RESEARCH ON HUMAN SUBJECTS pdf

1: Human Subjects | FSU Office of Research

Human Subjects Infographic - This one-page infographic is a guide to defining human subjects research at the NIH. It summarizes human subjects research, what you will need for your NIH application and what you will need if you are funded.

Description[edit] A key goal of IRBs is to protect human subjects from physical or psychological harm, which they attempt to do by reviewing research protocols and related materials. The protocol review assesses the ethics of the research and its methods, promotes fully informed and voluntary participation by prospective subjects capable of making such choices or, if that is not possible, informed permission given by a suitable proxy , and seeks to maximize the safety of subjects. IRBs are responsible for critical oversight functions for research conducted on human subjects that are "scientific", "ethical", and "regulatory". The equivalent body responsible for overseeing U. IRBs are most commonly used for studies in the fields of health and the social sciences, including anthropology , sociology , and psychology. Such studies may be clinical trials of new drugs or devices, studies of personal or social behavior, opinions or attitudes, or studies of how health care is delivered and might be improved. Human subject research legislation in the United States Formal review procedures for institutional human subject studies were originally developed in direct response to research abuses in the 20th century. Public Health Service , and numerous human radiation experiments conducted during the Cold War. The result of these abuses was the National Research Act of and the development of the Belmont Report , which outlined the primary ethical principles in human subjects review; these include "respect for persons", "beneficence", and "justice". An IRB may only approve research for which the risks to subjects are balanced by potential benefits to society, and for which the selection of subjects presents a fair or just distribution of risks and benefits to eligible participants. A bona fide process for obtaining informed consent from participants is also generally needed. However, this requirement may be waived in certain circumstances â€” for example, when the risk of harm to participants is clearly minimal. Additional requirements apply to IRBs that oversee clinical trials of drugs involved in new drug applications , or to studies that are supported by the United States Department of Defense. A secondary supplement to the FWA is required when institutions are undertaking research supported by the U. Research in conventional educational settings, such as those involving the study of instructional strategies or effectiveness of various techniques, curricula, or classroom management methods. In the case of studies involving the use of educational tests, there are specific provisions in the exemption to ensure that subjects cannot be identified or exposed to risks or liabilities. However, the organizational responsibilities and the scope of the oversight purview can differ substantially from one nation to another, especially in the domain of non-medical research. The United States Department of Health and Human Services maintains a comprehensive compilation of regulations and guidelines in other countries, as well as related standards from a number of international and regional organizations. Many simply capitalize the term "Institutional Review Board" as the proper name of their instance. At one time such a committee was named the "Committee for the Protection of Human Subjects". Originally, IRBs were simply committees at academic institutions and medical facilities to monitor research studies involving human participants, primarily to minimize or avoid ethical problems. The responsibilities of these IRBs are identical to those based at academic or medical institutions, and they are governed by the same U. For example, the minimum number of members is five, at least one scientist, and at least one non-scientist. The full requirements are set out in 21 CFR Research activity cannot be disapproved by expedited review. It defines Good Clinical Practice GCP , which is an agreed quality standard that governments can transpose into regulations for clinical trials involving human subjects. Safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid to trials that may include vulnerable subjects, such as pregnant women, children, prisoners, the elderly, or persons with diminished comprehension. Review both the amount and method of payment to subjects to assure neither presents problems of coercion or undue influence on the trial subjects. Payments to a subject should be prorated and not wholly contingent on completion of the trial by the subject. Information regarding payment to subjects, including the methods, amounts, and schedule of

