

# Research Ethics Informed Consent

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# Research Ethics

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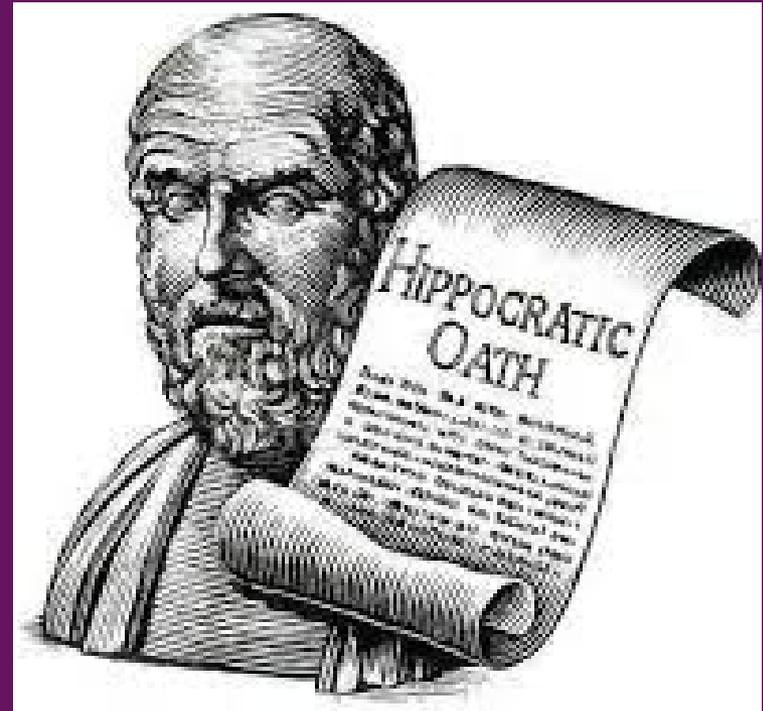


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# Introduction

The ethics of research involving human subjects have a long and troubled history. As a society, we have learned difficult lessons on how to ensure the ethical conduct of research while continuing in the advancement of scientific knowledge for the benefit of humanity. Ethical principles and regulations have been developed over the years designed to help ensure that the rights and welfare of human subjects in research are protected and maintain the public trust in the research enterprise.



[quora.com](https://www.quora.com)



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# Learning Objectives

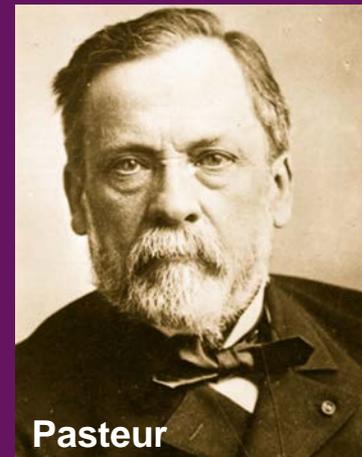
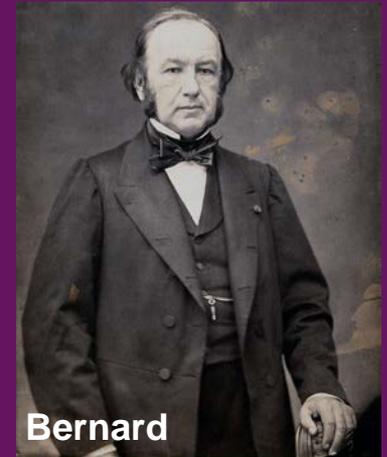
- **Research ethics**

- Understand history behind regulations governing human subjects research
- Identify ethical principles underlying research involving human subjects
- Understand federal regulations designed to implement ethical principles and preserve public trust



# Historical Context

- **Early researchers struggled with ethical concerns**
  - Edward Jenner (1789)
    - Smallpox vaccine
  - Claude Bernard (1865)
    - Developed ethical maxims
  - Louis Pasteur (1885)
    - Rabies vaccine
  - Walter Reed (1900)
    - Yellow fever



[en.wikipedia.org](https://en.wikipedia.org)



