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Research Ethics

# **Protecting Human Participants: Living with Evolving Research Ethics Guidelines**

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# ***Overview: Protecting Human Participants within an Evolving Research Ethics Framework***

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- Evolution of US Regulations for Protection of Participants in Human Research
- Evolution of Canadian Research Ethics System
- Tri-Council Policy Statement: Ethical Conduct for Research with Humans
- UW Research Ethics Guidelines, Application and Ethics Review Process
- Special Considerations in Student Course Research
- Researchers' Safety
- Responsibility of Researchers



# ***Evolution of Research Ethics Regulations: US***

- Prior to World War II, little concern for the treatment of humans in research
  - *no formal protections existed*



# ***Evolution of Research Ethics Regulations: US***

- **Nuremberg Code, 1947**
  - 10 standards for researchers/physicians
  - resulted from an American war crimes tribunal
  
- **Declaration of Helsinki, 1964**
  - 18 ethical principles for medical research with humans
  - developed by World Medical Association
  - individual patient interests before those of society

*'Informed consent and voluntary participation of subjects are essential to all ethical biomedical research'*



# ***Evolution of Research Ethics Regulations: US***

- **Post-Nuremberg Code:** abuses and exploitations of humans in research continued; for example:
  - Tuskegee Syphilis Study, 1932-1972
  - Willowbrook School Study, 1957-1963
  - Jewish Chronic Disease Hospital Study, 1963
  - Milgram Obedience Study, early 1960s
  - Tearoom Trade Study, mid 1960s



## ***Tuskegee Syphilis Study***

- 600 low-income African-American males recruited into longitudinal study of syphilis
- Participants given free medical exams and meals, and burial insurance
- Physicians told participants being treated for “bad blood”
- Participants were denied available treatment for syphilis



# ***Evolution of Research Ethics Regulations: US***

## **Belmont Report : Three Basic Ethical Principals (1979)**

- **Respect for Persons**
  - Individuals treated as autonomous agents
  - Protection of individuals with reduced autonomy
  
- **Beneficence**
  - Respect persons' decision, protect from harm
  - Maximize benefits and minimize harms
  
- **Justice**
  - Benefits and risks of research to be distributed fairly



# ***Evolution of Research Ethics Guidelines: Canada***

- MRC Guidelines - 1978, 1987
- SSHRC Guidelines – 1981
- Tri-Council Working Paper- early 1990s
- Tri-Council Code of Conduct - 1994-1996 (draft)
- Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans - 1998



# ***Evolution of Research Ethics Guidelines: Canada***

- Agencies adopted the TCPS as common research ethics policy for institutions receiving CIHR, NSERC and SSHRC funds (1998)
- Agencies' requirement for compliance with Section 1: Ethics Review (1999)  
<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>
- Memorandum of Understanding with granting agencies: Phase I includes 8 schedules (2002)
- Schedule 2: Ethics Review of Research Involving Humans  
[http://www.nserc.ca/institution/mou\\_sch2\\_e.htm](http://www.nserc.ca/institution/mou_sch2_e.htm)
- Phase II anticipated in late 2005



# ***Evolution of Research Ethics Guidelines: Canada***

## **TCPS: Eight Guiding Principles**

- Respect for human dignity
- Respect for free and informed consent
- Respect for vulnerable persons
- Respect for privacy and confidentiality
- Respect for justice and inclusiveness
- Balancing harms and benefits
- Minimizing harm
- Maximizing benefits

# ***Evolution of Research Ethics Guidelines: Canada***

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## **Interagency Advisory Panel on Research Ethics (PRE)**

- Established by federal granting agencies in Nov. 2001 with 5 year mandate
- Mandate has been extended to 2009
- 12 volunteer members with diverse backgrounds and expertise
- Provides advice to agencies on the TCPS with respect to:
  - evolution
  - interpretation
  - implementation
  - education resource implications and
  - governance discussions

<http://www.pre.ethics.gc.ca/english/index.cfm>

# ***Evolution of Research Ethics Guidelines: Canada***

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## **Interagency Advisory Panel on Research Ethics cont'd: 4 Standing Committees (SC)**