payment to trial subjects, should be set forth in the written informed consent form and any other written information to be provided to subjects. The way payment will be prorated should be specified. Continuing review of ongoing trials is required at intervals appropriate to the degree of risk to human subjects, but at least once per year. Numerous complaints by investigators about the fit between the federal regulations and its IRB review requirements as they relate to social science research have been received. In , the Office for Human Research Protections OHRP , in conjunction with the Oral History Association and American Historical Association , issued a formal statement that taking oral histories , unstructured interviews as if for a piece of journalism , collecting anecdotes, and similar free speech activities often do not constitute "human subject research" as defined in the regulations and were never intended to be covered by clinical research rules. In general, the NSF guidelines assure IRBs that the regulations have some flexibility and rely on the common sense of the IRB to focus on limiting harm, maximizing informed consent, and limiting bureaucratic limitations of valid research. A article on the hope to expand ethics reviews of such research included an example of a data breach in which a big data researcher leaked 70, OkCupid profiles with usernames and sexual orientation data. Such challenges broach familiar themes, such as mistaken identity , precrime , and persecution , in new applications. Managing conflicts of interest[edit] While the IRB approval and oversight process is designed to protect the rights and welfare of the research subjects , it has been the subject of criticism, by bioethicists and others, for conflicts of interest resulting in lax oversight. In one test, a fake product "Adhesiabloc" was submitted to a number of IRBs for approval for human tests. The product, company, and CVs of the supposed researchers were all fictitious and documents were forged by the GAO. However, none of the IRBs approached detected that the company and product were fake. HHS has only three staff to deal with IRB registrations and assurance applications per month. HHS stated that it would not be worthwhile to carry out additional evaluation even if they had the staff to do it.

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2: Human Subjects in Research | Center for health sciences | Oklahoma State University

Human subject research is systematic, scientific investigation that can be either interventional (a "trial") or observational (no "test article") and involves human beings as research subjects.

You can help by adding to it. July Clinical trials are experiments done in clinical research. Such prospective biomedical or behavioral research studies on human participants are designed to answer specific questions about biomedical or behavioral interventions, including new treatments such as novel vaccines , drugs , dietary choices , dietary supplements , and medical devices and known interventions that warrant further study and comparison. Clinical trials generate data on safety and efficacy. Clinical trials can vary in size and cost, and they can involve a single research center or multiple centers , in one country or in multiple countries. Clinical study design aims to ensure the scientific validity and reproducibility of the results. Trials can be quite costly, depending on a number of factors. The sponsor may be a governmental organization or a pharmaceutical , biotechnology or medical device company. Certain functions necessary to the trial, such as monitoring and lab work, may be managed by an outsourced partner, such as a contract research organization or a central laboratory. Human subjects in psychology and sociology[edit] Stanford prison experiment[edit] Main article: Stanford prison experiment A study conducted by Philip Zimbardo in examined the effect of social roles on college students at Stanford University. After only six days, the abusive behavior of the guards and the psychological suffering of prisoners proved significant enough to halt the two-week-long experiment. This study would show whether or not prisoners and guards have conflict which make conflict inevitable. This conflict would be due to possible sadistic behavior of guards dispositional or due to the hostile environment of the prison positional. Due to the fact that prisoners could lack respect for the law and guards could behave in a hostile manner due to the power structure of the social environment that are within prisons. Yet, if prisoners and guards behaved in a non aggressive way, this would support the dispositional hypothesis. If the prisoners were just to behave in the same way that people did in real life, this would support the positional hypotheses. Using human subjects for this experiment is vital because the results is based on the way a human would react, with behaviors only humans obtain. Human subjects are the best way to get successful results from this type of experiment. The results of this experiment showed that people will readily conform to the specific social roles they are supposed to play. The prison environment played a part in making the guards behavior more brutal, due to the fact that none of the participants showed this type of behavior beforehand. Most of the guards had a hard time believing they had been acting in such ways. This evidence concludes this to be positional behavior, meaning the behavior was due to the hostile environment of the prison. Milgram Experiment In , Yale University psychologist Stanley Milgram led a series of experiments to determine to what extent an individual would obey instructions given by an experimenter. Placed in a room with the experimenter, subjects played the role of a "teacher" to a "learner" situated in a separate room. The subjects were instructed to administer an electric shock to the learner when the learner answered incorrectly to a set of questions. The intensity of this electric shock was to be increased for every incorrect answer. The learner was a confederate i. When the subject raised questions or paused, the experimenter insisted that the experiment should continue. In a control group of participants, the percentage of error was less than one percent. However, when the confederates unanimously chose an incorrect answer, 75 percent of the subject participants agreed with the majority at least once. The study has been regarded as significant evidence for the power of social influence and conformity. The hostility continued and worsened until the end of the three-week study, when the groups were forced to work together to solve problems. Bystander effect The bystander effect is demonstrated in a series of famous experiments by Bibb Latane and John Darley [20] In each of these experiments, participants were confronted with a type of emergency, such as the witnessing of a seizure or smoke entering through air vents. A common phenomenon was observed that as the number of witnesses or "bystanders" increases, so does the time it takes for individuals to respond to the emergency. This effect has been shown to promote the diffusion of responsibility by concluding that, when surrounded by others, the individual expects someone else to take action. Cognitive dissonance Human subjects have been commonly used in experiments testing the theory of

