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# College of Central Florida Protection of Human Subjects

Presented by  
CF Institutional Review Board

*Adapted from materials provided by  
Frances Jeffries, Ph.D., Consultant, Bridgewater, Mass., to Sinclair Community College*



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# The Regulations and Roles of the Researcher and the IRB

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## 1947 Nuremberg Trials

Twenty-six Nazi physicians are tried at Nuremberg, Germany, for research atrocities performed on prisoners of war

Nazi War Crimes Tribunal issues first internationally recognized code of research ethics



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## Nuremberg Code

- Basic principles of voluntary consent
- Capacity of subjects to consent
- Freedom of subjects from coercion
- Comprehensive analysis of risks and benefits
- Minimization of risk and harm to subjects
- Favorable risk/benefit ratio
- Qualified investigators
- Appropriate research design
- Freedom of subjects to withdraw at any time





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## 1940s Tuskegee Studies

- Study of natural history of untreated syphilis in Tuskegee, Alabama
- Poor, black males uninformed about presence of disease and denied a treatment discovered in 1947
- Abuses revealed in 1972



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## 1962: Kefauver-Harris Bill

- Ensured greater drug safety in the U.S. after thalidomide found to be the cause of severe birth defects in thousands of babies in Western Europe





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## 1964: Declaration of Helsinki

- Recommendations guiding medical doctors in biomedical research involving human subjects
  - Similar principles to Nuremberg Code
  - Distinguishes therapeutic from non-therapeutic research
- Adopted by 18th World Medical Assembly



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## 1974: National Commission Established and Act Passed

- **National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research established**
- **National Research Act passed by Congress**
  - Established “institutional review boards,” IRBs, and required review of federally funded research involving human subjects





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## 1979: The Belmont Report

- Issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research as a guide for U.S. research with human subjects
- Principles for Human Subject Research
  - autonomy
  - beneficence
  - justice



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# Autonomy

- Give respect, time, and opportunity to subjects to make own decisions
- No pressure to participate
- Protection for potentially vulnerable populations such as
  - children
  - elderly
  - cognitive or emotionally impaired
  - prisoners





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# Beneficence

- Obligation to secure well-being of research participants
- Protection of subjects from harm
- Maximization of benefits
- Careful balancing of risks and benefits



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# Justice

- **Distribute benefits and burdens of research fairly and without bias**
- **Selection of subjects not based on**
  - convenience
  - subject availability
  - compromised position of subjects
  - subject manipulability
  - language barrier





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## Subject Selection Considerations

- Do not base on gender, class, race, or socioeconomic status  
(unless justified by study objectives)
- Be aware of perception of inequality of power roles and/or potential for coercion
  - counselor-client relationship
  - teacher-student relationship
  - employer-employee relationship



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## 1980s: Federal Regulations

- **FDA codified regulations in 1980**  
(For new drugs and devices)  
21 CFR 50 and 21 CFR 56
- **DHHS codified regulations in 1981**  
(45 CFR 46)  
Various revisions over the years





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## 1990s: Federal Regulations

- “Common Rule” adopted in 1991
  - Based on 45 CFR 46, Subpart A
  - Adopted by 16 Federal Agencies including:

DOE	NASA	USAID	HUD
DOJ	DOD	DOEd	EPA
NSF	DOT	DHHS	
  - Various revisions over the years
  - Expedited review criteria added November 1998



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## 1990s: Other Happenings

- 1993: Albuquerque Tribune publicizes 1940s secret radiation experiments
  - indigent patients and mentally retarded children deceived about the nature of their treatment
    - received plutonium injections





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## 1990s: Other Happenings

- 1994: National Bioethics Advisory Commission created
- 1995: President's Advisory Committee on Human Radiation Experiments concludes some of the 1940s radiation experiments were unethical



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## 2000 and Beyond

- 2000: U.S. Public Health Service mandates training for all researchers using human subjects
- 2000: U.S. Public Health Service proposes mandate for training of all researchers in “Responsible Conduct of Research”





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# Federal Regulations

- Code of Federal Regulations Title 45
  - Part 46 - Protection of Human Subjects
    - Subpart A - Basic DHHS Policy
    - Subpart B - Fetuses, Pregnant Women, and Human *in vitro* Fertilization
    - Subpart C - Prisoners as Subjects
    - Subpart D - Children as Subjects



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# Protection of Human Subjects

The Institutional Review Board  
or IRB





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# Federally Mandated IRB Responsibilities

- To safeguard the rights and welfare of human subjects
  - Review research protocols
  - Require protocol modifications
  - Approve or disapprove protocols
  - Ensure or waive informed consent
  - Conduct continuing review of research



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# Additional Responsibilities of the IRB

- To safeguard the rights and welfare of students and staff being recruited on campus by researchers not affiliated with College of Central Florida
  - Review research protocol applications and approvals from other IRBs
  - Require protocol modifications
  - Grant or deny permission to recruit on campus





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# The Authority of the IRB

The IRB's decision to deny approval of a protocol (or to deny permission to recruit subjects on campus) ***CAN NOT*** be overridden. The IRB's decision is ***FINAL***.