1. Evolution SC: Sub-group on Procedural and Issues (ProGroup)  
Social Sciences and Humanities Special Working Special Committee (SSHWC)
2. Interpretation SC: Online interpretation service
3. Implementation SC: Examining models for optimum implementation
4. Education SC: On-line Tutorial for TCPS

<http://www.pre.ethics.gc.ca/english/tutorial/>

# ***Evolution of Research Ethics Guidelines: Canada***

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- Ongoing discussions concerning federal standards for research ethics and oversight system for protection of humans in research
- Involves key players e.g. granting agencies, Health Canada, NCEHR, PRE and other stakeholder groups
- Would system involve accreditation?
- If so, accreditation of what? REBs, institutions' protection programs, other?
- By whom? What entity would do accreditation?
- Recent options paper by NCEHR on accreditation called for comments on NCEHR's role

[http://www.ncehr-cnerh.org/english/task\\_force.php](http://www.ncehr-cnerh.org/english/task_force.php)



# ***Research Ethics Accountability at UW***

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
- Memorandum of Understanding between Federal Granting Agencies and Institutions
- UW Statement on Human Research
- UW Guidelines for Research with Human Participants

# ***UW Research Ethics Guidelines***

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## **Office of Research Ethics Infrastructure**

- Established as Office of Human Research (1971)
- Mandate expanded to include animal research (1993), research integrity (1996)
- Office of Research Ethics (ORE)
  - Director, Research Ethics
  - Manager, Research Ethics
  - Research Ethics Coordinator
  - Animal Research Coordinator

# ***UW Research Ethics Guidelines***

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## **What Research Requires Ethics Review?**

All research that involves.....  
data collected from humans



# ***UW Research Ethics Guidelines***

*UW Research Ethics Guidelines apply to:*

- all UW faculty, staff and students (including P/T)
- any researcher recruiting UW faculty staff and students
- surveys, interviews, focus groups, observations, physiological measures, clinical trials, secondary data and others

*UW Research Ethics Guidelines also include:*

- program evaluation, quality assurance studies

# ***UW Research Ethics Review Process***

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## **Two Ethics Review Routes:**

- Ethics review by Director or Manager, Office of Research Ethics
- Ethics review through UW's Research Ethics Board- Human Research Ethics Committee (HREC)



# ***UW Research Ethics Review Process***

## **How is Ethics Review Route Determined?**

Based on identified level of risks to participants

- Applications that pose no more than minimal risk to participants are reviewed by Director or Manager
  - at other institutions, often referred to as 'expedited review'
- Applications that pose greater than minimal risk to participants are referred to the HREC
  - often referred to as 'full board review'



# ***UW Research Ethics Review Process***

## **What is Minimal Risk?**

....Participants reasonably expect to participate in research activities in which the potential risk of harm is no greater than that which they already experience in their everyday lives.



# ***UW Research Ethics Review Process***

## **Application Process:**

- online application form (ORE 101 or ORE 101A for course and administration projects)
- two, signed, paper copies of application form
- two copies of all attachments (recruitment materials, information letters, consent forms, interview questions, surveys)

<http://www.research.uwaterloo.ca/ethics/form101/index.htm>



# ***UW Research Ethics Review Process***

## **Primary Considerations of Ethics Review Process:**

- Recruitment materials and procedures
- Anonymity of participants and confidentiality of data
- Risks of procedures vs. benefits of study
- Informed consent process



# ***Recruitment of Participants***

- Variety of recruitment routes: telephone, email, internet, newspaper, radio, poster, flyer
- For minors, recruitment begins by contact with parents
- Recruitment materials must include:
  - Description of who is conducting study
  - Description of procedures and time commitment
  - Standard ethics review and clearance statement included in all recruitment materials
- Sample recruitment scripts on ORE website



## ***Recruitment of Participants: cont'd***

- Materials undergo ethics review to ensure free from coercive tone, wording, procedures
- Process must ensure arm's length between participants and person(s) responsible for recruitment  
e.g. when participants are students, patients, employees/workers
- Process must consider real or perceived power imbalance between participant and researcher; also conflict of interest



# ***Recruitment of Participants: cont'd***

## *Some Ethical Issues- Participant's Perspective:*

- Is participation really voluntary? Is it confidential?
- Can participant freely decline participation or subsequently withdraw consent without fear of reprisal or penalty?
- How easily can this be done?
- Is there an informed consent process involved?