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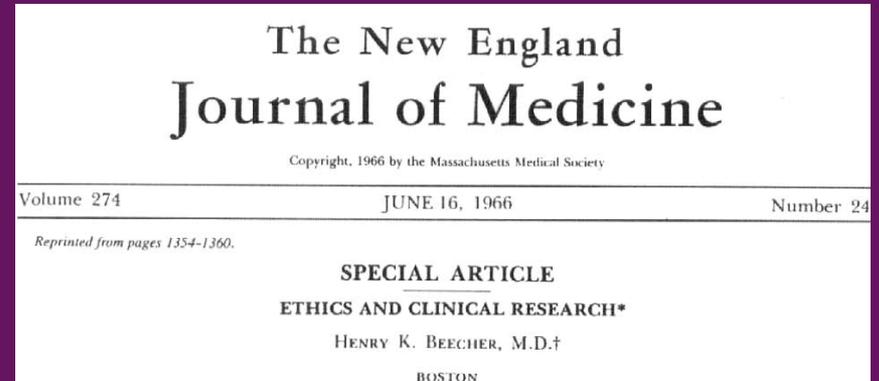
# The Nuremberg Code 1947

- **Modern concern regarding ethics of research involving human subjects were developed as a result of the Nazi regime's atrocities during World War II**
- **Nuremberg War Crimes Trials**
  - 23 Nazi doctors charged with crimes against humanity
- **Nuremberg Code**
  - Requirement of voluntary consent
  - Research has scientific merit
  - Benefits of research outweigh risks
  - Subjects have ability to terminate participation in the research at anytime



# Henry K. Beecher Article

- **Ethics and Clinical Research<sup>1</sup>**
  - Detailed 22 published medical studies presenting risk to subjects without consent
  - Demonstrated unethical research was not confined to Nazi atrocities



1. Beecher, *N Engl J Med* **274**:24, 1966.



# Tuskegee Syphilis Study

- **US Public Health Service<sup>1</sup>**
  - Monitored natural course of untreated syphilis in black American men for 40yrs
    - Originally 6mo study
    - 399 +syphilis
    - 201 –syphilis
    - Patients told being treated for “bad blood”
- **Findings**
  - Not offered treatments (penicillin available in late 1940s)
  - Exposed to public in 1972

1. Brandt, *Hastings Cent Rep* 8:6, 1978.



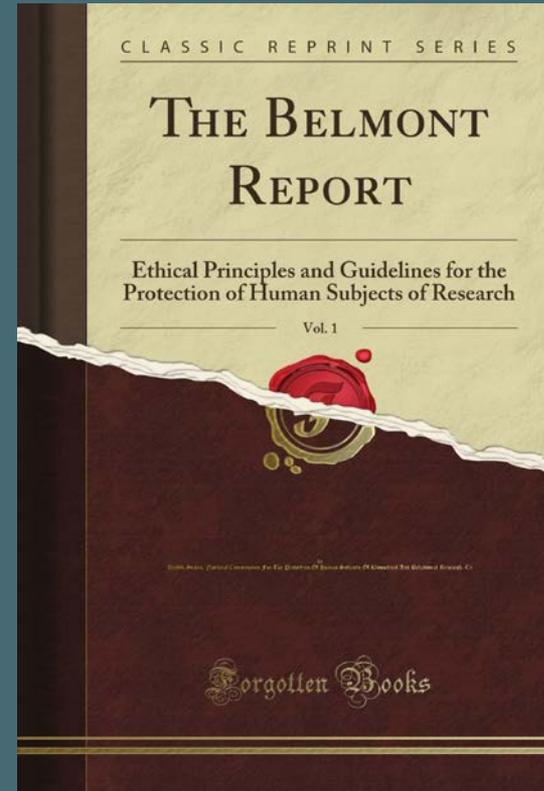
# National Research Act 1974

- **National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research**
  - Identify basic ethical principles underlying human subject research
  - Develop guidelines to ensure human subject is conducted according to these guidelines
  - Required establishment of Institutional Review Boards (IRB) at organizations receiving public support for human subjects research



# The Belmont Report 1979

- **Reports from The National Commission (1975-1978)**
  - Vulnerable populations
    - Fetuses
    - Children
    - Prisoners
    - "Mentally infirm"
  - Psychosurgery
  - Institutional Review Boards
  - Regulating human subjects research



