Clearinghouse designated by OMB as the repository of record where non-Federal entities are required to transmit the reporting packages require by Subpart F

**FAIN – Federal Award Identification No –** Beginning October 2013, federal agencies were required to assign a FAIN to every grant and ensure

* FAIN is used in all federal ward documents
* Pass-through entities must use FAIN on all subawards
* Enhance data quality on USASpending.gov

**FAPIIS – Federal Awardee Performance and Integrity Information System –** Web-enabled application that is used to collect contractor and grantee performance information.

**FISMA – Federal Information Security Management Act of 2002** – see Act section

**FR – Federal Register –** official journal of the federal government of the US that contains government agency rules, proposed rules and public notices

**FWA – Federal-wide Assurance** – institutional commitment to HHS that it will comply with the requirements of 45 CFR 46

**GOCO – Government Owned Contractor Operated –** owned by the Government and operated under contract by a non-government, private firm

**IACUC – Institutional Animal Care and Use Committees** – committee that reviews protocols for research involving animals, reviews programs, inspects facilities and suspends animal use if there is a violation of policies

**IBS – Institutional Base Salary –** Annual compensation paid by an IHE for an individual’s appointment, whether that individual’s time is spent on research, instruction, administration, or other activities.

**IHE – Institution(s) of Higher Education – (**20 U.S.C. 1001) an education institution in any State that

* Admits as regular students only person having a certification of graduation from a school proving secondary education (or recognized equivalent
* Legally authorized within such State to above a program of education beyond secondary education
* Provides an education program for which the institution awards a bachelor’s degree or provides not less than a 2-year program that is acceptable for full credit toward such a degree
* Is a public or other nonprofit institution
* Is accredited by a nationally recognized accrediting agency or association that has been recognized by the Secretary for granting a preaccreditation status

**IRB - Institutional Review Board** – a committee also known as an independent ethics committee or ethical review board that reviews biomedical and behavioral research involving humans to project human subjects from physical or psychological harm

* May not be usable for materials in projects supported by industry

**MTA – Material Transfer Agreement** – Binding contract that covers transfer of incoming and outgoing research materials

**OHRP – Office of Human Research Protections** – provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the US Department of Health and Human Services (HHS) – a cabinet-level department.

**OLAW - Office of Laboratory Animal Welfare** – governs the PHS Policy on Humane Care and Use of Laboratory Animals

**OMB – Office of Management and Budget**–oversees and coordinates the Federal procurement policy, performance and personnel management, information technology (e-Government) and financial management

* Recommended so that disputes about use do not arise
* Standard agreement developed in 1995 by NIH

**OS - Other Support** – includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included

**PII – Personally Identifiable Information –** information that can be used to distinguish or trace an individual’s identity

**PRHP – Post Retirement Health Plans –** Costs of health insurance or health services not included in a pension plan

**PTE – Pass through entity –** a non-Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program

**REUI – Relative Energy Usage Index –** Effective square footage allocated to research laboratory space must be calculated as the actual square footage times the REUI posted on the OMB Web site at the time of rate determination

**SPOC – Single Point of Contact –** From E.O. 12372 Intergovernmental partnership and strengthen federalism by relying on State and local processes for the coordination and review of proposed Federal Financial assistance and direct Federal development

**TFM – Treasury Financial Manual –** Overall Disbursing Rules for All Federal Agencies (TFM 4A-2000)

**UMBTA – Uniform Biological Material Transfer Agreement** – provides standardized approach for certain transfers between academic institutions

**USC – United States Code** – codification of all general and permanent laws of the U.S, excluding regulations issued by the executive branch agencies

**VAT – Value Added Tax** – Foreign taxes charged for the purchase of goods or services that a non-Federal entity is legally required to pay