## *Safeguards:*

- Neutral 'third party' responsible for recruitment e.g. recruitment of students
- Procedures used to promote arm's length: researcher remains 'blind' to who volunteers and who does not



## ***Recruitment Script: Sample***

Hello, my name is (*insert name*) and I am a 2nd year student conducting a course project under the supervision of Dr. (*name*) of Environmental and Resources Studies. I am studying how... This research may lead to...

If you volunteer as a participant in this study, you will be asked to...

The session should take approximately (*X minutes*) of your time. I would like to assure you that this study has been reviewed and received ethics clearance through the Office of Research Ethics.

If you are interested in participating, please fill out one of the individual confidential recruitment cards\* and I will be in touch with you. Alternatively, you can come to (*insert location*) and see me. Thank you.



# ***Anonymity and Confidentiality***

- Anonymity of participants is default and gives best protection for individuals' and confidentiality of their data
- Access to data is limited to research team
- Data must be secure; 'double lock'
- Personal identifiers if collected must be removed from questionnaires, tapes, other documents as soon as possible
- When sample is small, inadvertent identification of participants can occur



## ***Anonymity and Confidentiality: cont'd***

- Attribution may be preferred over anonymity by either or both researcher and participants e.g. oral history
- Participant must give consent for attribution
- Participant may be given opportunity to review transcript, or relevant text of report



# ***Anonymity and Confidentiality: cont'd***

## **Research with focus groups poses special consideration for confidentiality**

- Researcher can guarantee that s/he will maintain confidentiality of data from focus group
- But cannot ensure same for participants because of group context
- Information Letter addresses this by inclusion of a statement like:

*'...Participants are asked to keep confidential the information to which they are privy as members of the focus group...'*



# ***Risks of Procedures vs. Benefits of Study***

- Potential benefits of research must outweigh any potential risks
- Researcher must consider risks and benefits to participants and society; if no personal benefits, this must be stated
- Researcher must identify both known and potential risks of procedures
- Risks of procedures can be physiological, psychological, legal, economic and social
- Details must be included on mechanisms to mitigate risks
- Details on risks and benefits are included in information-consent letter and in the ORE application; there must be agreement between two descriptions



# ***Informed Consent Process***

## **Informed consent**

- Is an educational process
- Is not a single event in time and is not just a form to be signed

## **Informed consent includes**

- Full disclosure in lay language of researcher's and participant's role
- All 'elements of consent' to be included
- Sufficient interaction to enable potential participant to make informed decision



# ***Informed Consent Process***

## **‘Elements’ of an Information Consent Letter**

- Names of the Faculty Supervisor and Student Investigator conducting the project along with departmental affiliation and contact numbers
- The study purpose
- Description in lay language of all procedures. For questionnaires or interviews, examples of the type of questions are to be included
- For studies involving questionnaires or interviews, a statement indicating participants may decline answering any question(s)
- Description of all known or anticipated risks and benefits
- Details of time commitment required for participation in the project



# ***Informed Consent Process***

## **Elements of an Information Consent Letter cont'd**

- Assurance participants are free not to participate, or to subsequently withdraw their consent, without jeopardizing any entitlements
- Details about follow-up sessions or subsequent related project
- Procedures to ensure confidentiality of data and anonymity of participants -- any limitations on confidentiality should be noted
- Details concerning financial or other remuneration of participants
- Information on length of retention and security of data



# ***Informed Consent Process***

## **Elements of an Information Consent Letter cont'd**

- Opportunity to ask any questions related to study and receive satisfactory answers
- A statement that indicates that the project has been reviewed and received ethics clearance through the Office of Research Ethics (ORE), and that participants who have comments or concerns resulting from their involvement in the project may contact the Susan E. Sykes, Director, ORE. The telephone number for the ORE (519-888-4567, Ext. 6005) must be provided. Email address is also recommended.