cognitive dissonance after the landmark study by Leon Festinger and Merrill Carlsmith. After the completion of these tasks, the subjects were instructed to help the experiment continue in exchange for a variable amount of money. All the subjects had to do was simply inform the next "student" waiting outside the testing area who was secretly a confederate that the tasks involved in the experiment were interesting and enjoyable. A subsequent survey showed that, by a large margin, those who received less money for essentially "lying" to the student came to believe that the tasks were far more enjoyable than their highly paid counterparts. Human subject research is used across many industries, with one of those being the automotive industry. Research has shown that civilian volunteers decided to participate in vehicle safety research to help automobile designers create more impactful and sustainable safety restraints for vehicles. This research allows designers to inquire more data on the tolerance of a human body in the event of an automobile accident to better improve safety features in automobiles. Some of the tests conducted ranged from sled runs evaluating head-neck injuries, airbag tests, and even tests involving military vehicles and their constraint systems. It is important to note that from thousands of tests involving human subjects, results indicate no serious injuries were persistent. This fact is largely due to the preparation efforts of the researchers to ensure all ethical guidelines are followed and to ensure the safety and well-being of their subjects. Although this research provides positive contributions, there are some drawbacks and resistance to human subject research for crash testing due to the liability of injury and the lack of facilities that have appropriate machinery to perform such experiments. Overall, the experiments have helped contribute to the knowledge of human tolerance for injury in crash impacts. This research is additional data from which testing with cadavers or crash test dummies would prevent us from discovering. Cadavers and crash test dummies still provide meaningful purpose when testing for higher tolerance tests beyond human capability. Privacy , confidentiality , and informed consent are key concerns, yet it is unclear when social media users qualify as human subjects. It is nevertheless a matter of concern that the collection of the data by Facebook may have involved practices that were not fully consistent with the principles of obtaining informed consent and allowing participants to opt out. Prisoners were forced into participating; they did not willingly volunteer and no consent was given for the procedures. Typically, the experiments resulted in death, trauma , disfigurement or permanent disability , and as such are considered as examples of medical torture. Of those 23, 15 were convicted, 7 were condemned to death, 9 received prison sentences from 10 years to life, and 7 were acquitted. It induced epidemics on a very large scale from onward through the Second Sino-Japanese war. Operation Whitecoat involved the injection of infectious agents into military forces to observe their effects in human subjects. They were often performed illegally, without the knowledge, consent , or informed consent of the test subjects. Public outcry over the discovery of government experiments on human subjects led to numerous congressional investigations and hearings, including the Church Committee , Rockefeller Commission , and Advisory Committee on Human Radiation Experiments , amongst others. The Tuskegee syphilis experiment , widely regarded as the "most infamous biomedical research study in U. The study followed more than African-American men who were not told they had syphilis and were denied access to the known treatment of penicillin. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established and was tasked with establishing the boundary between research and routine practice, the role of risk-benefit analysis , guidelines for participation, and the definition of informed consent. Its Belmont Report established three tenets of ethical research: Southam , an important virologist and cancer researcher, injected HeLa cells into cancer patients, healthy individuals, and prison inmates from the Ohio Penitentiary. He wanted to observe if cancer could be transmitted as well as if people could become immune to cancer by developing an acquired immune response. Many believe that this experiment violated the bioethical principles of informed consent , non-maleficence , and beneficence.

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3: Human Subjects Division - UW Research

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS).

