Introduction

The goal of this module is to: Apply integrity in the conduct of applied research

Upon successful completion of this module, you will be able to:

- Identify the principles of responsible research
- Explore Tri-council Policy Statement (TCPS) for the ethical conduct of research involving humans
- Examine the requirements for free and informed consent, standards and procedures relating to competence, and essential components of relevant legislations
- Describe standards for managing actual, perceived, or potential conflicts of interest
- Consider the Canadian Council on Animal Care’s guidelines on biomedical research involving animals (online tutorial on research issues)
- Consider potential environmental impact related to field research
- Understand the concept of Intellectual Property and how to protect it
- Complete a Non-Disclosure Agreement for your proposed research project
Principles of Research Integrity

- **Be Honest.** Give credit to others for their work. Describe your own work without embellishment. Report activities and results honestly.

- **Manage Resources with Care.** Use college and other resources efficiently, safely and with care for the protection of resources.

- **Be Respectful of Agreements and Money.** Use grant and other monies as outlined in agreements. Manage money as if it were your own.

- **Be Respectful of Intellectual Property.** Follow policies on IP. Respect privacy and confidentiality concerns in all research activities. Disclose any conflicts of interest. Sign and respect non-disclosure agreements.

- **Be Sensitive to Research with Human Subjects.** Bring any research activity involving human subjects to the attention of an appropriate Research Ethics Board.


- **Conduct Research to the Best of your Ability.** Have personal integrity in all research activities. Do your very best. Take responsibility for the quality of work.
Tri-council and Canadian Ethics


The Tri-Council is composed of three **Boards:**

- Medical Research Council (MRC)
- Natural Sciences and Engineering Research Council (NSERC)
- Social Sciences and Humanities Research Council (SSHRC)

This joint policy from different boards across Canada is in place to ensure that the research taking place in Canada is conducted in an ‘**Ethical**’ manner.
Context of the Ethical Framework

- Always a consideration of **Balance**
- The Need For Research
- A Moral Imperative: Respect for Human Dignity
- Guiding Ethical Principles
- Minimizing harm
- Maximizing benefit
- Ethics has a Legal Framework
Tri-Council Policy on Research Involving Humans

1. **Respect for Human Dignity**: The cardinal principle of modern research ethics is respect for human dignity. This principle aspires to protecting the multiple and interdependent interests of the person -- from bodily to psychological to cultural integrity. This principle forms the basis of the ethical obligations in research that are listed below. It is unacceptable to treat persons solely as means (mere objects or things), because doing so fails to respect their intrinsic human dignity and thus impoverishes all of humanity. Second, the welfare and integrity of the individual remain paramount in human research.

2. **Respect for Free and Informed Consent**: Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent. The principle of respect for persons translates into the process and requirements for free and informed consent by the research subject.

3. **Respect for Vulnerable Persons**: Respect for human dignity entails high ethical obligations towards vulnerable persons -- to those whose diminished competence and/or decision-making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

4. **Respect for Privacy and Confidentiality**: Respect for human dignity also implies the principles of respect for privacy and confidentiality. Privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information. In doing so, such standards help to protect mental or psychological integrity.

5. **Respect for Justice and Inclusiveness**: Justice connotes fairness and equity, and concerns the distribution of benefits and burdens of research. On the one hand, distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. On the other hand, distributive justice also imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

6. **Balancing Harms and Benefits**: The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefit balance -- that is, that the foreseeable harms should not outweigh anticipated benefits.

7. **Minimizing Harm**: Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and societally important aims that cannot be realized without the participation of human subjects. In addition, it should be kept in mind that the principle of minimizing harm requires that the research involve the smallest number of human subjects and the smallest number of tests on these subjects that will ensure scientifically valid data.
Introductory Online Tutorial by the Interagency Advisory Panel of Research Ethics

The online tutorial by the Interagency Advisory Panel of Research Ethics assists anyone who participates in research activities develop understanding of ethical considerations when engaging in research involving human subjects. More specifically, it allows for a comprehensive review of the Tri-council Policy Statement for the ethical conduct of research involving humans.

When you click the link below, you will be asked to register. You will need to generate a login name and password, which will allow you to track your progress throughout the tutorial, save your work, and to obtain a Certificate of Completion when you have worked through the entire tutorial.

There are 5 main sections of the Tutorial and each take approximately 15 to 25 minutes to complete. There is no need to complete the tutorial in one sitting. A ‘save’ icon allows you to save your location in the Tutorial. This allows you to stop and start the Tutorial as you wish. After saving, when you log-in the next time you will begin automatically where you left off. Be sure to review the Welcome and Introduction section after you register to guide you through the Tutorial.

The Tutorial works with 4 main case studies used throughout, and allows you to test your learning by answering 5 multiple choice ‘Progress Check’ questions at the end of each section. At each session all Progress Checks questions must be answered correctly in order to receive the Certificate of Completion.