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# The Belmont Report 1979

- **Principles**
  - **Respect for persons**
  - **Beneficence**
  - **Justice**

*“Provide analytical framework that will guide the resolution of ethical problems arising from research involving human subjects”*

**The National Commission 1979**



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# The Belmont Report 1979

- **Principles**
  - **Respect for persons**
  - **Beneficence**
  - **Justice**
- **Individuals treated as autonomous agents**
- **Individuals with diminished autonomy need protections**
  - *“The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations”*



# The Belmont Report 1979

- **Principles**
  - **Respect for persons**
  - **Beneficence**
  - **Justice**
- **Informed consent**
  - **Information**
    - Information sufficient so that “reasonable volunteer” can decide whether to participate
  - **Comprehension**
    - Investigators responsible in determining if subject understands the information
  - **Voluntariness**
    - Participation valid only if voluntarily given
    - Avoid undue influence



# The Belmont Report 1979

- **Principles**
  - **Respect for persons**
  - **Beneficence**
  - **Justice**
- **Informed consent**
  - *“Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied”*



# The Belmont Report 1979

- **Principles**

- **Respect for persons**
- **Beneficence**
- **Justice**

- **Privacy**

- Respecting individual's right to control access to one's self and information
- Protecting the confidentiality of private, identifiable information



# The Belmont Report 1979

- **Principles**
  - Respect for persons
  - **Beneficence**
  - Justice
- **Systematic assessment of risks and benefits**
  - Account for magnitude of possible harm
  - Probability that harm may occur
- **Minimization of risk**
  - Consider alternative, less risky procedures or modifications to reduce magnitude or probability of harm



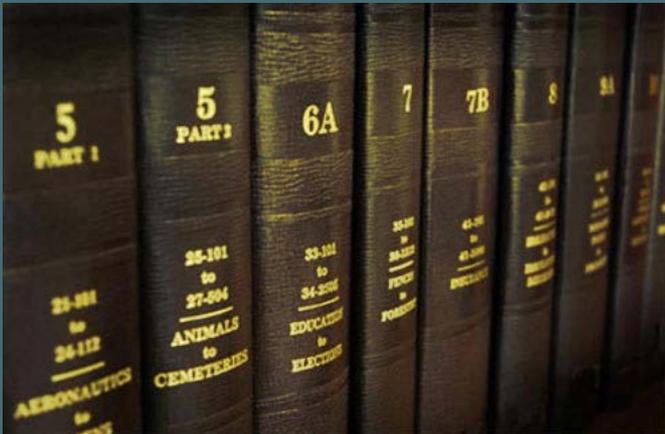
# The Belmont Report 1979

- **Principles**
  - Respect for persons
  - Beneficence
  - **Justice**
- **Equitable selection of subjects**
  - Fair sharing of burdens and benefits of research
  - Groups are not exploited
    - Prisoners
    - Institutionalized children
  - Avoid undue influence in recruitment
    - Financial incentives
    - Inequitable power relationships
    - Implied benefits from participating



# Development of US Regulations

- Subpart B
- Subpart C
- Subpart D
- **Assure independent determination**
  - Rights and welfare of the individual(s) involved
  - Appropriateness of methods used to secure informed consent
  - Risks and potential medical benefits of the investigation



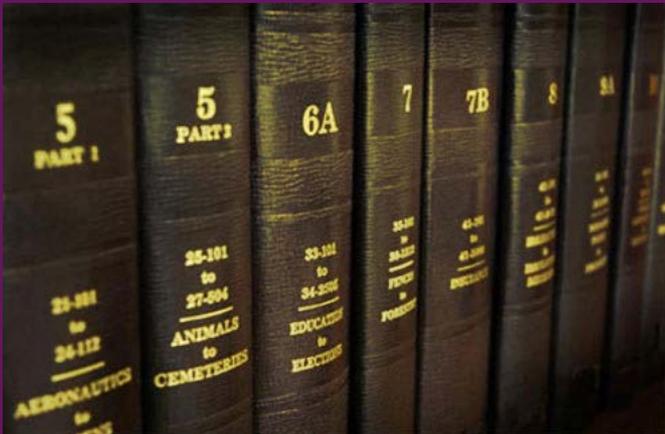
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# Development of US Regulations