The purpose of the IRB is to ensure that the rights of participants in human research are protected, in line with the federal guidelines 45 CFR All investigators conducting research with human subjects should submit a proposal to the IRB for review, and should only conduct the research AFTER the proposal is reviewed and approved. Instructions for selecting the review category can be found on the last two pages of the document. These instructions do not need to be submitted with the IRB proposal. You can also review an example IRB. You have two options for submitting a hard copy of your completed IRB proposal email proposals will not be accepted: The IRB mailbox is located on the top shelf of the bookshelf facing you as you walk in the door see picture below. Send the IRB proposal through campus mail allow a couple extra days for mail to: Bari Lynne Kersey RE: IRB In accordance with the Federal Guidelines for research with human subjects, you must obtain informed consent from all of your research subjects. If the subject is a minor age 17 or under , you must obtain written consent from a parent or guardian. Normally, proposals will be reviewed within five 5 business days of the date they are submitted to the review board. Proposals requiring full committee review may take up to ten 10 business days for review. Proposals submitted over breaks will take additional time. Following review, the primary investigator will receive email notification of the outcome of the review. The proposal may be approved, or it may require changes or additional information that must then be resubmitted for review. For all of these reasons, investigators are strongly encouraged to submit their proposals at least three 3 weeks before they intend to start the project. Renewals An important duty of the Institutional Review Board is to maintain a record of all active research protocols. Therefore, projects that have been previously approved by the Board must be re-submitted for renewal whenever the research project is repeated or extended. Please complete and submit Section I of Form C for project renewals. In instances of longitudinal research, the investigator must submit a brief paragraph that summarizes the findings of the study and the justifications for renewal. This form must be returned to the chair of the IRB Dr. Tia Murphy, tmurphy2 washcoll. If you have participated in research and feel that you were treated in an unprofessional manner or have concerns about your rights as a research participant, you can contact the Principal Investigator or the chair of the Review Board for Research with Human Subjects Dr.

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4: What is Human Subjects Research - Office of Research Support and Compliance

A human subject is defined by DHHS as a living individual about whom a research investigator (whether a professional or a student) obtains data through intervention or interaction with the individual or from individually identifiable information.

Human Subjects The Mission of the FSU Human Subjects Committee is to protect the welfare of human subjects participants by compliance with the federal regulations governing the protection of human subjects, and facilitating the research efforts of FSU faculty, students and staff. The IRB has no regulatory authority or jurisdiction to oversee activities that are legitimately classified as something other than research. Institutions prefer to have non-research activities handled by an entity other than the IRB, so that the IRB can focus its time and resources on managing its fundamental mission. As defined by DHHS When evaluating a specific project, it is helpful to focus on two key elements: One helpful question to aid in determining whether a project is "research", is whether the investigators desire or may desire to publish the results of their project in a journal, or present some aspect of the project at an academic meeting. While this is often a practical key factor in determining intent involving a project, there is a distinction between publication that is merely educational in intent, such as a medical journal that may contain an article that discusses information that is not the result of a research activity versus an article that addresses results of a research activity. After the project has been designated "research" as defined by the federal regulations, the next step is to determine whether the project involves "human subjects". Some examples of human subjects research: Interviewing cancer survivors about coping techniques Questionnaires about dating behaviors among college students Surveys about shopping preferences in rural communities Moderate exercise activities and venipuncture of individuals to determine certain depletions Music therapy intervention to determine whether it affects pain levels in a hospital environment. Surveys for evaluating the performance of faculty, staff, and students, or other studies for internal institutional use only not a "research" activity Oral history of New Orleans jazz artists and memories of post-WWII era information is not gathered for "generalizable knowledge". Secondary analysis of publically availably data, such as reviewing US Census data not "human subjects" â€” de-identified data. Established pursuant to federal regulations, the IRB is a committee composed of scientists and laypersons who review all proposed FSU human subjects research to ensure that the safety and welfare of subjects are protected. All human subjects research requires review and approval by an IRB prior to subject recruitment and data collection, and prior to the use of extant data or private information. The FSU HSC members have the responsibility for reviewing all research involving human subjects conducted by FSU faculty, students, or staff, regardless of the source of funding. The staff members provide support by performing recordkeeping duties, maintaining a database in order to address research protocol and compliance issues, and providing training regarding federal regulation requirements. The staff also serves as a resource for investigators and HSC members, and has delegated authority to determine the initial appropriate level of review required for each research proposal submitted for review. The Review Process for Human Subject Studies Federal regulations divide human subjects research into three categories according to the level of risk posed to subjects. The categories of review are as follows: To qualify for this category, the research must fall into one of six exemption categories by the HSC. Examples of research that qualify as exempt are: FSU uses the expedited review process for exempt protocols. Investigators are still required to document informed consent, and undergo continuing review of exempt research protocols. To qualify for this category, research must fall into one of the nine federal defined categories of research that may be reviewed through an expedited review process. Some examples qualifying for expedited review are: Studies involving collection of hair, saliva, or dental plaque samples Studies of blood samples from healthy volunteers Analysis of voice recordings Studies of existing pathological specimens with personal identifiers This type of review process involves a subset of the full committee membership, delegated this authority by the Chair, to independently evaluate the protocol, and when all reviewers concur, the protocol is approval. Reviews via the expedited process usually take approximately three weeks. Research involving prisoners Important Distinction: It is the policy of FSU that all