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## IRB Membership

- At least five members
- Members with varying backgrounds
- Diverse membership (gender, race, cultural background)
- Sensitivity to issues such as community attitudes





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## IRB Membership

- Knowledgeable in standards of professional conduct and practice
- Not all members of one profession
- At least one scientist
- At least one non-scientist
- At least one member not affiliated with College of Central Florida



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## IRB Meeting Issues

- Member with conflicting interest may not participate in initial or continuing review
- Outside consultants may be used
- IRB must review certain protocols at convened meetings
  - Majority of members must be present
    - At least one must be non-scientist
  - Majority of those present must approve





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## IRB Review Criteria

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent
  - is sought from each prospective participant or legally authorized representative
  - is documented
- Adequate preparation is taken to protect privacy and confidentiality of subjects
- Adequate provisions are made for ongoing monitoring of subjects' welfare



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# Protection of Human Subjects

## Definitions





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## What must be reviewed?

- *Research* that will be conducted by
  - a faculty member
  - a staff member OR
  - a student
- from College of Central Florida that involves
  - *human subjects* and
  - records gathered on human subjects
- and that will take place
  - at College of Central Florida
  - at another institution OR
  - in a community setting



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## What is “research?”

*A systematic investigation*

- research development
- testing
- evaluation

that is intended to develop or contribute to  
*generalizable knowledge*





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## Who is a “human subject?”

A *living* individual about whom the investigator obtains

- data through *intervention* or *interaction* with the individual and/or
- *identifiable* private information



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## What is “intervention?”

- **Physical procedures**
  - specimen collection
  - physical measurements
- **Manipulation of the subject**
- **Manipulation of the subject’s environment**





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## What is “interaction?”

- **Communication**
  - interviewing
- **Interpersonal contact**
  - surveying



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## What is “private information?”

- Information about behavior that the subject can *reasonably expect* is *not* being observed or recorded
- Information provided by the subject that he/she reasonably expects will not be made public





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## What is “private information?”

- **Must be readily identifiable**
  - Subject’s identity can be readily ascertained by investigator **OR**
  - Subject’s identity can be associated with the information



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## What is “minimal risk?”

...when the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests





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## Research Policy at CF

A Research Review Board has been appointed as CF's IRB. It will review all proposed research.

**ONLY** Research which is “exempt” (as defined below) and research approved by another college or university IRB will be allowed at CF.



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## Review Procedures

Investigators should complete this presentation and prepare an “Application for Research Protocol Exemption”





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# Protection of Human Subjects

## Types of Exempt Research



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# Federal Exemption Category 1

- Research conducted in established or commonly accepted educational settings, involving educational practices, such as
  - research on regular and special education instructional strategies
  - research on effectiveness of, or comparison among,
    - instructional techniques
    - curricula
    - classroom management methods





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## Federal Exemption Category 2

- **Research involving**
    - educational tests (cognitive, diagnostic, aptitude, achievement)
    - survey procedures
    - interview procedures or
    - observation of public behavior
- unless**
- information is recorded in such a way that subjects can be identified directly or through identifiers and
  - disclosure could reasonably
    - place subject at risk of criminal or civil liability or
    - be damaging to financial standing, employability, or reputation



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## Federal Exemption Category 2

### NOTE

- Exemption for survey and interview procedures does **NOT** apply to research involving children
- Exemption for observation of public behavior does not apply to research involving children except when the investigator does **NOT** participate in the activities being observed





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# Federal Exemption Category 3

- **Research involving**
    - educational tests (cognitive, diagnostic, aptitude, achievement)
    - survey procedures
    - interview procedures **OR**
    - observation of public behavior
- that is not exempt under Category 2 IF**
- subjects are elected or appointed public officials or candidates for public office **OR**
  - federal statute requires without exception that confidentiality of the personally identifiable information be maintained throughout the research and thereafter



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# Federal Exemption Category 4