- Subpart B
- Subpart C
- Subpart D
- Additional protections for pregnant women, human fetuses, and neonates involved in research (1975)
- Revised in 2001



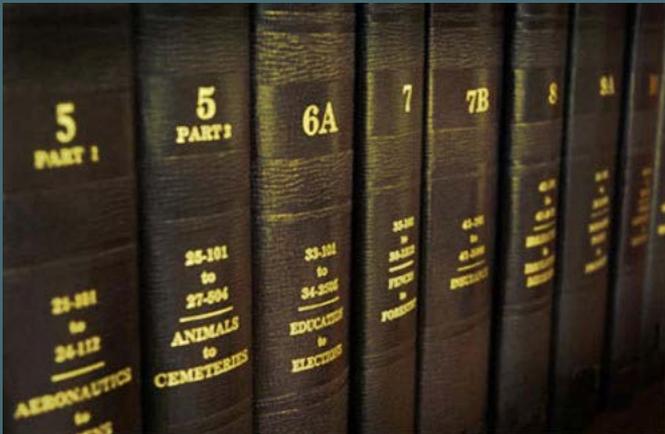
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# Development of US Regulations

- Subpart B
- **Subpart C**
- Subpart D
- **Additional protections pertaining to biomedical and behavioral research involving prisoners as subjects (1978)**



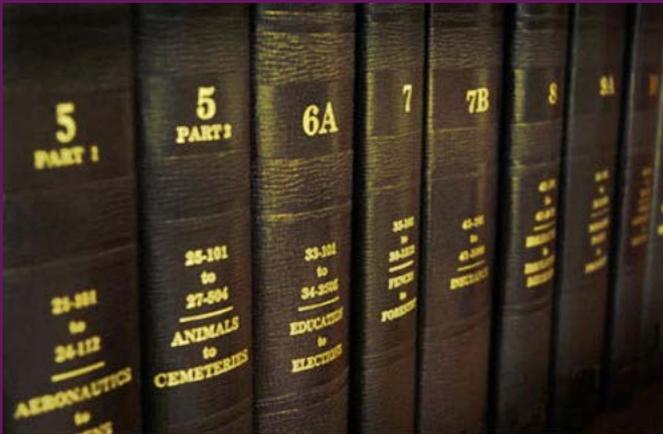
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# Development of US Regulations

- Subpart B
- Subpart C
- **Subpart D**
- **Additional protections for children involved as subjects in research (1983)**
- **Revised in 2013**



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# International Regulations

- **International codes and standards adopted to apply to ethical conduct of human subjects research**
  - Declaration of Helsinki
    - 1964
  - Council for International Organizations of Medical Sciences
    - 1982
  - International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
    - 1996
  - World Health Organization
    - 2001



# Human Research Protections Program

- IRBs are not enough to protect human subjects in research
- HRPP- comprehensive and organized system of shared responsibility
  - Ensure protection of human subjects in research
  - Ensure human subjects research is conducted ethically

Higher standards for IRB review



Increased responsibility for researchers



Increased requirements regarding conflict of interest



The accreditation of HRPPs



# Case Study

It has recently been report that, in the 1950s, researchers conducted prostate biopsies on over 1,000 individuals who were homeless and addicted to alcohol in New York. The purpose of the research was to learn whether this procedure would diagnose prostate cancer early and, if detected, study the effectiveness of various treatments. While the biopsy procedure had been used in patients with prostate problems, it had not been used in the general population to screen for prostate cancer. These individuals were used because no one else would volunteer for such as invasive study. The subjects were offered free meals, shelter, and treatment in return for being subjects in the research. While they were told about the procedure, they were not told about the risks of the biopsy or of the treatments.



# Case Study

- **In what way does this research violate the Belmont Report's principle of justice?**
  - The selection of subjects was not equitable. These individuals were used as subjects because less vulnerable subjects would not have volunteered. In addition, they bore the burden of the research, while the benefits, if any, would come to the general population. Finally, the offer of free meals and shelter to this population would be considered “undue influence”, exploiting these subjects because of their circumstances.



