

DYOUVILLE
Institutional Review Board (IRB)
Manual for the Researcher

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Acknowledgements

It is often the case that Manuals of this type are prepared by some, edited by others, then re-edited for many years afterward, and the authors, editors, and contributors become overlooked across the many versions of the Manual. This *IRB Manual for the Researcher (IRB Manual)* was initially separated from the College's Graduate Handbook by Dr. James Klyczek well before 1995, with the IRB developed initially at the College by Dr. Donald Sabo. Between 1995 and 1999, this Manual was reviewed several times.

By 1999, Dr. Roger Fiedler had assumed responsibility for the updates to the *Manual*, with contributions from researchers all across the College. On or about 2005, Dr. Fiedler handed the responsibilities over to Dr. Mark Garrison, and then Dr. Catherine Lalonde to head up the IRB, with the *Manual* benefitting from the editorial support of Ms. Chery Saramak, who helped considerably in the preparation of the final versions of the *Manual* up until 2012.

Over the next two years, Dr. Roger Fiedler resumed the responsibility for the *Manual*, and prepared substantial changes to the *Manual* with the extensive editing, support, and updates prepared by the Graduate Assistance of Dr. Dana Bagwell, who spent the 2012-2013 Academic Year reviewing federal policy changes and comparing our *Manual* to those provided from other Colleges and Universities across the country.

Dr. Bagwell's improvements resulted in a substantially revised *Manual*, and major policy changes from the posted *Manual* from 2010- 2011. However, the growth of the IRB, and the research at the College, prompted a final review that has resulted in the current 2017 *IRB Manual for the Researcher (IRB Manual)*.

Researchers across the College will recognize the extensive, and substantial improvements in this current *Manual*; these improvements so broad and comprehensive that they would not have been possible without the extraordinary contributions of Carla Beneduce. Ms. Beneduce spent the 2014-2015 Academic Year reviewing policies on the Belmont Report, the Code of Federal Regulations, the Common Rule, and HIPAA regulations; most of which had been updated since the original *Manual* from before 1995. Carla's contributions cannot be over-exaggerated; her skillset, knowledge, experience, and writing skills have made this *Manual* possible, and as my Graduate Assistant, it has taken me over 2 years to catch up with her work, and complete this final version. As the Coordinator of the IRB, I cannot thank Carla enough for the amount of time, effort, and skill she has provided to make this *Manual* as useful and accurate as it has become today. Thank you, Carla!

Over these past 2 years, this *Manual* has been advantaged by several members of the IRB at the College, without whom our IRB could not function. The IRB is a purely voluntary service by these folks, and the College owes a considerable debt of gratitude for their service to the researchers and students who take advantage of their expert guidance and support nearly every day of every calendar year. The IRB has included over 150 of these folks since 1986, some of whom served for over 10 years on the IRB; Dr. Paul Johnson (17), Dr. Edward Weiss (14), Dr. James Klyczek (11), Dr. Kathleen Mariano (11), and Dr. Eric Miller (10).

Members of the 2016-2018 IRB include Dr. Kathleen Border, Dr. Dion Daly, Dr. Shelby Edwards, Dr. Adi Garba, Dr. David Gettman, Dr. Rachel Gorodetsky, Dr. Stephen Grande, Dr. Connie Jozwiak-Shields, Dr. Joseph Jurkowski, Dr. Michele Karnes, Dr. Julie Kirsch, Dr. Catherine Lalonde, Dr. Kathleen Mariano, Dr. Eric Miller, Dr. Amy Nwora, Dr. Lynn Rivers, Dr. Jason Sprowl, Dr. Frank Stephen, Reverend Scott Thomas, and Dr. Christine Verni. All of these Members have made additional contributions to the *Manual*, and I am grateful to all who have made this new *Manual* possible.

Roger Fiedler

Dr. Roger Fiedler
Former Director of the IRB

CHAPTER I - INTRODUCTION

The Institutional Review Board (IRB) of D'Youville College was established in accordance with New York State and U.S. federal guidelines for institutions conducting research involving human subjects. It is the function of this IRB to assess the balance of risks and benefits to human participants that may be expected from the proposed research.

Mission of the D'Youville Institutional Review Board

The mission of the D'Youville IRB is to promote a research arena that protects the rights, privacy, and welfare of individuals participating in research activities conducted by the faculty, staff, and students at D'Youville. The IRB is committed to uphold the highest level of ethical and quality standards during human research, and to approve sound investigations that add to the knowledge of the scientific community and the public.

Purpose of This Manual

The purpose of the *IRB Manual for the Researcher (IRB Manual)* is to describe the different types of human subject review application forms and procedures, possible IRB dispositions of applications, and the definitions and examples of terms used in human subjects review applications. **The D'Youville Informed Consent and Assent Forms are provided in this *IRB Manual*. If necessary for the research, these exact forms must be used with no modifications.**

The information in this *IRB Manual* applies to all forms of research proposed by *any* faculty, staff, or student of D'Youville, or any researcher from outside the institution who wishes to conduct research on campus and has received any relevant prior permissions to do so. This includes research proposed by faculty, staff, employees, students, and outside researchers. *ALL* student projects, theses, and dissertations that involve recruitment of human subjects and/or review of human subject data (e.g., clinical chart review) must be reviewed by the IRB.

Shared IRB with Catholic Health

We have a shared IRB with the Catholic Health System [CHS]. This means CHS will accept the decisions of the DYC IRB and allow DYC to be responsible for research where the project is taking place at DYC or with DYC students as the subjects. And DYC will accept the decisions of the CHS and allow CHS to be responsible for studies where the research is taking place at CHS or with patients, staff, or medical records of CHS. This enables researchers to submit projects to one IRB for approval and the other IRB will be notified when approval has been received without going through a second IRB process.

How to Use This Manual

- Review the entire *IRB Manual* prior to beginning the preparation of your application to the IRB, and familiarize yourself with the regulations, processes, procedures, and terminology presented in Chapter III - *Definition and Examples of Terms* of this *IRB Manual*. The *Definition and Examples of Terms* chapter explains specific language pertaining to the protection of participants and provides a fuller understanding of how to prepare your IRB application.
- Review the three types of applications that may be submitted to the IRB. Note while some research is classified as *Exempt*, an Exempt Review Application (see Chapter V and Appendix A of this *Manual*) must still be submitted to the IRB. File the application that best represents the type of research being proposed. Only the IRB can make the final decision on how research will be classified and reviewed.

NOTE: Student, staff, or faculty projects that do not meet the Department of Health and Human Services definition of human subject research are not required to be submitted for IRB review. Researchers should be cautious in interpreting these guidelines.

The Department of Health and Human Services defines a Human Subject as a living individual about whom an investigator (whether professional or student) conducting research obtains: (a) data through intervention or interaction with the individual, or (b) identifiable private information... (Protection of Human Subjects, 45 C.F.R. Part 46; §46.102(f), 2009).

- Use the checklist entitled *Determining Which IRB Application to File: A Checklist* (see Chapter V of this *Manual*) as a worksheet to assist in determining which application to submit. Complete the form prior to preparing an application, but do not submit this form with the application.
- Once it has been determined which application to submit, follow the instructions for preparing the application provided in Chapter VI below, including submission of all supporting documentation and forms.
- Voluntary Informed Consent is one of the most important parts of the research process in terms of protecting human subjects. **The D'Youville Informed Consent and Assent Forms are provided in this *IRB Manual*. If necessary for the research, these exact forms must be used with no modifications.**

No research involving human subjects as defined by The Department of Health and Human Services, by any person affiliated with D'Youville, may be initiated until the D'Youville IRB has granted a disposition of Full Approval or Approval with Recommendations.

The Department of Health and Human Services defines a Human Subject as a living individual about whom an investigator (whether professional or student) conducting research obtains: (a) data through intervention or interaction with the individual, or (b) identifiable private information... (Protection of Human Subjects, 45 C.F.R. Part 46; §46.102(f), 2009).