To begin the tutorial, click on the following url:

http://www.pre.ethics.gc.ca/english/tutorial/signup.cfm
Animal Care Guidelines in Biomedical Research: Research Issues

The **Canadian Council on Animal Care** (CCAC)

‘is the national peer review agency responsible for setting and maintaining standards for the care and use of animals used in research, teaching and testing throughout Canada’.

The CCAC is a non-profit, autonomous and independent body funded by public monies through the Canadian Institutes of Health Research (CIHR) and the Natural Sciences and Engineering Research Council (NSERC), with additional contributions from federal science-based departments and private institutions.

‘The CCAC comprises 22 member organizations whose representatives include scientists, educators, veterinarians and delegates from industry and the animal welfare movement’. 
Animal Care Guidelines in Biomedical Research: Research Issues

The CCAC has developed a series of educational modules that assist anyone involved in the use of animals in research, teaching and testing to be adequately trained in the principles of animal care and use and the ethical issues involved in animal use.

While this section may or may not be relevant to your work, it is useful to know where to find this information for potential use in the future, and thus you are encouraged to browse through the CCAC website:

http://www.ccac.ca/en/CCAC_Main.htm
Environmental Impact Related to Field Projects

An environmental impact assessment (EIA) is an assessment of the possible impact—positive or negative—that a proposed project may have on the environment; considering natural, social and economic aspects. Projects may include applied research.
Environmental Impact Related to Field Projects

The International Association for Impact Assessment (IAIA) sets generic principles of EIA Best Practice which are designed primarily for reference and use by those professionally involved in environmental impact assessment.

The aim is to promote the effective practice of environmental impact assessment consistent with the institutional and process arrangements that are in force in different countries.
Environmental Impact Related to Field Projects

The Canadian Environmental Assessment Act (CEAA) is the legislation that regulates environmental impact assessments in Canada.

Conflict of Interest

Definition:
A conflict of interest is any situation where an individual’s private interests may be incompatible or in conflict with their responsibilities in a specific employment or contract situation.

Principles:
- Ethical standards – act honestly and uphold ethical standards and trust
- Public Scrutiny – act in a manner that will bear close public scrutiny
- Private Interests – disclose any private interests that may be in potential conflict of interest
As a researcher you will, from time to time, have certain proprietary information disclosed to you as a matter of course. It is very important that you understand your responsibilities regarding the confidentiality of this information. It is expected that you will agree to follow and sign a non-disclosure contract when requested.
What Constitutes Proprietary Information?

**Proprietary information** includes, but is not limited to, data or other information relating to products, plans, methods, and processes. This is especially true regarding developmental or experimental work due to the uncertainty of the results and conclusions. In addition, information concerning computer programs, databases, systems, software (including object code and source code), concepts and performance features are vulnerable and many require confidentiality. Anything that concerns the original works of authorship, for example, innovative designs and new inventions, are also covered by this provision.

There are also the business aspects of proprietary information. These aspects include customer lists (including names and buying habits or practices of customers), the names of vendors or suppliers, marketing methods, reports, analyses, business plans, financial information, or statistical information. Any and all information of this nature, and any explicitly stated by the employer or industry partner with whom you are working, must be treated with confidentiality.
What Kind of Information is Not Proprietary?

Proprietary information does not include information that:

- Is already known by the general public (in the “public domain”)
- Has been approved for release to the general public by written authorization of the company
- Has been independently developed without use of the disclosing party’s proprietary information

In short, you can discuss anything that has been approved for release by the company or anything that is generally considered common knowledge. If you are unsure whether a particular topic, idea, or piece of information is permissible for discussion, seek advice.
In your role as a research assistant/student researcher, you are likely to be asked to sign a non-disclosure/confidentiality agreement before you begin your work on an applied research and development project.

A non-disclosure agreement (NDA), also known as a confidentiality agreement, confidential disclosure agreement (CDA), proprietary information agreement (PIA), or secrecy agreement, is a legal contract between at least two parties that outlines confidential materials or knowledge the parties wish to share with one another for certain purposes, but wish to restrict access to. It is a contract through which the parties agree not to disclose information covered by the agreement. An NDA creates a confidential relationship between the parties to protect any type of confidential and proprietary information or a trade secret. As such, an NDA protects non-public business information.

- NDAs are commonly signed when two companies or individuals are considering doing business and need to understand the processes used in each others business for the purpose of evaluating the potential business relationship. NDAs can be "mutual", meaning both parties are restricted in their use of the materials provided, or they can restrict the use of material by a single party.

