Human Subjects
What is Human Research

Human research is defined as an activity designed to test a hypothesis (theory). The testing of this hypothesis lets an investigator draw conclusions as to whether the hypothesis is true, false or null (neither true or false). The results of hypothetical investigations ultimately contribute to generalizable knowledge; that is to say these investigations, although tested in relatively small numbers, may be applied to larger numbers.
Human Subjects

• Who Regulates Human Research
• HHS funding
  • *Office for Human Research Protections (OHRP)*
  • Aka Office for the Protection from Research Risks (OPPR)
• All of the Institution’s human subjects research activities, regardless of whether the research is subject to the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule)
• 45 CFR 46 Federal Policy for the Protection of Human Subjects
What is an Institutional Review Board (IRB)?

• The federal government established the Institutional Review Board (IRB) as a way of uniformly regulating human research protocols across the United States. The IRB is designed to protect the rights and welfare of human research subjects who have been recruited to participate in research activities. Human subjects are defined as living individuals about whom an investigator (whether professional or student) conducting research obtains data through (1) intervention or interaction, or (2) identifiable private information.
The Belmont Report

• Report created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
• September 30, 1978
• The Belmont Report summarizes ethical principles and guidelines for research involving human subjects
The Belmont Report

• Three core principles are identified:
  – Respect for persons
  – Beneficence
  – Justice
Glossary of Common Terms

- **Clinical Research** is medical research that involves people to test new treatments and therapies.

- **Healthy Volunteer** is a person with no known significant health problems who participates in clinical research to test a new drug, device, or intervention.

- **Inclusion/Exclusion Criteria** are factors that allow someone to participate in a clinical trial are inclusion criteria. Those that exclude or not allow participation are exclusion criteria.

- **Informed Consent** explains risks and potential benefits about a clinical trial before someone decides whether to participate.

- **Patient Volunteer** has a known health problem and participates in research to better understand, diagnose, treat, or cure that disease or condition.
Clinical trials are conducted in “Phases.” The trials at each phase have a different purpose and help researchers answer different questions.

- Phase I trials—An experimental drug or treatment in a small group of people (20–80) for the first time. The purpose is to evaluate its safety and identify side effects.
- Phase II trials—The experimental drug or treatment is administered to a larger group of people (100–300) to determine its effectiveness and to further evaluate its safety.
- Phase III trials—The experimental drug or treatment is administered to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard or equivalent treatments.
- Phase IV trials—After a drug is licensed and approved by the FDA researchers track its safety, seeking more information about its risks, benefits, and optimal use.

- Placebo is a pill or liquid that looks like the new treatment but does not have any treatment value from active ingredients.

- Protocol is a carefully designed plan to safeguard the participants’ health and answer specific research questions.
- Principal Investigator is a doctor who leads the clinical research team and, along with the other members of the research team, regularly monitors study participants’ health to determine the study’s safety and effectiveness.

- Randomization is the process by which two or more alternative treatments are assigned to volunteers by chance rather than by choice.

- Single- or Double-Blind Studies are studies in which the participants do not know which medicine is being used, so they can describe what happens without bias.

- Types of Clinical Trials
  - Diagnostic trials determine better tests or procedures for diagnosing a particular disease or condition.
  - Natural history studies provide valuable information about how disease and health progress.
  - Prevention trials look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning.
  - Quality of life trials (or supportive care trials) explore and measure ways to improve the comfort and quality of life of people with a chronic illness.
  - Screening trials test the best way to detect certain diseases or health conditions.
  - Treatment trials test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.
Questions?
Animal Care

• The Office for Protection from Research Risks (OPRR) of the National Institutes of Health (NIH) develops, implements, and oversees compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy). The PHS Policy and the U.S. Department of Agriculture's (USDA) Animal Welfare Regulations, are the two principal federal documents that set forth requirements for animal care and use by institutions using animals in research, testing, and education.
Office of Laboratory Animal Welfare

- OLAW oversees PHS-funded animal activities by the authority of the Health Research Extension Act of 1985 and the PHS Policy on Humane Care and Use of Laboratory Animals (Policy). The PHS Policy, section IV.A., requires that: “No activity involving animals may be conducted or supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS, setting forth compliance with the Policy.”
Animal Care

• AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. AAALAC stands for the "Association for Assessment and Accreditation of Laboratory Animal Care."
• Institutional Animal Care and Use Committee (IACUC) which is responsible for local compliance
• Animal testing on vertebrates is primarily regulated by the Animal Welfare Act of 1966 (AWA), and the Animal Welfare Regulations which is enforced by the Animal Care division of the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA).
Accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), a non-governmental, nonprofit association, is regarded by the industry as the "gold standard" of accreditation. Accreditation is maintained through a prearranged AAALAC site visit and program evaluation hosted by the member institution once every three years.
Intellectual Property
Intellectual Property