CHAPTER II - REGULATIONS

The regulations set forth in this *IRB Manual* are based on the Belmont Report (from the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, and the *Code of Federal Regulations*, Title 45 - Public Welfare, Part 46 - Protection of Human Subjects). The Belmont Report is a statement of general ethical principles that is meant to act as a guide in resolving ethical problems that surround the conduct of research with human subjects. The Belmont Report is concerned with the ethics of research, while Part 46 of Title 45 of the Code of Federal Regulations (which is based on the Belmont Report) addresses more specifically the recommended guidelines for the protection of human subjects (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>; <http://www.hhs.gov/ohrp/policy/ohrpreulations.pdf>).

The Belmont Report

The Belmont Report was developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. This Commission was created when the National Research Act (PL 93-348) was passed in 1974. The Belmont Report summarizes the general ethical principles identified by the Commission that should underlie the conduct of biomedical and behavioral research involving human subjects.

In carrying out its mission, the Commission considered the boundaries between biomedical/behavioral research and the accepted routine practice of medicine, the role of the assessment of the risk and benefit balance in determining whether humans should be used in the research, guidelines for the selection of human subjects, and the nature and definition of informed consent.

Since *research* and *practice* often occur together, it is necessary to distinguish between these two terms in order to know what activities ought to be reviewed for the protection of human subjects. The term *practice* is used to mean a commonly accepted intervention or procedure that is designed to enhance the well-being of an individual or client and is considered by the practicing community to have a reasonable expectation of success. *Research* is used to mean an activity designed to test a hypothesis or answer research questions, so that conclusions may be drawn and contributions to the general knowledge of a field may be made. While research and therapy, or research and education, may be carried out together, for example, when evaluating the safety and efficacy of a therapy or of an educational strategy, this need not cause confusion regarding whether the activity requires review by the IRB. The general rule is that if there is an element of research in any activity involving human subjects, the activity should be reviewed by the IRB.

The following summary identifies the boundaries between medical/behavioral research and the practice of medicine, and the three basic ethical principles which, when practically applied, lead to informed consent, assessment of risk and benefits, and the selection of subjects. The three principles identified by the Commission as generally accepted in our cultural tradition are labeled: (a) respect for persons, (b) beneficence, and (c) justice. These principles are stated in a sufficiently general manner to allow scientists, subjects, reviewers, and informed citizens to understand the ethical issues that are an integral part of research using human subjects. In stating these principles, the objective is to provide an analytical framework that will guide the resolution of ethical problems involving research with human subjects.

Respect for Persons

The first principle, which in its practical application gives rise to the idea of informed consent, is *Respect for Persons*. Respect for Persons entails two moral requirements: that we acknowledge the autonomy of individuals, and that we protect those individuals with diminished autonomy. The autonomous person is capable of choice; that is, capable of deliberation about personal goals and acting freely in the pursuit of those goals. To respect that autonomy is to allow the individual the freedom to pursue those goals without interference when there are no compelling reasons not to do so (such as goals or actions that are detrimental to others).

Although the capacity for self-determination is a process that is expected to mature during an individual's life, some individuals lose this capacity because of illness or mental disability. So, not every individual is capable of self-determination; thus, some individuals require extensive protection. The extent of the protection offered to individuals who are considering participation in a research activity depends upon an assessment of the risk of harm, and the likelihood of benefit from the research. These individuals must also enter into the research activity voluntarily and with adequate information.

In its practical application, the Respect for Persons principle requires that autonomous individuals, insofar as they are capable, be given the opportunity to choose what will and what will not happen to them. The possibility of such choice occurring is maximized when three standards for informed consent are satisfied. The first of these standards is *information*; generally including the procedure, purpose of the research, possible risks, anticipated benefits, and opportunity to ask questions, and to withdraw from the research. A simple listing of these items, however, does not convey the full meaning of the term information. A general rule often used to determine what information to give requires the researcher to provide information that reasonable persons would wish to know in order to make a decision regarding their care. Even then, subjects should clearly understand the range of the probable risks and the voluntary nature of their participation. Information concerning risk should

never be withheld for the purpose of eliciting the cooperation of subjects, but care should be taken to avoid disclosures that would invalidate the research.

The second standard to ensure informed consent is *comprehension*. This standard is met when the information is conveyed in a manner that the subject can understand. This means that the researcher must adapt the presentation of the information to the subject's capacities for intelligence, rationality, language, and level of maturity. The obligation of the researcher to determine whether or not the subject comprehends the information increases with the seriousness of harm and probability of risks.

The third standard for informed consent is *voluntariness*. Agreement to participate in research is valid only if the consent is voluntary. This means that the consent must be obtained without coercion, undue influence, unjustifiable pressure, or deception.

Beneficence

The second principle that the Commission established to guide resolution of ethical issues inherent in research was the principle of *beneficence*. This is the obligation to secure the well-being of participants in research by maximizing possible benefits and minimizing possible harms. In practical terms, this involves determining when it is justifiable to seek certain benefits despite the risks, and when the benefits should be abandoned because of the risks.

The assessment of benefits and risks is concerned with the probabilities and magnitudes of possible harms, such as psychological, physical, legal, social, and economic harm, measured against the possible benefits to the subject and to society. This assessment of risks and benefits requires the researcher's careful consideration of data, including consideration of alternate means of obtaining the same research information, and concern for the subject, the subject's family, and society at large. This is accomplished by a systematic, non-arbitrary approach by the reviewing Committee (the IRB) that requires those making decisions about the justifiability of the proposed research to be thorough in gathering and assessing information about all aspects of the research.

This includes a determination of the presuppositions of the research, clarification of the probability and magnitude of risk, and estimation of compliance with five considerations: (a) brutal and inhumane treatment is never justified; (b) risks are reduced to those necessary to obtain the research goals; (c) if risk involves the possibility of serious impairment, review Committees should require a very high level of justification; (d) the use of vulnerable populations must be justified; and (e) relevant risks and benefits must be communicated to the subject in the appropriate language.

Justice

The third principle is *justice*, which requires that there be fair procedures and outcomes in the selection of research subjects. Two questions that are relevant to the principle of justice are: Who ought to receive the benefits of research? and, who ought to bear its burdens? This principle is applicable at both the individual and social levels.

At the individual level, research is constrained to offer the benefits of research to *all* subjects, and not to seek *vulnerable* subjects exclusively for research procedures involving higher levels of risks.

Social justice requires that a distinction be made with respect to the ability of the social class selected for research to bear the burdens of the research. For example, this moral requirement would require the selection of adults before children, all other factors being reasonably equal. Thus, the selection of research subjects needs to be examined in order to determine whether some classes (e.g., racial and ethnic minorities, welfare recipients, children, or prisoners) are being selected simply because of their easy availability, rather than for reasons directly related to the problem under investigation. Except where research is directly related to the specific conditions of the class involved, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits of the research.

Justice demands that the results of publicly funded research be available to all individuals and not just to those who can afford the benefits, and that publicly funded research not be confined to groups of individuals who are unlikely to be among the recipients of the benefits. This principle is far too often overlooked. Therefore, the IRB must exercise a heightened degree of vigilance to ensure that the principle of justice is fully applied to all proposed research.

Summary

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission during its deliberations. The Commission was charged to consider the boundaries between medical/behavioral research and medical practice, the role of risk benefit assessment, the appropriate guidelines for selection of human subjects, and the nature and definition of informed consent. The Report is a statement of basic ethical principles and guidelines to assist scientists in resolving the ethical problems surrounding the conduct of research with human subjects.

Code of Federal Regulations

The *Code of Federal Regulations* (CFR) is a codification of the general and permanent rules published in the *Federal Register* by the executive departments and agencies of the Federal Government. The CFR is divided into 50 titles, each representing subject areas of the Federal regulations. The purpose of the CFR is to present the official and complete text of agency regulations in one organized publication and to provide a comprehensive and convenient reference for all those who may need to know the text of general and permanent Federal regulations.

The *Code of Federal Regulations on Public Welfare Title 45 Part 46 Protection of Human Subjects* is disseminated by the Office for Human Research Protections (OHRP). The OHRP is part of the Office of the Assistant Secretary for Health (OASH) in the Office of the Secretary (OS), U.S. Department of Health and Human Services (HHS). Further information and frequently asked questions may be found at <http://www.hhs.gov/ohrp/>.