# Case Study

- **In what way does this research violate the Belmont Report's principle of respect for persons?**
  - Because the researchers did not fully explain the risks of the biopsy or treatments to the subjects, they did not obtain true informed consent. The undue influence of the free meals and shelter means that the subjects were not able to give free, voluntary consent to the research. No additional protections were provided for these vulnerable subjects. Because of the socially vulnerable situation of the subjects, additional protections should have been included to ensure that they were giving true informed consent, such as access to social worker subject advocates.



# Case Study

- **In what way does this research violate the Belmont Report's principle of beneficence?**
  - Because this procedure had not been tried as a screening tool before and had significant risks, even though they received treatment, there is some question as to whether the benefits of the research justified the risks involved.



# Moral Principles

- **Make ethical decisions**
  - Commitment
    - Do the right thing regardless of cost/time required
  - Consciousness
    - Act consistently, applying moral convictions to daily behavior
  - Competency
    - Ability to collect and evaluate data, identify alternatives, foresee potential consequences and risks
  - Good decisions are both ethical and effective
- **Evaluate credibility of data before making research decisions**
- **Provide credit to any researcher who contributes substantially to the project**



# Conclusion

- **Apply principles of Belmont Report**
  - **Respect for persons**
    - Informed consent
    - Privacy
  - **Beneficence**
    - Systematic assessment of risks and benefits
    - Minimization of risk
  - **Justice**
- **Human Research Protections Program**
  - Protect human subjects
  - Ensure research is ethical
- **Online human subjects training course**
  - IRB requires training certificate
  - CITI Program



<https://about.citiprogram.org/en/homepage/>

- **Standards continue to evolve**



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# Informed Consent

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# Introduction

- **Informed consent process includes**
  - Recruitment efforts encompassing means of first creating awareness of contact and spanning medical record review to recruitment materials
  - Providing information and answering questions that is understandable while giving subjects adequate time to consider participation
  - Obtaining voluntary agreement and verifying continued willingness to participate
  - Making plans for provision of new information to be shared with former subjects even after study ends



# Mandated Regulation 45 CFR 46

- **Informed consent demonstrates how researchers show respect to research subjects**
  - Protect human subjects
  - Ensure potential study subjects clearly understand benefits and risks associated with participation in study
  - Provide potential study subjects all information needed to reach decision on whether or not to participate in a research study



# Learning Objectives

- **Informed consent**
  - Describe requirements for complying with informed consent regulations
  - Describe process for obtaining informed consent
  - Discuss when subjects may be vulnerable to undue influence or coercion
  - Describe regulations for waiving informed consent



[fda.gov](http://fda.gov)



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# Key Term Definitions

- **Broad consent**
  - Option in lieu of informed consent
    - With respect to storage and maintenance
    - Secondary research use of identifiable private information / biospecimens
- **Key information**
  - Brief description of elements of informed consent presented at beginning of a consent discussion
    - Comprehension
    - What is needed by a “reasonable person” to make informed decision



# Key Term Definitions

- **Legally authorized representative (LAR)**
  - Individual or judicial or other body authorized to consent on behalf of prospective subject to the subjects participation in the procedure(s) in the research



# Key Term Definitions

- **Vulnerable**
  - Subjects in research studies vulnerable to the possibility of coercion or undue influence
- **Written or in writing**
  - Refers to writing on a tangible medium or in electronic format



# Informed Consent Elements

## 1. Statement that the study involves research

- Purpose(s)
- Expected duration of participation
- Description of procedure(s)
- Identification of any procedure(s) that is experimental

## 2. Description of reasonably foreseeable risks or discomforts

## 3. Description of any benefits to subjects or others that may reasonably be expected from research



# Informed Consent Elements

4. **Disclosure of appropriate alternative procedure(s) of treatment**
  - If any, that might be advantageous
5. **Describe extent to which confidentiality of records identifying the subject will be maintained**
6. **For research involving more than minimal risk, explanation as to whether any compensation and explanation as to whether any medical treatments are available if injury occurs**
  - If so, what they consist of or where information may be obtained



