Institutional Review Board (IRB)

Overview

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Presenters

Dr. David DiMattio
Dean of Science and Mathematics
CT State

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Campus Director of Institutional Research
CT State Naugatuck Valley

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Agenda

- What is the purpose of IRBs?
- Human Subjects
- Exempt Research
- When is IRB review required?
- CT State IRB
  - Background
  - Membership
  - Application & Other Documents
  - Due Dates & Meeting Schedule
  - Contact Information
- Q&A

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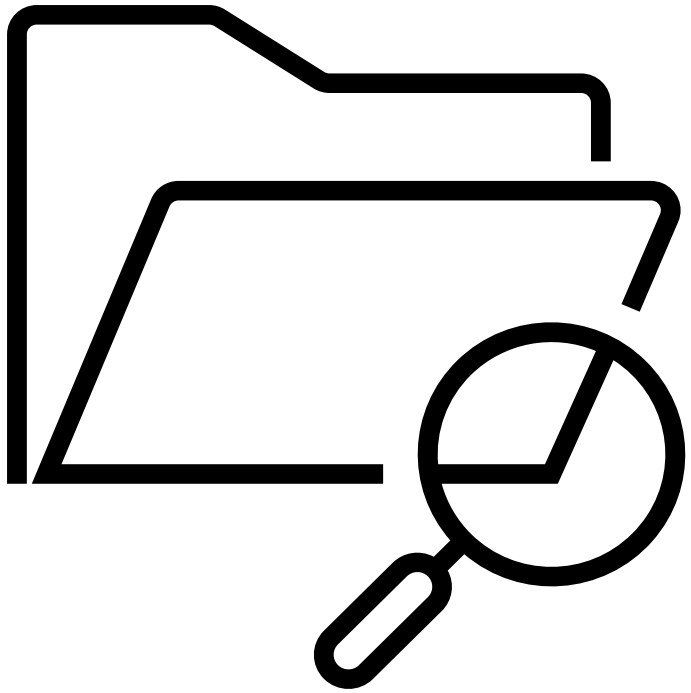
What is the purpose of IRBs?



IRB reviews research studies to ensure that they:

- Comply with applicable regulations
- Meet commonly accepted ethical standards
- Follow institutional policies
- Protect research participants

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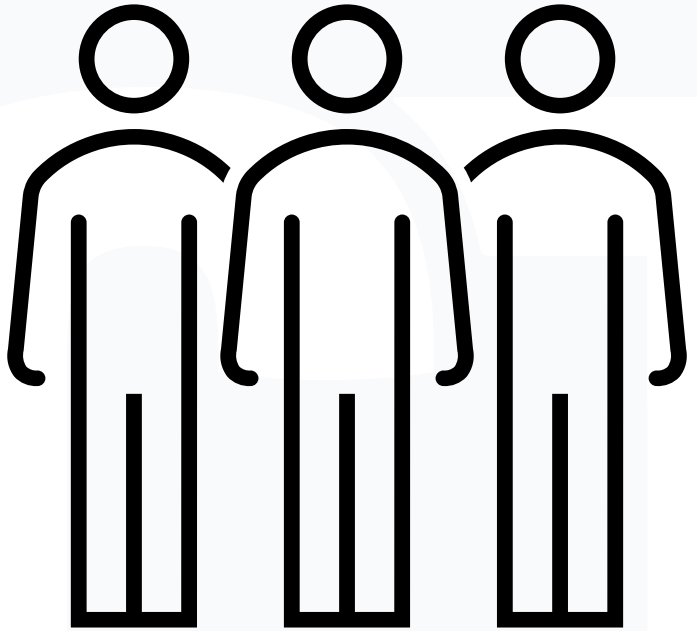
Does the research involve human subjects?

A human subject is a living individual about whom an investigator conducting research obtains:

- Data through intervention or interaction, or
- Identifiable private information



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Vulnerable Populations

- Children
- Economically disadvantaged persons
- Human fetuses
- Individuals with mental disabilities or cognitive impairments
- Individuals with physical disabilities
- Institutionalized persons (e.g., persons in nursing homes or mental health facilities)
- Neonates
- Pregnant women
- Prisoners
- Racial or ethnic minorities
- Socially disadvantaged persons
- Terminally ill or very sick patients

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Categories of Exempt Research*

1. Normal educational practices in established educational settings
2. Educational tests, surveys, interviews, or observation of public behavior unless identified and sensitive (risk of criminal or civil liability, etc.)**
3. Benign behavioral interventions (e.g., play an online game, solve puzzles)
4. Research using existing data, if publicly available or recorded without identifiers
5. Research or demonstration project designed to study, evaluate, improve, or examine public benefit or service programs (e.g., internal studies by federal employees)
6. Taste and food quality evaluation and consumer acceptance studies
7. (and 8.) Certain secondary research for which broad consent is required