The CFR applies to all research involving human subjects and provides definitions for the terms *research* and *human subject*. The CFR defines *research* as a systematic investigation designed to develop or contribute to generalizable knowledge. *Human subject* is defined as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

The CFR describes four basic requirements for the conduct of an IRB: (a) a statement of principles, (b) designation of one or more IRBs, (c) appointment of IRB members, and (d) written procedures for the IRB. It is within these parameters that the D'Youville College IRB operates.

Human Subjects vs. Non-Human Subjects Research

Under the *Code of Federal Regulations (Protection of Human Subjects 45 CFR Part 46; §46.102(f), 2009)*, a *Human subject* is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains: (a) data through intervention or interaction with the individual, or (b) identifiable private information.

Research that is conducted only using cadaver specimens is, therefore, not human subject research, and hence it is not regulated by 45 CFR Part 46. However, research involving cadavers is subject to other federal, state, and local laws, and researchers should familiarize themselves with these additional regulations.

To determine the scientific value of the research conducted on deceased individuals, D'Youville College IRB reserves the right to review research proposals on cadavers to:

1. Protect the dignity of the deceased individual and honor respectful and humane treatment of the body parts,
2. Guarantee that permission (consent) for the use of body parts for research purposes has been given by either the individual prior to his or her death or by a family member of the deceased individual whose body is being donated to research/education. Permission of the individual documented under the Uniform Anatomical Gift Act is acceptable (see more details at: http://www.uniformlaws.org/shared/docs/anatomical_gift/uaga_final_aug09.pdf),
3. Safeguard the confidentiality of the deceased and protect the personal health information (also known as protected health information – PHI) regulated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (see more details at: <https://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/pdf/CFR-2011-title45-vol1-part164.pdf>),
4. Assure that the study is being conducted in a suitable laboratory research environment where the cadaver body parts are being safely and securely kept so as to not risk the health, nor cause any emotional distress of the College community not directly involved with the proposed research,
5. Monitor the use and the time required to complete the research activities in order to minimize inappropriate and long-term use of the cadaver behind the reasonable time requested to complete the research project.

Research on human specimens, cells, cell lines acquired through the American Type Culture Collection or similar repository is not considered human subjects research because the information is publicly available, and therefore not subject to the IRB review. However, for any specimens collected from a living donor, the College IRB must review the research proposal ONLY if it is determined by the researcher donor personal identifiers can be readily ascertained during the research activities.

Health Insurance Portability and Accountability Act (HIPAA)

The *Health Insurance Portability and Accountability (HIPAA) Privacy Rule* establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Under the HIPAA Privacy Rule, research is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

The Privacy Rule also defines how research participants will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct research.

D'Youville enforces the HIPAA Privacy Rule at its Chiropractic Clinic. The Privacy Rule may be found at: <http://www.dycchc.com/files/2014/08/hipaa.pdf>. The IRB at D'Youville operates under the *Common Rule*, the federal policy for the Protection of Human Subjects.

Additional Readings

- The Nuremberg Code: http://www.hhs.gov/ohrp/archive/irb/irb_appendices.htm#j5
- Declaration of Helsinki: http://www.hhs.gov/ohrp/archive/irb/irb_appendices.htm#j6
- [The Federal Policy and 45 CFR 46:](http://archive.hhs.gov/ohrp/documents/OHRPRegulations.pdf) <http://archive.hhs.gov/ohrp/documents/OHRPRegulations.pdf>
- HIPAA and Research: <http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/>
- Common Rule: <http://www.hhs.gov/ohrp/humansubjects/commonrule/>

CHAPTER III - DEFINITIONS AND TERMS

Anonymity

Anonymity refers to the best practices of data collection implemented by the researcher to secure the privacy of the research participant, by eliminating the “link” between research participant data and personal identifiable information. Using these practices will not allow the researcher or any other individual to identify participants by the data collected. This approach is common in research involving one-time data collection, such as that which occurs when using survey methods, taking only one set of physical or psychological measurements, or having participants complete questionnaires without asking for their names.

It is important to inform potential participants:

- a) Surveys or questionnaires requiring extensive demographic data may violate the principle of anonymity by providing enough information to allow the researcher indirectly to identify one subject from all others.
- b) When data are recorded anonymously, subjects will not have the right to withdraw from the research once the data have been collected, because it will not be possible to determine which data belong to which subject.

Assent

Assent means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent (*Protection of Human Subjects, 45 CFR Part 46; §46.402(b)*, 2009). This means the child must actively show their willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. **The Informed Consent Form and Assent Form are included in Appendix B of this Manual. If necessary for the research, these exact forms must be used, with no changes.**

Although there is no prescribed minimum age at which assent is required, the researcher must consider the age, maturity, and psychological state of the participant, as well as the complexity of the research tasks or activities the potential subject is being asked to perform. Based on available evidence, the IRB ultimately determines whether assent is required and when parental/guardian permission is also necessary (*Protection of Human Subjects, 45 CFR Part 46; §46.408*, 2009).

Beneficence

Beneficence is one of three ethical principles in the Belmont Report. It refers to the action taken to treat persons in an ethical manner; not only by respecting their decisions and protecting individuals from harm, but also by making efforts to secure the well-being of participants in research. Beneficence comprises two fundamental rules: (1) do not harm, and (2) maximize possible benefits and minimize possible harms (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html#xbenefit>).

Cadaver

Cadaver is defined as the body of a deceased person (http://www.hhs.gov/ohrp/archive/irb/irb_glossary.htm).

Child

Child is a person who has not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (*Protection of Human Subjects, 45 CFR Part 46; §46.402(a)*, 2009).

Coercion

Coercion means to compel or force someone to participate in or perform an action not ordinarily done under the free choice of an individual. This involves influencing an individual decision about whether to do something by using explicit or implied threats (loss of good standing in a job, poor grades, etc.). Coercion may be present even when not obvious when recruiting subjects for research. For example, telling parents or guardians of subjects or subjects themselves how much they will be helping the investigator by participating in research can be interpreted as coercive. Participation should be free and voluntary, with no overriding statements.

Mentioning a relationship that exists between the researcher and the potential subjects may be coercive. Subjects may feel obligated to participate because they know or have seen the researcher at various times. In cases of infants and children, mentioning the researcher cares for or has cared for the child puts parents in a very awkward and unfair position.

Face-to-face recruitment has the potential to be coercive. It is difficult for individuals to say no to someone who is directly in front of them and talking about their research. Inflection, tone of voice, and nonverbal cues can inadvertently slip into the recruitment process without researcher awareness, thus implying threats the investigator is not aware are being conveyed. Coercion can be reduced if an impartial third party presents the request for participation.

Participants must be protected from coercion. If participants are not protected, the IRB application must include an explanation of why coercion is necessary as well as any possible repercussions of the coercion. The methods to be used for coercing subjects must be detailed in the research proposal. A plan for informing subjects at the end of the research of how and why they were coerced must be fully explained (see *Debriefing*). Potential physical and/or psychological risks incurred by participants due to the coercion must be identified, and procedures for addressing the risks must be established as part of the debriefing procedures.

Compensation

Compensation refers to the amount of payment a subject may receive for participation in a research study. The IRB should review both the amount of payment and the proposed method of disbursement to assure neither entails problems of *coercion* or undue influence. Such problems might occur, for example, if the entire payment were to be contingent upon completion of the study, or if the payment were unusually large. Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation.

Confidentiality

Confidentiality refers to protection of participant privacy, so information collected about them, as part of the research process, is not disclosed. Information may be revealed in group form, or as individual examples, but not in a way an individual may be identified.

If the investigator collects information on subjects over a period of time, such as in test-retest reliability or in pretest-posttest study designs, there must be a mechanism to match various data to the same subject. This may be done by using codes or identifiers (e.g., subject ID numbers) on both sets of data only the researcher can trace to a master name-number list. Because names and numbers can be related, this list must be kept confidential by storing it in a private and secure location, such as a locked file cabinet.

If data are recorded in cases where the researcher personally knows subjects, it must be acknowledged the researcher knows the participants personally, and the data must be treated confidentially, because anonymity is not possible. It is important to acknowledge subjects may waive the right of confidentiality. This may occur, for example, when a subject specifically requests to be quoted.