# Informed Consent Elements

- 7. Explanation of whom to contact to answer pertinent questions about research and research subjects' rights**
- Whom to contact in event of research-related injury

- 8. Statement that participation is voluntary**
- Refusal to participate will involve no penalty or loss of benefits which subject is entitled
  - Subject may discontinue participation at any time without penalty or loss of benefits to which subject is entitled



# Informed Consent Elements

## 9. One of the following statements about research that involves collection of identifiable private information or identifiable biospecimens

- Statement that identifiers might be removed from identifiable private information / biospecimens
  - After removal, information / biospecimens could be used for future studies or distributed for further research studies without additional informed consent
- Statement that collected information / biospecimens will not be used for future research studies



# Informed Consent

## Additional Requirements

A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.

Anticipated circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's or legally authorized representative's consent.

A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

The approximate number of subjects involved in the study.

Any additional costs to the subject that may result from participation in the research.

A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (that is, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.



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# Broad Consent Requirements

- **Basic elements**
  - Risks
  - Benefits
  - Confidentiality
  - Voluntary participation statement
  - Commercial profit (when appropriate)
  - Whole genome sequencing (when appropriate)



[medscape.com](https://www.medscape.com)

46.116(d)(1)



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# Broad Consent Requirements

- **Requires general description of types of research that may be conducted**
  - IRB assesses if research description is adequate to permit reasonable person to provide consent for currently proposed secondary research study
- **Requires description of information or biospecimens that might be used in future research**
  - If sharing might occur
  - Types of institutions or researchers that might conduct research

46.116(d)(2)

46.116(d)(3)



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# Broad Consent Requirements

- Requires description of length of time that information or biospecimens may be stored, maintained, and used
- Requires statement whether subjects will or will not be informed of details of any subsequent research

46.116(d)(4)

46.116(d)(5)



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# Broad Consent Requirements

- Requires statement that clinically relevant research results will or will not be disclosed to subjects
- Requires contact information be provided in the broad consent

46.116(d)(6)

46.116(d)(7)



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# Non-Exempt Research

- **IRB must determine**
  - Description of research in broad consent meets reasonable person standard to explain secondary research
  - Elements of broad consent included



# Exempt Research

- **For storage or maintenance for secondary research for broad consent is required per exempt category 7**
  - Broad consent obtained
  - Broad consent documented or waiver of documentation appropriate
  - If change made for research purposes to identifiable private information / biospecimens are stored
    - Adequate provisions to protect privacy and maintain confidentiality



# Exempt Research

- **For secondary research (research involving use of identifiable private information or identifiable biospecimens for secondary research use) for broad consent is required per exempt category 8**
  - Broad consent obtained
  - Broad consent documented or waiver of documentation appropriate
  - Limited IRB review determines that research is within scope of broad consent and adequate provisions to protect privacy and maintain confidentiality
  - Does not include returning individual results to subjects as part of study plan



# Clinical Trials Consent Form Requirements

- **Clinical trial (HHS)**
  - Research study in which human subject(s) are prospectively assigned to intervention(s), may include placebo or other control, to evaluate effects of intervention(s) on biomedical or behavioral health-related outcomes
- **Supported by federal department or agency**
  - IRB-approved consent form must be posted on publicly available federal website
  - Consent form must be posted after trial is closed to recruitment



# Obtaining Informed Consent

- **Providing information to the subject**
- **Answering questions to improve comprehension**
- **Obtaining the subject's voluntary agreement to participate in the study**



# Obtaining Informed Consent

- **Providing information to the subject**
- Answering questions to improve comprehension
- Obtaining the subject's voluntary agreement to participate in the study
- **Advertising for recruitment**
  - Cannot be coercive or make false promises
  - Consider laws, guidelines, policies if multi-site research
  - If compensation allowed, how will it be noted in recruitment materials
  - What are the “norms” in recruitment location



# Obtaining Informed Consent

- **Providing information to the subject**
- **Answering questions to improve comprehension**
- **Obtaining the subject's voluntary agreement to participate in the study**
- **Advertising for recruitment**
  - Screening subjects for eligibility must protect rights and welfare
  - Information clearly communicated in organized fashion and with understandable language
  - Information should not use exculpatory language in written consent