*Exception for prisoners
**Exception for children

Source: § 46.104 Exempt research

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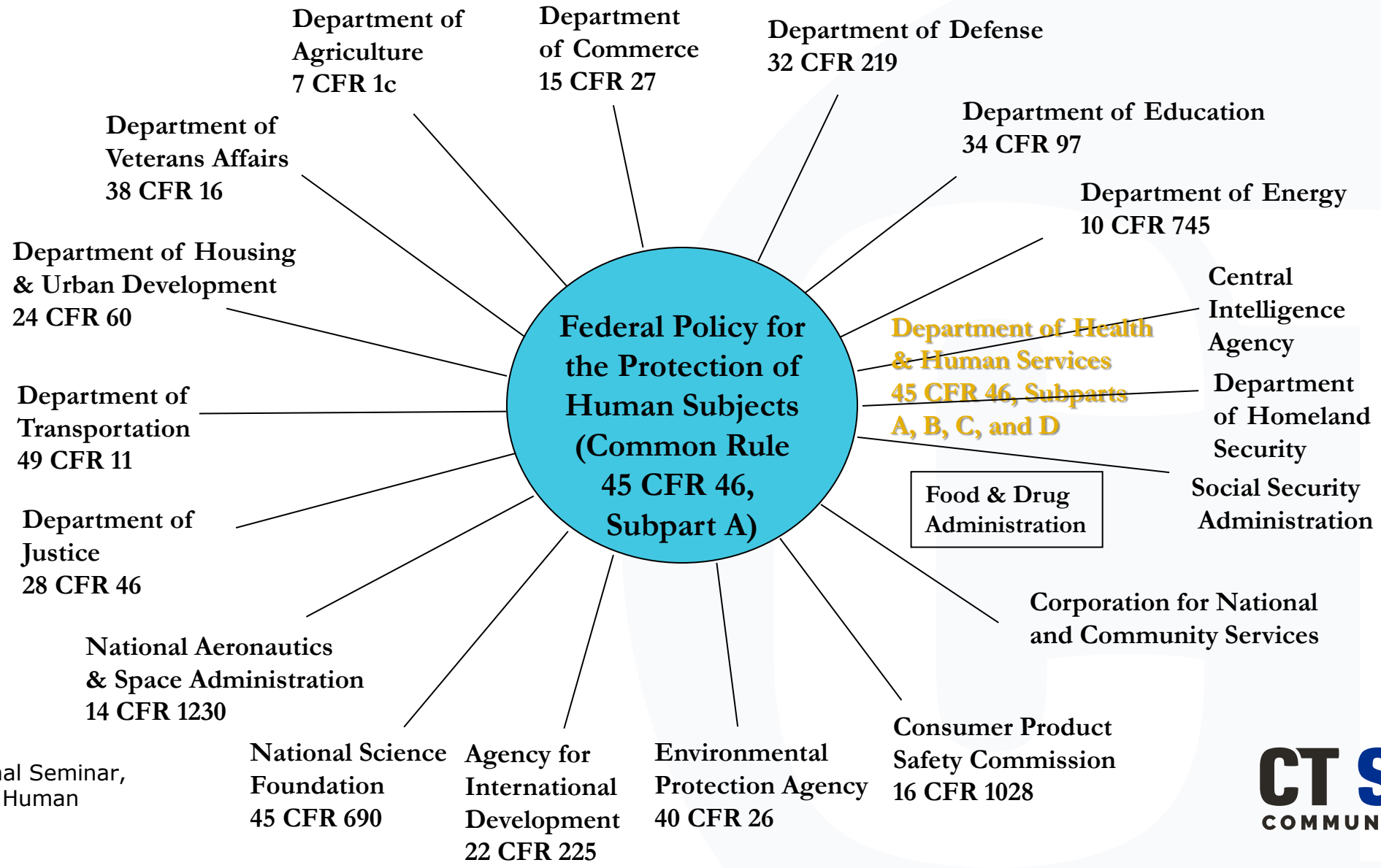
Common Rule Departments & Agencies



Source: NIH Regional Seminar, Research Involving Human Subjects

When is IRB review required?

- The research uses non-public information to identify or contact human research participants or prospective participants
- The research uses as human subjects CT State students, faculty, or staff
- The research collects data which will result in an article, master's thesis, doctoral dissertation, poster session, abstract, or any other publication, presentation, or any dissemination
- To help decide if an activity is research involving human subjects that must be reviewed by an IRB, use the **Human Subject Regulations Decision Charts** at https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html

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CT State IRB Background

- Beginning this year, we developed the CT State IRB policies, procedures, and membership based on feedback and recommendations from the following stakeholders:
  - Legacy CT Community College IRBs
  - CT State Senate
  - CT State Institutional Effectiveness & Planning
  - CT State Academic Deans
- Over the summer, the U.S. Department of Health and Human Services' Office for Human Research Protections (OHRP) accepted the CT State IRB registration and assigned it **ID numbers IORG0011801 and IRB00013976**.
  - This registration is listed on OHRP's website. Funding agencies use this website to verify that an IRB has an active registration.