- It is also possible for an employee to sign an NDA or NDA-like agreement with an employer. In fact, some employment agreements will include a clause restricting employees use and dissemination of company-owned "confidential information."
Components of Non-disclosure Agreements

Heading

Letterhead: e.g. Office of Research and Innovation, Niagara College

Title: NON-DISCLOSURE AGREEMENT

Effective Date: This Agreement is made effective as of:

__________

Parties to the Agreement: This Non-Disclosure Agreement ("Agreement") is entered into by ________________ ("Employee/Consultant/Student Research Assistant")

and ________________ (Company)
Components of Non-disclosure Agreements

Definitions

CONFIDENTIAL INFORMATION

Confidential Information may include, without limitation, information about customers, pricing strategies, prices obtained from suppliers; employee lists or names of individual employees; financial information; inventions, improvements and other intellectual property; trade secrets; know-how; designs, processes or formulae; materials or apparatus; methods; ways of business; research and development data, results or products; software or programs; market or sales information or plans; customer lists; and business plans, prospects and opportunities (such as possible acquisitions or dispositions of business) which have been discussed or considered. Information developed by the Employee/Consultant pursuant to the Employee’s/Consultant’s employment/contract by the Partner is Confidential Information of the Partner.
Components of Non-disclosure Agreements

Terms and Conditions

Confidentiality

The Employee’s/Consultant’s employment/contract creates a relationship of confidence between the Employee/Consultant and the Partner. The Employee/Consultant agrees that, during and following his or her employment/contract, the Employee/Consultant will not disclose or communicate any Confidential Information with or to anyone, and will not use any Confidential Information for the benefit of Employee/Consultant or any person or entity other than the Partner. Information not specifically known to be in the public domain is considered confidential until otherwise specified by the Partner. The Employee/Consultant will deliver immediately to the Partner all copies of any Confidential Information upon the Partner’s request and/or upon the termination of Employee’s/Consultant’s employment/contract with the Partner.
Components of Non-disclosure Agreements

Assignment of Company-Related Inventions or Developments

All Inventions or Developments will be the sole property of the Partner unless otherwise agreed through a Memorandum of Understanding or other Agreement. The Partner will be the sole owner of all patents, copyrights and other proprietary rights in and with respect to all Inventions or Developments. The Employee/Consultant hereby transfers and assigns to the Partner all proprietary rights which he or she may have or acquire in any Inventions or Developments, and he or she waives any other special rights including, without limitation, moral rights, which he or she may have or accrue through the Research Project.

The Employee/Consultant agrees to promptly disclose to the Partner all relevant Research Project-Related Inventions or Developments.
Components of Non-disclosure Agreements

Miscellaneous

- **Governing Law:** *e.g.* This Agreement shall be governed by and construed under the laws of Ontario, Canada.

- **Survivorship:** *e.g.* The Employee’s/Consultant’s obligations under this Agreement shall survive the termination of his or her employment/contract for whatever reason.

- **Assignment:** *e.g.* The Employee’s/Consultant’s rights and obligations under this Agreement may not be assigned by Employee/Consultant to any other party.

- **Amendments:** *e.g.* This Agreement may not be amended, rescinded, superseded, or canceled except by a written instrument signed by Employee/Consultant and the Partner. No terms of this Agreement may be waived except by a written instrument signed by the party waiving compliance.

- **Entirety of Agreement:** *e.g.* This Agreement constitutes the entire agreement between the parties with respect to the matters addressed in this Agreement and supersedes all prior agreements between the parties concerning such matters.

- **Acknowledgement:** *e.g.* The Employee’s/Consultant’s signature below indicates his understanding and acceptance of this Agreement and acknowledgment that nothing contained in this Agreement shall be deemed to alter or modify the nature of his or her employment/contract with the Partner.
Components of Non-disclosure Agreements

Signatures

Employee/Consultant/Student Name:

________________________________________

Signature:

________________________________________ Date: ______  

Company Name:

________________________________________

Signature:

________________________________________ Date: ______
NON-DISCLOSURE AGREEMENT

PROJECT: ________________________________________

INDUSTRY PARTNER: ______________________________

RESEARCH TEAM: __________________________________

I agree that I will not, directly or indirectly, divulge, disclose or communicate any information to a third party, except as it may be required in the course of any formal business association or dealings with the disclosing party, relating to the above project. I also acknowledge that no license of the proprietary information, by implication or otherwise, is granted to me. Additionally, I acknowledge that I may only use the proprietary information in connection with business dealings with the disclosing party…and for no other purpose, without prior written consent.

I further agree that all proprietary information, including but not limited to, documents, files, reports, notebooks, samples, lists, correspondence, software, or other written or graphic records provided by the disclosing party (or produced using the disclosing party’s proprietary information) will be held strictly confidential by me, and returned upon the request of the disclosing party or Niagara Research.

AGREED AND ACKNOWLEDGED:

__________________________________                           Date  ___________________

Print Name                                      Signature