# ***Informed Consent Process***

**Written consent is normally the default.**

## **Exceptions to written consent:**

- Anonymous survey research
- Research in cultures where written consent is not norm
- Research where written consent might put participant at risk
- Methodologies where written consent is not practical (e.g. large scale telephone interviews, Internet)



# ***ORE Website: Sample Materials***

- ORE website is intended to be an educational resource for researchers, course instructors, students
- Provides sample recruitment materials, information letters, consent forms, and feedback letters
- Purpose: copy and modify sample materials to suit specifics of project

<http://www.research.uwaterloo.ca/ethics/human/application/101samples.htm>



# ***Special Considerations: Web-based Studies***

Web-based questionnaire studies introduce different requirements to ensure participants' anonymity; namely, assurance that the site will not collect potentially identifying information (e.g. machine identifiers).

*“..Furthermore, the web site is programmed to collect responses on the questionnaire and job analysis items alone. That is, the site will not collect any information that could potentially identify you (such as machine identifiers). Additionally, if you begin entering responses to the questionnaire on the Web and then choose not to complete the questionnaire, the information that you have already entered will not be transmitted to us”.*



# ***Special Considerations: Web-based Consent***

## **Use of Radio Buttons to Indicate Consent**

“...I have read the information presented in the information letter about a study being conducted by *(insert researcher names)* of the Department of *(insert department name)* at the University of Waterloo. I am aware that I may withdraw from the study without penalty at any time by advising the researchers of this decision.

This project has been reviewed by, and received ethics clearance through, the Office of Research Ethics at the University of Waterloo. I was informed that if I have any comments or concerns resulting from my participation in this study, I may contact the Director, Office of Research Ethics at (519) 888-4567 ext. 6005”.

- o I agree to participate in this study.
- o I do not agree to participate in this study.



# ***Special Considerations: Student Course Research***

## *Various Approaches to course-based research:*

- Students work on same topic/theme assigned by instructor. Students may develop their own questions for the theme.
- Each student develops his/her own theme but uses one assigned procedure e.g. interview
- Students work individually or in groups on projects with topics and procedures of their choice



# ***Student Course Research: Challenges and Suggestions***

## *Challenges*

- Pressure on students due to course timelines
- Requirement for ethics review: application process and review timelines
- Quality of applications varies: impacts time for revisions
- Scope and feasibility of projects often not reasonable for term courses
- Supervision of students: time for instructor
- Burden on public: multiple projects



# ***Student Research: Challenges and Suggestions***

## *Collaboration Can Reduce Challenges*

- Pre-course consultation between ORE and instructor
- In-class presentation by Director or Manager, ORE
- Familiarity with ORE Guidelines for Undergraduate Course Projects
- Templates for all materials by the course instructor in consultation with ORE Instructor obtains prior approval from organization
- Instructor can place reasonable 'boundaries' on projects
- Instructor can adopt procedures to increase authenticity of projects from publics' perspective: introduction letter, departmental letterhead, UW email accounts



## ***Researchers' Safety***

- Risks to researcher may exist from procedures, participants, location of study etc.
- Review methodology from the perspective of what could pose possible risks to the researcher
- Avoid door-to-door surveys or data collection in semi-secluded areas and/or consider:
  - Work in pairs
  - Check in and out
  - Cell-phone



## ***Researchers' Responsibilities***

- Researchers expected to design and implement research consistent with TCPS and with UW's Guidelines
- Researchers ensure all their research involving humans undergoes ethics review and receives ethics clearance prior to commencement of the project
- Researchers conduct research in accordance with their description in the application for which ethics clearance has been granted



## ***Researchers' Responsibilities***

- Researchers responsible for submitting all subsequent modifications to the protocol for ethics review and clearance before changes are undertaken (ORE 104)
- Researchers responsible for submitting an annual Progress Report for all ongoing research projects (ORE 105)
- Researchers responsible for submitting an adverse event form for any events related to the procedures used that adversely affect participants (ORE 106)

# ***Contact Information***

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