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CT State IRB complies with all federal regulations and adopts best practices

- 2018 Common Rule
  - Code of Federal Regulations (CFR)
    - Title 45 Public Welfare
      - Department of Health and Human Services (HHS)
        - Part 46 Protection of Human Subjects
- UConn IRB/Human Research Protection Program (HRPP)
- Connecticut State Universities IRBs

CT State IRB Membership

- The Common Rule requires **at least five members** with varying backgrounds on the IRB, so that research is reviewed from a collection of different perspectives. At minimum, members must include:
  - Someone who provides the perspective of a scientist,
  - Someone who provides the perspective of a nonscientist, and
  - Someone who is not affiliated with the research institution.

- In addition, representation from the following areas was considered:
  - Institutional Research (IR)
  - Diversity, Equity, and Inclusion (DEI)
  - Faculty
  - Student Services

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CT State IRB Membership

- Michael Amico, Assistant Professor of Psychology
- Parth Desai, Goodwin University
- Luz Londono Diaz, Associate Professor of Economics
- David DiMattio, Dean of Science & Mathematics (Co-Chair)
- Sohair Omar, Campus Director of Institutional Research (Co-Chair)
- Francine Rosselli-Navarra, Professor of Psychology
- Joshua Searcy, Dean of Social & Behavioral Sciences
- Meredith Yuhas, Director of Mental Health and Wellness

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CT State IRB Forms & Templates

Forms

- **Application**
- Application for Exempt or Limited IRB Review
- Application for Certain Research Courses
- Human Subjects Research (HSR) Determination Form
- Data Security Assessment Form
- **CT State Employees Conducting Research for External Purpose(s) Form**

Templates

- **Adult Informed Consent Form Template**
- Parent Permission Form Template
- Assent Form for Minor Participants (under 18 years-old) Template
- **Request for Additional Information Letter**
- **Approval Letter**
- Disapproval Letter

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CT State IRB Application

- Contact Information of Principal Investigator (PI) and Faculty Advisor
- National Institutes of Health (NIH), Protecting Human Research Participants (PHRP), HHS, or other comparable training
- Title, Introduction, and Purpose of Research Study
- Source of Funding
- Design, Procedures, Materials, and Methods
- Privacy and Confidentiality
- Informed Consent
- Conflict of Interest

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Umbrella Protocol - Research Courses

- Every student completes National Institutes of Health (NIH), Protecting Human Research Participants (PHRP), HHS, or other comparable training
- The umbrella projects:
  - Meet the regulatory definition of minimal risk human subject research
  - Do not have any federal funding sources
  - Do not involve Food and Drug Administration (FDA) regulated products
  - Do not require parent permission for children as subjects
  - Do not target pregnant women
  - Do not involve prisoners
- Principal Investigator (PI) Oversight Plan

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Informed Consent

- Title, Introduction, and Purpose of Research Study
- Procedures: What will the participant be asked to do?
- Describe any potential risks, discomfort, or inconvenience. If applicable, provide a list of relevant help lines.
  - Example: *If you are experiencing mental health related distress, please dial 988 for the suicide and crisis lifeline or 866-903-3787 for the National Mental Health Hotline.*
- Privacy and Confidentiality: How will data be stored securely? How will confidentiality be maintained?
- Voluntary Participation: Human subjects have the right to stop participating at any time.

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CT State Employees Conducting Research for External Purpose(s)

As a Connecticut State Colleges and Universities (CSCU) employee, I, [INSERT NAME], agree not to access student or employee information maintained within any CSCU information system, including but not limited to Banner, for the purpose of conducting "[INSERT TITLE OF RESEARCH STUDY]," an external research project unrelated to my duties as a college official. Further, I agree not to seek out additional information from any CSCU information system about any student or attempt to re-identify any individual involved in "[INSERT TITLE OF RESEARCH STUDY]" research study.

Signature: _____

Date: _____

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CT State IRB Important Dates

Due Dates

- IRB applications are due on **September 30** or **February 15** each year
  - Internal researchers (CT State employees) may request an off-calendar review if the proposed research is part of a grant application

Meeting Schedule

- The CT State IRB meets on the second Thursday of October and November during fall semesters and on the second Thursday of March and April during spring semesters
  - Meeting dates may be adjusted due to holidays

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CT State IRB Contact Information

- **Web Page URL**: https://ctstate.edu/irb
  - Policies & Procedures
  - Forms & Templates
  - Meeting Dates & Due Dates
  - Frequently Asked Questions (FAQs)
  - Contact Information
- **E-mail Address**: CTState-IRB@ct.edu
  - Subject: Title of Research Study

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Latest Actions

- Assembled IRB decisions (Exemptions/Approvals/Disapprovals) of 12 Legacy CT Community Colleges from the past five years
  - The CT State IRB will honor and uphold them.
- Recruited initial CT State IRB members and conducted NIH, PHRP, HHS, or other comparable training
- Registered CT State IRB with the U.S. Department of Health & Human Services' (HHS) Office for Human Research Protections (OHRP)
- The CT State IRB is accepting applications!

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Questions & Answers

ctstate.edu/irb