# Obtaining Informed Consent

- Providing information to the subject
- **Answering questions to improve comprehension**
- Obtaining the subject's voluntary agreement to participate in the study
- **Consent is understandable and provides sufficient detail**
  - Providing consent in language<sup>1</sup> that is understandable to subject or subject's LAR
  - Providing non-English speaking subjects translated informed consent document



# Obtaining Informed Consent

- Providing information to the subject
- **Answering questions to improve comprehension**
- Obtaining the subject's voluntary agreement to participate in the study
- **Consent is understandable and provides sufficient detail**
  - If translator used, providing written translation of consent document is still required
  - Giving subject enough time to think about participation in research before giving consent



# Obtaining Informed Consent

- Providing information to the subject
- Answering questions to improve comprehension
- **Obtaining the subject's voluntary agreement to participate in the study**
- **Legally effective consent shall**
  - Be obtained from subject or subject's LAR
  - Obtained under circumstances that provide subject with opportunity to consider whether or not to participate and minimizes coercive influences



# Obtaining Informed Consent

- Providing information to the subject
- Answering questions to improve comprehension
- **Obtaining the subject's voluntary agreement to participate in the study**
- **Legally effective consent shall**
  - Not include language through which subject waives or appears to waive any legal rights or language that releases researcher, sponsor, or organization from liability for negligence



# Obtaining Informed Consent

- Providing information to the subject
- Answering questions to improve comprehension
- **Obtaining the subject's voluntary agreement to participate in the study**
- **Legally effective consent shall**
  - Subjects unable to read or write can “make their mark” on the informed consent document as long as it is consistent with state laws



# Special Challenges

- Language issues
- Cultural issues



# Special Challenges

- Language issues
- Cultural issues
- **Consent process should be conducted in language spoken by subject and consent form should be translated into that language**
  - If subject is not literate, then interpreter must be present to explain study to the subject and translate questions and answers between subject and person getting consent



# Special Challenges

- Language issues
- **Cultural issues**
- **Cultural customs may affect comprehension**
  - In some cultures, it may be considered rude to ask questions of researchers or rude to decline what is perceived as a request for a favor
  - Who conducts the consent process and how it is explained becomes even more important



# Vulnerable Populations

- Regulations require that “when some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects”
- **Examples**
  - Children
  - Prisoners
  - Pregnant women
  - Handicapped persons
  - Mentally disabled persons
  - Economically or educationally disadvantaged persons



# Regulations for Waiving Informed Consent

- **Permitted under specific circumstances with IRB approval**
  - IRB may not waive consent if individual was asked to provide broad consent and refused
  - IRB may not alter or omit required elements of consent if broad consent was used
- **HHS regulations for waivers and alterations**
  - Government projects
  - General waivers and alterations
  - Screening, recruiting, or determining eligibility



# Regulations for Waiving Informed Consent

- **Permitted under specific circumstances with IRB approval**
  - IRB may not waive consent if individual was asked to provide broad consent and refused
  - IRB may not alter or omit required elements of consent if broad consent was used
- **Common rule general waivers and alterations**
  - Research involves no more than minimal risk to subjects
  - Research could not be carried out without waiver or alteration
  - If research involves identifiable private information / biospecimens, research could not be carried out without identifiable format



# Regulations for Waiving Informed Consent

- **Permitted under specific circumstances with IRB approval**
  - IRB may not waive consent if individual was asked to provide broad consent and refused
  - IRB may not alter or omit required elements of consent if broad consent was used
- **Common rule general waivers and alterations**
  - Waiver or alteration will not adversely affect rights and welfare of the subjects
  - When appropriate, subjects or LAR will be provided with additional pertinent information after participation



# Regulations for Waiving Informed Consent

- **Permitted under specific circumstances with IRB approval**
  - IRB may not waive consent if individual was asked to provide broad consent and refused
  - IRB may not alter or omit required elements of consent if broad consent was used
- **Screening, recruiting, or determining eligibility**
  - Researcher will obtain information through oral or written communication with prospective subject or LAR
  - Researcher will obtain identifiable private information / biospecimens by accessing records or stored identifiable identifiable biospecimens