- Research involving collection or study of existing
    - data
    - documents
    - records
    - pathological or diagnostic specimens
- if
- sources are publicly available or
  - information is recorded by the investigator in such a manner that subjects cannot be identified
    - directly or
    - through identifiers linked to the subjects





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# Federal Exemption Category 5

- **Research and demonstration projects**
  - conducted by, or subject to, approval of a federal department or agency
  - that are designed to study, evaluate, or examine
    - public benefit or service programs
    - procedures for obtaining benefits or services under those programs
    - possible changes in, or alternatives to, benefit or service programs or procedures **or**
    - possible changes in methods or levels of payment for benefits or services under these programs



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# Federal Exemption Category 6

- **Taste and food quality evaluation and consumer acceptance studies if**
  - wholesome, additive-free foods are consumed or
  - if a food is consumed that
    - contains an ingredient at or below the level, and for a use, found to be safe or
    - contains an agricultural chemical or environmental contaminant at or below the level found to safe by the FDA or approved by the EPA or the USDA





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# Other Exempt Research

- **Student Research**
  - A normal part of student's coursework
  - Supervised by a faculty member
  - Primary purpose is to develop student's research skills
  - Presents no more than minimal risk to subjects or the student investigator
  - Does not deal with issues of a sensitive nature  
**AND**
  - Is not genuine research expected to result in publication or dissemination



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# Non-Exempt Student Research

- Research to satisfy requirements for the following is **NOT** automatically exempt:
  - independent Study
- Review by the IRB is required to confirm the protocol meets federal exemption criteria





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# Important Notes About Exemptions

- Applications for exemption are acted on in 10 working days
- Written informed consent is not required for exempt protocols
- If written consent is desired by the investigator, the IRB provides specific wording to be used



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# The Protection of Human Subjects

## Informed Consent

Due to CF's policy restricting research to only exempt categories, the following requirements for informed consent do not apply. However, an understanding of their purpose helps one to understand the principles of protection of human subjects.





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# Informed Consent

## Required Elements

- Identification and affiliation of researcher
- Statement that study involves research
- Explanation of purpose of research
- Expected duration of subject's participation
- Description of procedures
- Identification of experimental procedures



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# Informed Consent

- **Required Elements**
  - Description of reasonably foreseeable risks or discomforts to subject
    - Minimal
    - more than minimal
  - Description of any benefits which may reasonably be expected
    - for subject
    - for society





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# Informed Consent

- **Required Elements**
  - Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
  - Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained



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# Informed Consent

- **Required Elements**
  - An explanation of any costs associated with participation
  - An explanation of any compensation for participation
  - For research involving more than minimal risk...
    - An explanation of any medical treatments available if injury occurs
      - what treatments consist of
      - where to obtain further information





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# Informed Consent

- **Required Elements**
  - Statement that...
    - Participation is voluntary
    - Refusal to participate will involve no penalty or loss of benefits to which subject is otherwise entitled
    - Subject may discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled



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# Informed Consent

- **Required Elements**
  - Name of contact person to...
    - provide answers to questions about the research
    - provide information about research subjects' rights
    - inform about research-related injuries





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## Additional Elements of Consent

- **As appropriate...**
  - Statement that there may be unforeseeable risks to subject and/or embryo or fetus
  - Anticipated circumstances under which subject may be terminated from the study without regard to his/her consent



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## Additional Elements of Consent

- **As appropriate...**
  - Any additional costs to the subject that may result from participation
  - Consequences of a subject's decision to withdraw from the research
  - Procedures for orderly termination of participation by the subject





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## Additional Elements of Consent

- **As appropriate...**
  - Statement that significant new findings during the study which may relate to subject's willingness to continue participation will be provided
  - Approximate number of subjects involved in the study



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## Informed Consent

- Is an educational process
- Is about people's understanding and willingness to participate in the research study
- Is more than a signed form
- Is ongoing
- Is respectful





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## Informed Consent

- Begins with non-coercive subject identification and recruitment
- Involves a proxy for subjects who are not of legal age or who are deemed incompetent
- Involves full disclosure about the study



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## Informed Consent

- Involves disclosure of researcher conflict of interest
- Gives subject adequate time to consider participation
- Uses understandable language
- Gives the participant the opportunity to ask questions and reflect





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## Suggested Consent Process

- Give prospective participant a copy of the consent document
- Allow him/her to take the document home for review with family and friends
- Meet him/her again



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## Suggested Consent Process

- Ask open-ended questions about nature of study and participation to ensure understanding and describe in your own words the purpose of the study
  - “What more would you like to know?”
  - “Would you please explain to me what you think I’m going to ask you to do.”
  - “What are your concerns?”