• Intellectual property (IP) rights are the legally recognized exclusive rights to creations of the mind. Under intellectual property law, owners are granted certain exclusive rights to a variety of intangible assets, such as musical, literary, and artistic works; discoveries and inventions; and words, phrases, symbols, and designs. Common types of intellectual property rights include copyright, trademarks, patents, industrial design rights, trade dress, and in some jurisdictions trade secrets.
Patents and Trademarks
Patent

- A patent (ˈpætənt/ or ˈpeɪtənt/) is a set of exclusive rights granted by a sovereign state to an inventor or assignee for a limited period of time in exchange for detailed public disclosure of an invention. An invention is a solution to a specific technological problem and is a product or a process. Patents are a form of intellectual property.
Trademark

• A trademark, trade mark, or trade-mark is a recognizable sign, design or expression which identifies products or services of a particular source from those of others. The trademark owner can be an individual, business organization, or any legal entity. A trademark may be located on a package, a label, a voucher or on the product itself.

• Registered trademark symbol = ® unregistered = ™
United States Patent and Trademark Office

- The United States Patent and Trademark Office (USPTO) is the federal agency for granting U.S. patents and registering trademarks. In doing this, the USPTO fulfills the mandate of Article I, Section 8, Clause 8, of the Constitution.

- The USPTO advises the president of the United States, the secretary of commerce, and U.S. government agencies on intellectual property (IP) policy, protection, and enforcement; and promotes the stronger and more effective IP protection around the world.
United States Patent and Trademark Office

• On July 31, 1790, the first U.S. patent was issued to Samuel Hopkins for an improvement "in the making of Pot ash and Pearl ash by a new Apparatus and Process". This patent was signed by then President George Washington.

• The X-Patents (the first 10,280 issued between 1790 and 1836) were destroyed by a fire; fewer than 3,000 of those have been recovered and re-issued with numbers that include an "X".

• Each year, the PTO issues over 150,000 patents to companies and individuals worldwide. As of December 2011, the PTO has granted 8,743,423 patents and has received 16,020,302 applications.
In the United States the term of patent:

For applications filed on or after June 8, 1995, the patent term is 20 years from the filing date of the earliest U.S. application to which priority is claimed (excluding provisional applications).

For applications filed before June 8, 1995 and for patents that were still in force on June 8, 1995, the patent term is either 17 years from the issue date or 20 years from the filing date of the earliest U.S. or international (PCT) application to which priority is claimed (excluding provisional applications), the longer term applying.
Controversial patents

- U.S. Patent 5,443,036, "Method of exercising a cat", covers having a cat chase the beam from a laser pointer. The patent has been criticized as being obvious.
- U.S. Patent 6,004,596, "Sealed crustless sandwich", issued in 1999, covers the design of a sandwich with crimped edges. However, all claims of the patent were subsequently canceled by the PTO upon reexamination.

Controversial trademarks

- U.S. Trademark 77,139,082, "Cloud Computing" for Dell, covering "custom manufacture of computer hardware for use in data centers and mega-scale computing environments for others", was allowed by a trademark attorney on July 8, 2008. Cloud computing is a generic term that could define technology infrastructure for years to come, which had been in general use at the time of the application. The application was rejected on August 12, 2008, as descriptive and generic.
Copyrights
Copyright

- Copyright is a legal right created by the law of a country, that grants the creator of an original work exclusive rights to its use and distribution, usually for a limited time, with the intention of enabling the creator (e.g. the photographer of a photograph or the author of a book) to receive compensation for their intellectual effort.
Copyright does not cover ideas and information themselves, only the form or manner in which they are expressed.[18] For example, the copyright to a Mickey Mouse cartoon restricts others from making copies of the cartoon or creating derivative works based on Disney's particular anthropomorphic mouse, but does not prohibit the creation of other works about anthropomorphic mice in general, so long as they are different enough to not be judged copies of Disney's.[18] Note additionally that Mickey Mouse is not copyrighted because characters cannot be copyrighted; rather, Steamboat Willie is copyrighted and Mickey Mouse, as a character in that copyrighted work, is afforded protection. In many jurisdictions, copyright law makes exceptions to these restrictions when the work is copied for the purpose of commentary or other related uses (See fair use, fair dealing). Meanwhile, other laws may impose additional restrictions that copyright does not – such as trademarks and patents.
Several exclusive rights typically attach to the holder of a copyright:

• to produce copies or reproductions of the work and to sell those copies (including, typically, electronic copies)
• to import or export the work
• to create derivative works (works that adapt the original work)
• to perform or display the work publicly
• to sell or cede these rights to others
• to transmit or display by radio or video.
Licensing
Licensing

• A licensor may grant a license under intellectual property laws to authorize a use (such as copying software or using a (patented) invention) to a licensee, sparing the licensee from a claim of infringement brought by the licensor. A license under intellectual property commonly has several components beyond the grant itself, including a term, territory, renewal provisions, and other limitations deemed vital to the licensor.