# Regulations for Exceptions from Informed Consent Requirements

- **Situations when requirements for exception from informed consent are met for emergency research**
- **Requirements**
  - Researcher, with concurrence of another physician, believes situation necessitates use of test article
  - Subject and/or LAR unable to communicate consent
  - Insufficient time to obtain consent
  - No alternatives exists that will provide equal or better chance of survival of saving subject's life



# Waiver of Signed Consent

- **FDA- 21 CFR 56.109(c)(1)**
  - Study presents minimal risk to subject
  - Research involves no procedures requiring consent outside the context of participation in research study
  - IRB may require researcher to provide subject with written materials



# Waiver of Signed Consent

- **HHS- 45 CFR 46.117**

- Consent would be only link between research and subject
  - Principle risk to subject would be due to breach of confidentiality
  - Subjects asked if they want consent to be documented



- Participation presents minimal risk of harm to subject and research involves no procedure(s) requiring consent
- If subjects or LAR are members of distinct cultural group or community in which signing forms is not the norm and there is alternative mechanism for documenting that informed consent obtained



# Telephone Consent

- **FDA- 21 CFR 50.27(a)**
  - Not approved in 21 CFR 56.109(c)(1)
  - Acceptable to send informed consent to LAR by fax and conduct consent interview by telephone while LAR reads consent as discussed (may return signed consent by fax)



# Telephone Consent

- **HHS- 45 CFR 46**
  - If granted by IRB
  - Signature must be from subject or LAR
  - Allows exchange of consent information
    - Face-to-face
    - Mail
    - Telephone
    - Fax
    - Video
    - Electronic format



# Case Study

A researcher proposes a randomized trial of an investigational drug in subjects about to undergo surgery for acute appendicitis. The investigational drug (or placebo) is administered immediately prior to the surgery. If the investigational drug works, it will mean less pain and maybe less need for other pain medicines. The researcher who is also the surgeon, proposes to have a nurse explain the research in the “pre-op” area. The nurse will explain the research while the subject is being prepared for the surgery and having an IV started, as well as blood pressure and other measurements. The surgeon will then arrive, get consent for the surgery, and get the subject’s signature on the research consent form. If the subject does not speak English, an interpreter will answer the subject’s questions. The subject will sign the English language consent form.



# Case Study

- **Is the proposed consent process appropriate for this situation? No**
  - Federal regulations mandate that researchers provide subjects or LAR sufficient time to consider whether to participate or not. Obtaining the consent in the “pre-op” area immediately before emergency surgery and while other procedures are being performed is not conducive to thoughtful deliberation or decision making.



# Case Study

- **Is the proposed consent process appropriate for this situation? No**
  - Researchers must obtain consent under circumstances that minimize possibility of coercion or undue influence. In this case, the surgeon is obtaining consent for research immediately before performing a lifesaving procedure. Subject may be under undue influence to participate in the research even though it may be against the subject's actual wishes. In addition, the aspect of this subject being vulnerable must be considered. In this stressful situation, how can one assess the subject's ability to comprehend information and make sound decisions?



# Case Study

- **Is the proposed consent process appropriate for this situation? No**
  - Obtaining consent at the same time for both the surgery (clinically-indicated procedure) and for participating in the research, might confuse the subject. It may be difficult for the subject to understand which procedures are standard care and which are part of the research.



# Case Study

- **Is the proposed consent process appropriate for this situation? No**
  - Researchers must present information about the research in a language understandable to the subject or LAR. Having an interpreter available only to answer questions and not present for the explanation, and using a consent form written in English, rather than a subject's native language, does not fulfill this requirement.



# Case Study

- **Is the proposed consent process appropriate for this situation? No**
  - Obtaining informed consent in this setting may be nearly impossible. It would be more appropriate to choose a different subject population. For example, subjects undergoing elective procedures where consent can be obtained well in advance of the research and subjects will have time to ask questions and demonstrate understanding.



# Conclusion

- **Researcher responsible to obtain informed consent before involving a subject in a clinical trial**
- **Consent must be legally effective**
  - Minimize potential for undue influence or coercion
  - Process must also be documented according to regulatory requirements
  - Signature obtained after subject understands information and has had enough time to consider participation





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