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## Suggested Consent Process

- If participant is willing, have him/her sign consent document
- Remind participant to continue to ask questions as they occur during participation



## Documentation of Consent

- If subject is a minor and...
  - Is too young to agree or refuse to participate in the research
    - Get parent/guardian consent
  - Is old enough to agree or refuse to participate in the research
    - Get parent/guardian permission **AND**
    - Get child's assent (written or verbal)





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# Comparison: APA Ethical Principles for Dispensing with Informed Consent

- Informed consent is **NOT** required for
  - anonymous questionnaires
  - naturalistic observations
  - some kinds of archival research

**UNLESS** required by

- governmental regulations
- IRB requirements



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# The Protection of Human Subjects

Expedited Review is a procedure used by some IRBs BUT NOT CF. It is described here to help illustrate the types of research that is NOT exempt, for the time being, and NOT permitted at CF unless another institutions IRB has approved and notified CF.





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## Expedited Review

- Must be minimal risk research
- Must meet federal criteria for expediting
- Cannot include request for waiver of written informed consent
- Review is done by expediting team (IRB chair may expedite in emergency)
- Approval subject to full IRB concurrence at next convened meeting
- Expediter may recommend convened review



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## Expedited Review Category 1

- Clinical studies of drugs and medical devices only when
  - the investigational device exemption application is not required **OR**
  - the medical device is cleared/approved for marketing and is being used in accordance with its cleared/approved labeling





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## Expedited Review Category 2

- Collection of blood samples by finger stick, heel stick, or venipuncture from
  - healthy, non-pregnant adults
  - weighing at least 110 pounds



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## Expedited Review Category 3

- **Prospective collection of biological specimens by non-invasive means, including, but not limited to,**
  - hair and nail clippings (in a non-disfiguring manner)
  - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction
  - permanent teeth if routine patient care indicates need for extraction
  - sweat
  - uncannulated saliva
  - placenta removed at delivery
  - amniotic fluid at time of rupture





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## Expedited Review Category 3 (Cont'd.)

- supra- and subgingival dental plaque and calculus
- mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings
- sputum collected after saline mist nebulization



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## Expedited Review Category 4

- Collection of data through non-invasive procedures
  - not involving general anesthesia or sedation
  - routinely employed in clinical practice
  - excluding procedures involving x-rays or microwaves
  - including, but not limited to...
    - physical sensors applied to the body surface or at a distance that do not involve
      - input of significant amounts of energy into the subject
    - OR**
    - invasion of the subject's privacy





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## Expedited Review Category 4 (Cont'd.)

- weighing or testing sensory acuity
- magnetic resonance imaging
- electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
- moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate, given the age, weight, and health of the subject



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## Expedited Review Category 5

- **Research involving materials such as**
  - data
  - documents
  - records
  - specimens

**that have been collected – or will be collected solely for non-research purposes, such as**

- medical treatment
- diagnosis





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## Expedited Review Category 6

- Collection of data from
  - voice recordings
  - video recordings
  - digital recordings
  - image recordings**made for research purposes**



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## Expedited Review Category 7

- Research on individual or group characteristics or behavior, including, but not limited to, research on
  - perception
  - cognition
  - motivation
  - identity
  - language
  - communication
  - cultural beliefs or practices
  - social behavior





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## Expedited Review Category 7 (Cont'd.)

OR

- Research employing the following methodologies:
  - survey
  - interview
  - oral history
  - focus group
  - program evaluation
  - human factors evaluation
  - quality assurance



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# The Protection of Human Subjects

Miscellaneous...





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# Required Review Time

(Assuming complete application)

- Exemptions
  - 1-5 working days
  - Done by RRB Chair



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## Failing to Follow the Rules

The RRB has the authority to suspend or terminate approval of research and destroy data that is not being conducted in accordance with RRB requirements or that has been associated with unexpected serious harm to subjects. Most technical journals will not publish research results without evidence of IRB approval.

*Failure to follow the rules may result in charges of scientific misconduct!*





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## For more information

- U.S. Department of Health and Human Services,  
Office of Protection from Research Risks
  - <http://ohsr.od.nih.gov/OHSR/index.php>
- Sinclair Community College
  - <http://www.sinclair.edu/about/offices/grants/>
- Jillian Ramsammy, CF Executive Director,  
Institutional Effectiveness, 352-854-2322, ext. 1665