• Term: many licenses are valid for a particular length of time. This protects the licensor should the value of the license increase, or market conditions change. It also preserves enforceability by ensuring that no license extends beyond the term of the agreement.

• Territory: a license may stipulate what territory the rights pertain to.
• Examples of intangible assets include
• Song (“Somewhere Over The Rainbow”)
• Character (Donald Duck)
• Name (Michael Jordan)
• Brand (The Ritz-Carlton)
• An arrangement to license a brand requires a licensing agreement. A licensing agreement authorizes a company which markets a product or service (a licensee) to lease or rent a brand from a brand owner who operates a licensing program (a licensor).
University – Industry Research Relationships

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Research Type

- Industry funded research
  - Pfizer, GlaxoSmithKline, etc.
- Private funded research
  - American Heart, Komen, etc.
- No direct Federal Funding
• Will not be discussing
  • Contract Language
  • Clinical Trials
Definitions

• CDA /NDA = Confidentiality Disclosure Agreement
• CRA = Clinical Research Agreement
• IDC / F&A / Overhead = Indirect costs
• IDC Waiver = Administrative approval to accept a reduced rate of IDC lower than Federal Rate
• IP = Intellectual Property
• ORA = Office of Research Administration/ Central Research Office
• PI = Principal Investigator
• SOW = Statement of Work
• Know Your Sponsor
  • PI Expertise
  • University
  • Cost at Minimum
  • Own IP
  • Indirect Costs
  • Results Focused
    • Timely
• Differences with Federal Grants
  • Approve terms in advance
  • Allowable Costs
  • Allowable IDC
• Budget
  • Industry or Private Funding
  • Simple or Detailed
  • Fixed Price or Cost Reimbursable
• Fixed Price vs. Cost Reimbursable
  • Fixed Price operate under an established price that cannot be revised.
  • Cost-Reimbursable sponsored projects allow costs to be expended up to a set amount.
• Cost Reimbursable Advantages
  • No incentive to cut corners
  • Quality vs. time
  • Less risk

• Cost Reimbursable Disadvantages
  • Sponsor requires more financial reporting
  • Refund unused funds
  • Less incentive to be efficient
    • http://govwin.com/knowledge/cost-reimbursement
• **Fixed Price Advantages**
  • Know total price upfront
  • Best interest to Control Cost
    • Leftover money to PI/Department

• **Fixed Price Disadvantages**
  • No Price Adjustments
  • Maximum risk
Questions?
Thank You for Your Participation

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Test Taking Tips

• Every Research Administration Office is different

• Eat before a test. Having food in your stomach will give you energy and help you focus but avoid heavy foods which can make you groggy.

• Don't try to pull an all nighter. Get at least 8 hours of sleep before the test.
Test Taking Tips

• Go to the bathroom before walking into the exam room. You don't want to waste anytime worrying about your bodily needs during the test.

• Keep a positive attitude throughout the whole test and try to stay relaxed. If you start to feel nervous take a few deep breaths to relax.
Test Taking Tips

• If you don't know an answer, skip it. Go on with the rest of the test and come back to it later.

• Don't worry if others finish before you. Focus on the test in front of you.

• If you have time left when you are finished, look over your test. Make sure that you have answered all the questions. Only change an answer if you misread or misinterpreted the question because the first answer that you put is usually the correct one.
If you can dream it, you can do it
- Enzo Ferrari
Multiple Choice Test Taking Tips

• Read the question before you look at the answer.
• Come up with the answer in your head before looking at the possible answers.
• Eliminate answers you know aren't right.
• Read all the choices before choosing your answer.
• If there is no guessing penalty, always take an educated guess and select an answer.
• Don't keep on changing your answer, usually your first choice is the right one, unless you misread the question.
• In "All of the above" and "None of the above" choices, if you are certain one of the statements is true don't choose "None of the above" or one of the statements are false don't choose "All of the above".
• In a question with an "All of the above" choice, if you see that at least two correct statements, then "All of the above" is probably the answer.
• A positive choice is more likely to be true than a negative one.
• Usually the correct answer is the choice with the most information.
KEEP CALM AND EXAM SUCCESS
Good Luck!