In the United States, all confidential data must be stored by the researcher for at least three (3) years from the end of the study. In Canada, data must be stored for at least six (6) years from the end of the study.

Consent

Consent is defined as a willingness to participate as a subject in research by individuals 18 years of age or older. Consent is obtained from a research subject in one of two (2) forms: Implied Consent, or Informed Consent document. When the Informed Consent document is used, a copy shall be given to the person signing the form (Protection of Human Subjects, 45 C.F.R. Part 46; §46.117(a), 2009). **The Informed Consent Form is included in Appendix B of this Manual. If necessary for the research, this exact form must be used, with no changes.**

Consent Process

The *consent process* is defined as an active process of sharing information between the investigator/research personnel and the prospective subject and should ensure that: (a) all critical information about a study is completely disclosed, (b) the information must be conveyed in language understandable to those being asked to participate – or continuing to participate - as subjects in the research, and (c) that prospective subjects or their legally authorized representatives adequately understand the research so that they can make informed choices (Protection of Human Subjects, 45 CFR Part 46; §46.116, 2009).

The *informed consent process* is therefore an ongoing exchange of information between the investigator and the subject; it begins with the initial approach of an investigator or research personnel with the potential subject (e.g., through a flyer, brochure, or any advertisement regarding the research study) and continuing until the completion of the research study. The informed consent process could include, for example, use of question-and-answer sessions, community meetings, and videotape presentations. In all circumstances, however, individuals should be provided with an opportunity to have their questions and concerns addressed on an individual basis. **The Informed Consent Form is included in Appendix B of this Manual. If necessary for the research, this exact form must be used, with no changes.**

Informed consent must be legally effective and prospectively obtained (Protection of Human Subjects, 45 CFR Part 46; §46.116-117, 2009).

Covered Entity

A *covered entity* is 1.) a health care provider that conducts certain standard administrative and financial transactions in electronic form (i.e., transmits any health information electronically in connection with certain transactions); 2.) a health care clearinghouse; or 3.) a health plan. A business associate is a person or entity (other than a member of the covered entity's workforce) who performs certain functions or activities on behalf of, or provides certain services to, a covered entity that involve the use or disclosure of protected health information. A covered entity may use a business associate to de-identify PHI on its behalf only to the extent such activity is authorized by their business associate agreement (Protection of Human Subjects, 45 CFR Part 160; §§160.102; 160.103; 164.500).

Debriefing

Debriefing is a process of informing the subject about all the information related to the research initially withheld and explaining the reasons for withholding the information. Debriefing is used when subjects have been deceived or coerced, and as a means of briefly informing subjects about the research purpose(s) immediately after data have been collected (if possible, without compromising the remaining data collection). Debriefing may take the form of dehoaxing or desensitizing subjects which should not be confused with the release of a summary of the research results.

Deception

Deception is defined as the intentional action to misrepresent, trick, or mask some aspect of the research. Deception is common in some research. For example, in the Milgram (1963) experiments, the subjects were informed the purpose of the experiment was learning. However, the true purpose of the study was to measure subjects' obedience to presumed authority figures. The subjects must, of course, be aware of what measurements will be taken, what questionnaires will be administered, etc. so they can sign an informed consent to participate in the research, but the researcher may choose not to tell participants what is looked for in order to prevent the subjects from biasing the results.

Subjects should be protected from deception. If subjects are not protected, the researcher must explain in the IRB application why this is necessary, as well as any possible repercussions for the subjects. The methods to be used for deceiving subjects must be detailed in the research proposal, and a plan for informing subjects at the end of the research as to how and why they were deceived must be fully explained (see *Debriefing*). Potential physical and/or psychological risks that may be incurred by subjects due to deception must be identified, and procedures for addressing the risks must be established.

Dehoaxing

Dehoaxing is the process of convincing subjects who have been deceived as part of research that they have in fact been deceived. The purpose of dehoaxing is to prevent possible future harm to the subject. For example, subjects may be given false pretest scores to test the effect of these scores on subsequent tests of motivation levels. If participants believe the false scores represent their true abilities, their level of self-esteem may become jeopardized. In cases such as these, simply informing participants they were deceived, and the pretest scores were false may not be sufficient. In addition to informing the subjects, some form of demonstration may be needed to convince participants they were deceived and thereby diminish the undesirable effects of the experiment.

Desensitization

Desensitization is the process of helping subjects deal with information they learn about themselves because of participating in research. Again, consider the outcome of the Milgram (1963) study in which some subjects thought they had administered lethal electrical shocks to another person because the experimenter told them to do so. This knowledge of their behavior, along with their previous self-perception, required counseling for some participants who became depressed because of participating in the study

One way to desensitize subjects is to reinforce the idea their behavior resulted from the circumstances of the research, and their behavior was not abnormal or unusual. Desensitization is used to help subjects accept behaviors performed which seemed inconsistent with their self-perceptions.

Discomfort

Discomfort refers to the extent to which a participant may be made physically or psychologically uncomfortable by the topic or activity that is the focus of the research.

Guardian

A *guardian* is an individual authorized under applicable state or local law to consent on behalf of a child to general medical care (Protection of Human Subjects, 45 CFR Part 46; §46.402(e), (2009)).

Health Insurance Portability and Accountability Act (HIPAA)

The *Health Insurance Portability and Accountability Act (HIPAA)* Privacy Rule provides federal protections for individually identifiable health information held by covered entities and their business associates and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so it permits the disclosure of health information needed for patient care and other important purposes.

The HIPAA Privacy Rule also establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. Research is defined in the Privacy Rule as, “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (Security and Privacy, 45 CFR 164.501, 2011). A covered entity may always use or disclose for research purposes health information that has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions below.

Human Subject

The Department of Health and Human Services defines a *Human Subject* as a living individual about whom an investigator (whether professional or student) conducting research obtains: (a) data through intervention or interaction with the individual, or (b) identifiable private information... (Protection of Human Subjects, 45 C.F.R. Part 46; §46.102(f), 2009).

Identifiable Information

Identifiable information is information individually identifiable and may easily identify the subject and/or may facilitate the determination by the research personnel of participant identity (i.e., the identity of the participant is or may readily be determined by the investigator or associated with the information).

Implied Consent

Implied consent means subjects give their consent to participate in the research by virtue of their participation in a given research activity. That is, the voluntary participation of the subject in the research is accepted as their consent to be a part of the research. Completion of electronic or mail anonymous surveys, questionnaires, or interviews are examples of research activities where implied consent is used.

Implied consent is a type of a waiver of documentation of the formal Informed Consent. When reviewing a research project where an implied consent mechanism is used, the IRB may require the researcher(s) to disclose to the potential participants with a written summary or an information sheet about the research, including: (1) purpose of research; (2) time involved; (3) assessment of minimal risk; (4) statement regarding benefit to participants; (5) contact for questions about the research; and (6) contact for questions about rights as a research participant.

There are several instances where this type of consent is helpful. For example, research involving the mailing of a survey. If the survey does not ask for any identifiable information, the cover letter accompanying the survey could be written in such a manner as to serve as the “implied” informed consent form. The letter would need to contain a statement indicating completion and return of the survey implies consent to participate in the research. As a result of such implied consent, subjects must be informed they cannot withdraw their data once provided to the researcher, since there is no way to know which data are theirs.

Implied consent may be used when coding mechanisms, such as master name-number lists, are employed in the survey design such that the researcher knows which subject returned which survey, ONLY when (a) subjects are informed coding is being used, (b) the researcher destroys the coding mechanism at the completion of data collection (thus, at this point, the once-confidential data become anonymous), and (c) subjects are informed of the date on which the coding mechanism is to be destroyed.

Informed Consent

The Informed Consent Form and Informed Assent Form are included in Appendix B of this *Manual*. If necessary for the research, these exact forms must be used, with no changes. *Informed consent* should be viewed as a process and not just a form. Full, accurate, and comprehensible information must be provided to individuals to enable them voluntarily to decide whether they want to participate in research. The explanation of procedures used to obtain informed consent should be presented to the individuals being asked to participate in the research in terms they can understand. It must be made clear to individuals their signature on the form serves as documentation of their consent to willingly participate in the research.