research involving vulnerable populations, such as prisoners, children, decisionally impaired, pregnant women and fetuses, neonates be reviewed by the full committee. Note that protocols involving the deception of research subjects, or other potentially vulnerable populations such as students or economically disadvantaged persons may be reviewed by the full committee. Full committee meetings are held monthly at a time and location that is subject to change from semester to semester. Information regarding the time and place of meetings may be obtained by contacting the HSC Office, and is posted on the website. Protocols that require review at a convened full committee meeting must be received in the FSU HSC office no later than 5: HSC members may not participate in the review and approval process of their own protocols. Full committee review process takes approximately six weeks. HIPAA regulates the protection of private health information for individuals. An adverse event is a serious, undesirable, and unintended result involving risks to research participants or others. The Investigator must provide a description of the adverse event and state whether or not changes are needed in the protocol and the informed consent process. These revisions must be reviewed by the full committee. If the events are determined to place participants at increased risks, the Chair may request resubmission of the protocol for full committee review. If the committee determines that the research participant may be placed at an immediate risk, the Committee has the authority to suspend or terminate approval of a protocol, requiring the immediate cessation of data collection from research participants. Amendments or Changes to the Protocol: A protocol change may affect the risks involved with a study, in addition to adverse events, unanticipated problems, or complaints about the research â€" all of which should be reported to the HSC. Minor changes proposed to previously approved protocols i. All other proposed modifications major changes will be reviewed using the same process used for the review of the original protocol. Only when it is necessary to eliminate apparent immediate hazards to research participants, may, according to the federal regulations, an Investigator be permitted to modify an approved protocol without the prior review and approval of the IRB; however, the IRB must be promptly informed of the change upon implementation. All protocols approved by the FSU HSC are subject to continuing review at intervals appropriate to the degree of risk, but not less than once in the 12 months following approval. If the Principal Investigator does not receive a form for request for continuing review renewal within one month prior to the expiration date of the current FSU HSC approval, a request for the form should be made by contacting the HSC office. If the HSC approval of a protocol expires before it has been re-reviewed, the protocol shall be suspended. While in a suspended status, new subject recruitment must cease, and interventions under the research protocol must be halted. The only exception to this requirement is when there are concerns for the safety or well-being of the research subjects. In such a case, the Investigator must contact the HSC promptly. The suspension will be removed when and if the protocol is re-approved by the HSC. The HSC, as a courtesy, sends out a written reminder to the Principal Investigator that the approval date is approaching expiration, and a renewal form is attached to the notice. If the protocol has not been re-approved, then the approval expires and data collection must cease. If the protocol has been re- approved, the notice will be labeled as "Re-Approval". Closing a Study at FSU:

5: Human Subjects Research | NIDDK

Important information regarding recent IRB changes Before you implement research that involves the use of human subjects, your project must be reviewed and approved by the Kent State Institutional Review Board (IRB).

6: Stanford RCO â€“ Human Subjects Research and IRB

Human Subjects Education: certification that any person identified as senior/key personnel involved in human subjects research has completed an education program in the protection of human subjects must be submitted.

7: Institutional review board - Wikipedia

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Human subjects All ASU research projects involving humans as subjects must be reviewed and approved by ASU's Institutional Review Board (IRB) prior to implementing studies, including recruitment and screening activities.

8: Research Policy | Human Subjects Research | Washington College

45 CFR Pre Requirements. Requirements. Content created by Office for Human Research Protections (OHRP) Content last reviewed on February 16,

9: Human subjects | Research Integrity and Assurance

All Human Subjects Research conducted by students, faculty, or staff of American University must receive approval from the American University IRB. If your research meets the definitions of both research and human subjects, you must complete the IRB www.enganchecubano.com view the definitions based on federal guidelines, click here.

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