Intervention

Intervention includes both physical procedures and manipulations of the subject or their environment that are performed for research purposes and data are gathered (Protection of Human Subjects, 45 CFR Part 46; §46.102(f), 2009).

IRB

The *Institutional Review Board (IRB)* is a committee whose primary responsibility is to protect the rights and welfare of people involved in research. While researchers may think of the IRB as an impediment or an imposed delay of their research, the IRB may also be viewed as an extra protection for inexperienced researchers, preventing difficulties arising from their lack of knowledge of safe and effective human subject research. The IRB thus provides a “free” and efficient service to researchers by providing considerable expertise and counsel regarding research activities across the College.

IRB Approval

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements (Protection of Human Subjects, 45 CFR Part 46; §46.102(h), 2009).

Justice

Justice is one of three basic ethical principles regarding the conduct of research described in the Belmont Report. This principle requires fair procedures and outcomes in the selection of research participants.

Legal Age

Legal age is defined as 18 years old or older.

Legally Authorized Representative (LAR)

Legally authorized representative (LAR) means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research (Protection of Human Subjects, 45 CFR Part 46; §46.102(c), 2009).

Maintenance of Data

Maintenance of data is an important responsibility of the researcher. Confidential data must be securely maintained in a locked file cabinet, locked desk, or through some other secure method. Applicants must specify where the data will be maintained. Data must be stored for three (3) years in the United States and six (6) years in Canada (see Retention and Access Requirements for Records, 45 CFR Part 74.53 and 45 CFR Part 92.42).

Minimal Risk

Minimal risk means 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 the performance of routine physical or psychological examinations or tests (Protection of Human Subjects, 45 CFR Part 46; §46.102(i), 2009).

Misconduct in Science Policy and Procedures

The D’Youville official *Policy and Procedures on Misconduct in Science* are included in Appendix D this *Manual*. These policies and procedures are designed to ensure that the rights of faculty, administration, staff, and students are protected; that the obligations of the College to the public at large, and various funding agencies and authorities are observed; and to ensure the maintenance of the highest quality research environment.

Non-Participation

Non-participation occurs when an individual who previously consented to participate in research fails to appear for scheduled sessions with the researcher, or who initially participates but then stops. Researchers may use all data that were collected on any individual who ceases participation in a study, but has not withdrawn from the study, as long as this was specified on the Informed Consent.

Permission

Permission is defined as “the agreement of parent(s) or guardian to the participation of their child or ward in research” (Protection of Human Subjects, 45 CFR Part 46; §46.402(c), 2009).

Physical Risk or Discomfort

Physical risks or discomforts are important considerations for researchers, as subjects should be protected from more than minimal physical risk/discomfort (see the definition of *minimal risk* above). If the planned research does not protect

participants, the researcher must indicate why this is necessary, the possible consequences for subjects, and what will be done to restore physical balance.

Further, participants must be informed of any potential for physical risk or discomfort. For example, in testing the concurrent validity of two tests of hand dexterity, subjects may be required to perform tests that could cause fatigue or pain in the hand musculature. Subjects must be protected from this discomfort, or else informed of the possibility for this discomfort, and must have enough information to make an informed decision as to whether they still wish to participate in the research and endure the potential physical risk.

Privacy

Privacy refers to persons and their interest in controlling access to his/her personal information. Privacy of the individual should be respected, and special provisions should be implemented on how research personnel receive and access private information of potential subjects. In research settings, private information can be received and accessed through, but not limited to, interventions, interactions, and collection of identifiable private information.

Private Information

Private information includes information about behavior that occurs within a context the participant can reasonably expect no observation or recording is taking place. Private information includes information provided for specific purposes by an individual that the individual can also reasonably expect will not be made public.

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by researcher or associated with the information) for obtaining the information to constitute research involving human subjects (Protection of Human Subjects, 45 CFR Part 46; §46.102(f), 2009).

Protected Health Information

Protected health information is information, including demographic information, which relates to:

- the individual's past, present, or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual, and that identifies the individual, or for which there is a reasonable basis for believing that it can be used to identify the individual. Protected health information includes many common identifiers (e.g., name, address, birth date, Social Security Number) when they can be associated with the health information listed above.

The HIPAA Privacy Rule protects most "individually identifiable health information" held or transmitted by a covered entity or its business associate, in any form or medium, whether electronic, on paper, or oral. The Privacy Rule calls this information *protected health information* (PHI).

Psychological Risk or Discomfort

Psychological risks or discomforts are also important considerations for researchers, as subjects should be protected from more than minimal psychological risk or discomfort (see the definition of *minimal risk* above). If the proposed research does not protect subjects, the researcher must indicate why this is necessary, what the possible consequences are for subjects, and what will be done to restore psychological balance.

Subjects must be informed of any potential for psychological risk or discomfort. For example, in a study of workplace job satisfaction, subjects may be surveyed about their evaluation of superiors, which may lead to psychological discomfort for some individuals. Subjects may feel they are *passing judgment* on their leaders, and their leaders may experience discomfort by evaluations (*judgments*) from their subordinates. Subjects must have enough information to make an informed decision as to whether they want to participate in the research and endure any potential psychological risks.

Research

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research, whether or not they are conducted or supported under a program that is considered research for other purposes (Protection of Human Subjects, 45 CFR Part 46; §46.102(d), 2009).

Respect for Persons

Respect for persons is an ethical principle described in the Belmont Report that states that individuals should be treated as

autonomous agents, and that individuals with diminished autonomy are entitled to extra protection.

Risk

Risk means the probability of harm or discomfort.

Subject/Participant

The 7th Edition of the *American Psychological Association's Publication Manual* encourages using “participant” over “subject” to denote a human involved in a research study. Summary of Results

Subjects often agree to participate in research without compensation. One way to thank them is to share the research findings by *offering a summary of the research results*. To do so, the researcher should include space on the consent form for subjects to write their address, should they wish to receive a copy of the summary of results.

The researcher must be careful to write a summary of the results especially for the participants, and not simply give them a copy of the full results section of the research. Students engaged in graduate research should always seek the guidance of their graduate research director when preparing a summary of their results. In cases where research is performed at clinics or locations other than on the D'Youville campus, the researcher should prepare a draft of the summary of the results for review by the site supervisor or official assigned to the research project. No summary should be sent to participants without approval by the site official.

Researchers must also make sure to send a copy of the summary of results to all subjects who indicated a desire to receive this summary. In the rush to complete one's research, the researcher must keep in mind that it was the subjects' agreement to participate in the research that made completion of the research possible, and that the subjects' requests for results must be honored. The honoring of this agreement between subject and researcher encourages future participation in research efforts, while the failure to honor this agreement serves as a deterrent to all future research.

Withdrawal

Withdrawal refers to how subjects in a research study may discontinue their involvement prior to the completion of the research. When a subject exercises this right, the informed consent to participate in the research may specify whether the data collected from a subject's participation can be used in any analyses. If this is not specified in the informed consent, the data cannot be used in any analyses, and must be destroyed immediately upon notification of withdrawal from the study. This *Manual* includes an example of informed consent that states that if the subject decides to withdraw while the study is still ongoing, only the data collected up to that point may be used for data analysis purposes.

The Procedures section of the research proposal, the script of introduction to recruit subjects, and the Informed Consent form must specify how and when subjects may exercise this right, and that there are no consequences for the subject if this right is exercised.

As an example, a subject may agree to participate in a 30-minute exercise session, twice per week, for 6 weeks. If, after the fourth exercise session, the subject no longer wishes to participate in the research, the subject may choose to discontinue participation in the research and notify the researcher of withdrawal from the research study.

How a subject may withdraw refers to procedures established by the researcher for the subject to exercise this right. For example: “Subjects may withdraw from the study by informing_(specify name of a person) either verbally or in writing, of their desire to withdraw.” Verbal notification allows the subject to notify the contact person, either face-to-face, or over the telephone. Written notification may be in the form of a letter or handwritten note delivered to the contact person.

When a subject may withdraw refers to the maximum timeframe during which the subject may exercise the right of withdrawal. No minimum timeframe for participation can be established. That is, the researcher cannot require a subject to participate for any minimum time; otherwise, the subject would not truly have the right of withdrawal. The maximum timeframe refers to the longest period during which a subject may exercise the right of withdrawal. This timeframe is established to prevent subjects from withdrawing from the study after the research has been completed. For example: *Subjects may withdraw from the study at any time up to 3 days after the subject's participation has been completed*. In this example, subjects have only 3 days after their completed participation in the research to decide that the researcher may not use data from their participation.

It should be clearly explained to subjects that data collected anonymously limit their right to withdraw from the research. Anonymous subject withdrawal is limited to the duration of subject involvement, as there would be no way for the researcher to identify anonymous data to withdraw subjects once they have been collected.

There can be no penalty or loss of benefits for subjects to which they are otherwise entitled if they choose to withdraw from the study.

CHAPTER IV – IRB APPLICATION GUIDELINES

The College's IRB Website (<http://www.dyc.edu/academics/research/institutional-review-board.aspx>) describes the application process thoroughly, and provides Forms for IRB Application completion, as well as directions for submission of materials for IRB review. The Guidelines may be periodically updated on the website, should policies and procedures change. The website Guidelines, therefore, will remain more current than the ones presented here, as the IRB Manual is more typically updated annually.

The Guidelines are summarized here:

1. Read this entire *IRB Manual for the Researcher (IRB Manual)*.
2. Complete the mandatory online CITI course.
3. After you have read this *IRB Manual*, you should understand which type of research you are proposing Exempt, Expedited, or Standard. You will then need to submit one of the following completed forms and all associated documentation to the IRB committee (all materials should be submitted electronically).

Any additional or supplemental application materials should be scanned and sent to irbhelp@dyc.edu.

IRB Review Application (choose one):

- [Standard \(PDF\)](#)
- [Exempt \(PDF\)](#)
- [Expedited \(PDF\)](#)
- [Human Subjects Research Proposal form \(PDF\)](#)
- Any supporting documentation
- CITI certificate of completion
- D'Youville Informed Consent Form and Assent Form, with No Changes (if necessary for the research)

Complete electronic applications should be scanned and sent to irbhelp@dyc.edu.

Important considerations when preparing IRB Applications for submission

- **IRB FULL APPROVAL TO CONDUCT RESEARCH IS FOR ONE YEAR.** The start date is the date on the Full Approval letter. The annual follow-up/expiration date will be stated on the Full Approval letter, which is 12 months after the start date.
- **IF SUBMITTING TO THE CHS IRB,** go to this link to create an IRBNet Login, and then to submit to IRBNet.org <https://www.chsbuffalo.org/for-physicians/resources/boards/institutional-review-board>

If needed, contact Katy DeWitt, the IRB Director at CHS, for further information (kdewitt@chsbuffalo.org).

- The IRB expects either a Study Closure Form or a Renewal Submission from the Principal Investigator [PI] every 12 months or at the end of any Expedited or Standard study, whichever comes first. No changes are to be made in the approved procedures during the 12 months. In rare instances where minor changes are requested, the PI should send an explanatory letter on DYC letterhead to Julia Hall (hallj@dyc.edu) and irbhelp@dyc.edu.
- **SEE THE IRB WEBPAGE** for our **FILLABLE STUDY CLOSURE FORM**. After 12 months, Renewal Resubmissions with no changes can be submitted with an Exempt Application. If submitting for Renewal, please state "Renewal" in parentheses next to the study title on the application form. The Closure Form or Renewal Resubmission are to be sent to irbhelp@dyc.edu. Upon receipt of a Study Closure Form, the IRB will log the study as closed. The researcher will then receive an official Closure Letter from the IRB. If the IRB does not hear from the researcher before the expiration date noted in the letter, the study will be terminated, and a closure letter will be issued.

- **ANY ADVERSE EVENTS OR MISHAPS IN THE COURSE OF THE RESEARCH MUST IMMEDIATELY BE REPORTED TO THE IRB. REPORT THIS BY EMAIL TO JULIA HALL (hallj@dyc.edu) AND irbhelp@dyc.edu.**
- If applicable, The DYC IRB will report study closure, termination, or adverse events or mishaps in research to the CHS IRB, and vice versa.
- When submitting an IRB application, applicants should include their **STUDY TITLE** and **EMAIL ADDRESS**.
- **ALL APPLICATIONS MUST BE SUBMITTED IN THE FUTURE TENSE.** Exceptions include previous pilot work, CITI training, or creation of instruments (past tense), or instances when present tense makes sense (e.g., "I am a Professor of Nursing..."). Any recruitment, research to be conducted, etc. should be in the future tense.
- **PAGE NUMBERS MUST BE INCLUDED** on all EXPEDITED and STANDARD application materials. While IRB Forms do not include page numbers, all other supporting materials, including appendices and any tools or surveys to be used in the research, must be on numbered pages, or the application will be returned to the applicant without review.
- The **IRB MAY RETURN ANY APPLICATION WITHOUT REVIEW** if the application does not carefully follow D'Youville Guidelines for IRB submission. Researchers should be careful to observe **ALL** the required documentation and include **ALL** required signatures on **ALL** forms before submitting their applications to the IRB.
- Students should **NOT** submit their **ENTIRE** Project, Thesis, or Dissertation Proposals for IRB review. The direction for submitting materials makes clear supplemental information should be provided; but unnecessary materials, such as Literature Reviews, copyright pages, Lists of References, etc. should not be included with IRB application materials.

For ALL Researchers Conducting Research at an Institution other than D'Youville

When research is being conducted at a location other than D'Youville or authorized off-campus clinic(s) or academic site(s), the researcher is encouraged to obtain written permission from the other institution to conduct the study at that location. The written permission letter shall be submitted to the D'Youville IRB Office as a supporting documentation of the researcher's IRB submission packet. If the selected location also has an IRB that requires review and approval of the research study, the D'Youville researcher should first formally apply for approval through the D'Youville IRB. Once Full Approval or Approval with Recommendations has been granted by the D'Youville IRB, the researcher will then formally apply for approval at the other institution. Once the other IRB approves the research, the researcher must provide the external IRB approval letter to the D'Youville IRB.

IRB Application Submission Deadlines

The following Application Deadline schedules apply for the following submissions:

Expedited AND Exempt applications	These may be electronically submitted for IRB Review at any time. They will be reviewed over a period of 7-10 working days, and replies will be directed to the Researcher Applicant by email contact.
Standard IRB applications	<p>These may also be submitted electronically for IRB Review at any time. However, these applications are reviewed at monthly meetings. Therefore, for any Standard application materials to be included in any single monthly review meeting, lead time is necessary for IRB Members in anticipation of the monthly meetings.</p> <p>Thus, STANDARD applications will be included in the next IRB monthly meeting ONLY IF they are received according to the schedule posted on the IRB web page.</p>

CHAPTER V - TYPES OF HUMAN SUBJECTS REVIEW

There are three (3) types of human subject review: EXEMPT, EXPEDITED, and STANDARD. The criteria for each are detailed here.

EXEMPT Review

Any form of research which does not utilize human subjects, such as historical and library research, may not need to be considered for IRB review. However, submissions received that do not involve human subjects may still qualify for Exempt review.

As defined by the Code of Federal Regulations Title 45 Public Welfare Part 46 Protection of Human Subjects 45 CFR 46.101(b), research activities in which the only involvement of human subjects will be in one or more of the following categories will qualify for Exempt review (Protection of Human Subjects, 45 CFR Part 46; §46.101(b), (2009)):

1. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
2. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as:
 - (i) research on regular and special education instructional strategies, or
 - (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), anonymous survey or interview procedures, or observation of public behavior, AND:
 - (i) information obtained is recorded in such manner that human subjects cannot be identified, directly or through identifiers linked to the subjects; AND,
 - (ii) any disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

4. Taste and food quality evaluation and consumer acceptance studies,
 - (i) if wholesome foods without additives are consumed, OR,
 - (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

5. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (2) of this section, if:
 - (i) the human subjects are elected or appointed public officials or candidates for public office; or
 - (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

6. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under those programs;
 - (iii) possible changes in or alternatives to those programs or procedures; or,
 - (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Only the IRB Chair or IRB Chair designee may determine whether a submitted research project meets the requirements for exemption from IRB review. If the research project does not meet criteria for exemption, the researcher will be notified, and the project will require resubmission for either expedited review or standard review by the full IRB.

These are some examples of research for which the Exempt review will not be allowed:

- prisoners, pregnant women, children under the age of 18, fetuses, or those decisionally impaired,
- in vitro fertilization,
- deception,
- the use of school records of identifiable students or interviewing instructors about specific students,
- survey or interview procedures with children (participants under the age of 18 years),
- observation of public behavior when the researcher(s) participates in the activities being observed,
- data collected that includes protected health or medical information when there is a direct or indirect link that would identify the participant,
- sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol,
- FDA research except in emergency circumstances.

EXPIDITED Review

Research activities that present no more than minimal risk to human subjects and involve only procedures listed in one or more of the following categories, may be reviewed by the D'Youville IRB through the Expedited review procedure. The Expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects such as compromise the financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risks (<http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html>):

1. 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, and social behavior) or research employing confidential surveys, interviews, oral histories, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies.
2. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications).

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
3. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
4. Collection of data from voice, video, digital, or image recordings made for research purposes.
5. Clinical studies of drugs and medical devices only when condition (i) or ii) is met:
 - (i) Research on drugs for which an investigational new drug application (IND) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (ii) Research on medical devices for which (a) an investigational device exemption application (IDE) is not required; or (b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
6. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - (i) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than two times per week; or
 - (ii) from other adults and children of at least 18 years of age, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than two times per week.

7. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

8. Continuing review of research previously approved by the convened IRB as follows:

- (i) where (a) the research is permanently closed to the enrollment of new subjects; (b) all subjects have completed all research-related interventions; and (c) the research remains active only for long-term follow-up of subjects; or
- (ii) where no subjects have been enrolled and no additional risks have been identified; or
- (iii) where the remaining research activities are limited to data analysis

9. Continuing review of research, not conducted under an IND application or IDE where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

STANDARD Review

Any type of research involving human subjects that the D'Youville IRB determines to be more than minimal risk and therefore cannot be approved through either Exempt or Expedited human subjects review must be processed through Standard review procedures.

Therefore, research activities conducted with vulnerable or special subject populations such as, for example, minors, prisoners, and decisionally-impaired subjects; and involve elements, procedures, or interventions that require additional provisions or safeguards will be reviewed by the Standard IRB Committee.

Determining Which IRB Application to File: A Checklist

To determine which IRB application to file for the proposed research, answer each of the questions below with yes or no. Then follow the directions listed after each set of questions to complete the appropriate IRB application. Does the proposed research involve:

1. Y N the use of human subjects or information about human subjects?

Check: *If you answered no to question 1 STOP. You may complete the Exempt Review Application following procedures listed in this Manual. If you answered yes, continue to question 2 through 7 that follow.*

2. Y N the collection or study of existing data, documents, records, or pathological or diagnostic specimens, from publicly available sources?
3. Y N the collection or study of existing data, documents, records, or pathological or diagnostic specimens, and the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects?
4. Y N normal educational practices, such as research on regular or special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods in established or commonly accepted educational settings?
5. Y N the use of educational tests (cognitive, diagnostic, aptitude, or achievement), **anonymous** survey or interview procedures, or observation of public behavior and the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, **and** any disclosure of the human subjects' response outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.?
6. Y N taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or in which a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration, or approved by the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture?
7. Y N the use of educational tests (cognitive, diagnostic, aptitude, or achievement), anonymous survey or interview procedures, or observation of public behavior, and the subjects are elected or appointed public officials or candidates for public office?

Check: *If you answered yes to any of questions 2 through 7 STOP. You may complete the Exempt Review Application following procedures listed in this Manual. If you answered no to all questions 2 through 7, continue to question 8 through 14 that follow.*

8. Y N individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, or research involving **confidential** surveys?
9. Y N recording of data using noninvasive procedures routinely employed in clinical practice? This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy. It includes such procedures as weighing or testing sensory acuity, MRIs, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echo-cardiography?
10. Y N moderate exercise muscular strength testing, where appropriate, given the age, weight, and health of subjects?
11. Y N the study of data, documents, records, or specimens collected solely for non-research purposes?
12. Y N voice, video, digital, or image recordings made for research purposes such as investigations of speech defects?
13. Y N clinical studies of drugs or devices when an investigational new drug application (IND) or investigational device exemption (IDE) are not required?

14. Y N collection of blood samples by finger, heel, or ear stick; or venipuncture from adults, by considering the amounts drawn, and the age, weight, and health of the adults?
15. Y N prospective collection of for research purposes by non-invasive means, including: hair and nail clippings, in a nondisfiguring manner; deciduous and permanent teeth if patient care indicates a need for extraction; excreta and external secretions (including sweat); or uncannulated saliva?
16. Y N prospective collection of placenta removed at delivery; amniotic fluid at the time of rupture of the membrane prior to or during labor, supra- and subgingival dental plaque and calculus; mucosal or skin cells; or sputum?

Check: *If you answered yes to any of questions 8 through 16 you may complete an Expedited Review Application. If you answered no to all questions 8 through 16, you must complete a Standard Review Application. Follow the procedures listed in this Manual for each application.*

CHAPTER VI – IRB APPLICATION SUBMISSION INSTRUCTIONS

This section of the manual provides instructions on satisfying the research training requirements and how to complete and what to submit to the D'Youville IRB.

Complete applications must be submitted the Institutional Review Board (IRB) to obtain approval to begin the collection of data for any research project, thesis, or dissertation.

Research Training Certification Requirements, CITI Training

All members of the research team involved in the design, conduct, or reporting of the research must complete CITI training. Members of the research team who have not completed human research protections training may not take part in aspects of the research that involve human subjects until the research certification requirements are satisfied.

All applications to the D'Youville IRB regardless of the type of submission must include current documentation of research training of the researcher(s). The D'Youville IRB will accept ONLY documentation of research training that has been successfully completed within the last three (3) years and applicants must include one (1) copy of their training records with their IRB submission.

Depending on the type of research, the research team may require additional research training as mandated by other federal, state, or organizational policies. The D'Youville IRB encourages the researchers to contact the IRB Office directly for questions related to research training requirements.

Collaborative Institutional Training Initiative Instructions

CITI training can be accessed by clicking on this link: <https://about.citiprogram.org/en/homepage/>

1. On the upper right-hand side, click register. Be sure to “Select Your Organizational Affiliation” by typing “D'Youville” into the search bar and selecting it. Do not choose “Independent Learner Registration.”
2. Once you register, log in. (If you already have a login, you should click “log in” on the upper right-hand side instead
3. Once you log in, click on the “add a course button.” Then you will be able to scroll and view all the courses available to you.
4. Scroll to question 1 and select one of the first three courses: Biomedical Research Investigators, Social & Behavioral Research Investigators, or Research with Data or Laboratory Specimens Only. Choose the one that best applies to you. (You may see additional courses you want to take after completing the required one.)
5. All certificates are good for 3 years.

A detailed “getting started” guide is available here: <https://support.citiprogram.org/s/article/updated-guide-to-getting-started>

At the completion of the course, the researcher must attach an electronic copy of the certificate with the IRB application.

Financial Conflict

D'Youville is committed to ensuring Institutional and Investigator compliance in accordance with the U.S. Department of Health and Human Services, Public Health Service Regulations (42 CFR Parts 50 and 94) regarding the “Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors.” As per the Final Rule, this regulation is commonly referred to as the Financial Conflict of Interest (FCOI) regulation. The College's policy may be located at: http://www.dyc.edu/academics/research/docs/phs_fcoi_policy_dyc.pdf. Defined by the regulation, this policy applies to Institutions and Investigators, that plan to apply for, participate in, or receives research funding through a Public Health Service (PHS) Agency grant, cooperative agreement or contract. The policy provides for the procedures for Investigator's disclosure of Significant Financial Interests, Institutional management and reporting of any identified Financial Conflicts of Interest including public accessibility, Institutional compliance with PHS Agency requirements, and Investigator training requirements.

Individual IRB Application Form Completion

All applicants must complete at least one of the three possible Forms of IRB Applications: EXEMPT, EXPEDITED, or STANDARD. Every one of these Application Forms requires the following general information:

SECTION I- IDENTIFYING INFORMATION: the applicant must include the applicant's name (for students, this is their own name). Applicants must record the address, phone number, and email address to which questions may be directed, or correspondence from the IRB may be sent. The IRB should be notified immediately of any change in address, name, or email address. Program refers to the student's degree program, and not the Division of Academic Affairs. The title of the research may be abbreviated as necessary to fit on one line. The name of the Graduate Research Director must be provided for all student applications. If the application is submitted with material written in the past tense, the IRB must be notified by checking the provided checkbox on the Form.

Section II – CRITERIA: the applicant must indicate under which criterion the applicant seeks review. Most graduate research will require marking only one criterion. Applications without ANY selected criteria (X in any of the boxes preceding criteria) will be returned to the applicant. **This section is NOT INCLUDED for STANDARD applications.**

Section III – DESCRIPTION: the applicant must (1) describe the nature of the research and, even more importantly, (2) **how the research meets the criteria checked in Section II** of the form. This description should not simply repeat the criteria marked in Section II, but instead should elaborate on the reasons for choosing the criteria marked in Section II. **This section is NOT INCLUDED for STANDARD applications.**

Section IV – SIGNATURES: for student applications, **BOTH** the applicant and the Research Director must sign. The student and the Research Director should carefully read this section of the Form that describes what their signatures mean before signing.

ALL IRB Applications require:

1. Properly completed Application Forms as described above,
2. CITI Training Certificate within the last 3 years,
3. One (1) electronic copy of an abstract detailing the proposed research. A 1-page abstract that describes the research with details about how the research will be conducted is required. Applicants should include details (as applicable) about human subjects, recruitment techniques, study methods, potential risks and benefits, management of any risks, and additional details for protection of human subjects. The abstract is a summary of the *who, what, why, when, where,* and *how* of the proposed research. The study abstract provides the IRB with an overview of the planned research.
4. The Informed Consent Form and Informed Assent Form, in Appendix B of this *Manual*. If necessary for the research, these exact forms must be used, with no changes.

Any IRB Application failing to include all these necessary elements cannot be accepted and will instead be returned to the applicant.

Where to Submit the IRB Review Application Packets

All applications are submitted to irbhelp@dyc.edu.

IRB Decision Guidelines

Decisions on EXEMPT Review applications may take up to two (2) weeks.

Decisions on EXPEDITED Review applications may take between two (2) to four (4) weeks. Decisions on STANDARD Review applications may take up to one (1) month.

Four decisions are possible from these reviews:

- **Full Approval**
- **Approval with Recommendations**
- **Approval with Conditions**
- **Disapproval**

Explanations of each of these decisions are included in the section on IRB Dispositions below in this *Manual*.

The applicant is notified by email of the IRB Committee decision. The letter will be emailed to the address provided on the application form. When other than a Full Approval disposition has been made, the letter includes the recommendations, conditions, or reasons for disapproval. **IRB COMMITTEE DECISIONS ARE NOT GIVEN IN PERSON OR OVER THE PHONE.** Graduate Research Directors are also notified of the IRB decisions via email when the studies involve student research.

EXEMPT or EXPEDITED Review Application Instructions

One (1) electronic copy of the following application packet must be submitted to the D'Youville IRB.

The material must be submitted in the order listed below.

- One (1) electronic copy of the CITI Certificate. For applications that involve more than 1 researcher, every researcher involved **must** submit their own CITI Certificate.
 - One (1) electronic copy of the completed *EXEMPT* or *EXPEDITED* Application Form.
 - One (1) electronic copy of the complete Human Subjects Research Proposal Form, if research involves research subjects **ONLY**. ALL *EXPEDITED* applications **require** these Forms.
 - One (1) electronic copy of an abstract detailing the proposed research. A 1-page abstract that describes the research with details about **how** the research will be conducted is required. Applicants should include details (as applicable) about human subjects, recruitment techniques, study methods, potential risks and benefits, management of any risks, and additional details for protection of human subjects. The abstract is a summary of the *who, what, why, when, where, and how* of the proposed research. The study abstract provides the IRB with an overview of the planned research.
 - One (1) electronic copy of any surveys or interview materials used in the proposed research, along with a brief summary of administration procedures.
-

For EXPEDITED applications only, the following **additional materials** must be included:

- One (1) electronic copy of the Description of Procedures of the research:
 - Setting of the research
 - Population and Sample
 - Data Collection Methods
 - Human Rights Protection
 - Tool(s) to be used for data collection
- One (1) electronic copy of any data gathering tools
- One (1) electronic copy of the information used to recruit subjects (e.g., postings, newspaper ad, verbal presentation to classes, etc.)
- One (1) electronic copy of the information to be provided to subjects to obtain Informed Consent
- One (1) electronic copy of the Informed Consent form (actual form; not a “reduced copy”)

STANDARD Review Application Instructions

One (1) electronic copy of the following application packets must be submitted to the D'Youville IRB.

The material must be submitted in the order listed below.

- One (1) electronic copy of the CITI Certificate. For applications that involve more than 1 researcher, every researcher involved must submit their own CITI Certificate.
- One (1) electronic copy of the complete Human Subjects Research Proposal Form.
- One (1) electronic copy of the completed STANDARD Review Application Form.
- One (1) electronic copy of the Description of Procedures of the research:
 - Setting of the research
 - Population and Sample
 - Data Collection Methods
 - Human Rights Protection
 - Tool(s) to be used for data collection
- One (1) electronic copy of any surveys, interview materials or other data gathering tools
- One (1) electronic copy of the information used to recruit subjects (e.g., postings, newspaper ad, verbal presentation to classes)
- One (1) electronic copy of the information to be provided to subjects to obtain Informed Consent or Assent
- One (1) electronic copy of the Informed Consent and/or Assent form (actual form(s); not “reduced copy(s)” of the form(s))

The HUMAN SUBJECTS RESEARCH PROPOSAL (HSRP) FORM: Instructions

FOR STUDIES THAT DO NOT INVOLVE HUMAN SUBJECTS, THIS FORM IS NOT REQUIRED.

The Human Subjects Research Proposal Form (Appendix A) contains 13 questions to be answered by the applicant regarding the protection of human subjects in the proposed research. Applicants should take care to answer each question concisely but fully, to complete the yes/no answer blocks in Questions 1, 4, 5, and 6, the anonymous/confidential answer block in Question 9, and the data storage answer block in Question 10. Incomplete forms will not be reviewed by the IRB Committee which will result in delay with the review process.

Question 1: *Are participants exposed to any possibility of physical or psychological risk or discomfort? If yes, describe how subjects are exposed, the methods to be used to protect participants, and what will be done to restore physical and psychological homeostasis.*

The purpose of this question is to determine whether participants will be exposed to any risk or discomfort, and if so, how they are exposed, how participants will be protected, and what will be done to diminish the effects of the risk or discomfort after the research (restore physical and/or psychological balance). Review the definitions of *risk*, *discomfort*, *physical risk or discomfort*, and *psychological risk or discomfort* in Chapter III - Definitions and Terms of this *Manual*. An explanation is necessary for each occurrence of a “yes” response to the four risk and discomfort questions. If “no” is checked for all four options, no explanation is necessary.

Question 2: *What are the possible benefits that can be derived by those who participate in the research?*

The purpose here is simply to determine whether subjects who participate in the study can expect to receive any benefits from their participation in the research, and what those benefits may be. Note that this question applies to participants, and not to the community or society as a whole. *Benefits* are broadly defined in this question to include psychological or physical benefits, but the specific benefits must be listed. Most importantly, the benefits must be realistic and equally possibly attainable by most participants. In other words, do not list benefits that only a minority of participants might receive, but rather list those benefits that most participants are likely to receive. Often, researchers will indicate that there will be no direct benefit to the participants.

Question 3: *What are the possible benefits that can be derived from the research?*

While Question 2 was concerned with the benefits to be derived by the participants in the research, this question pertains to the possible benefits that may be provided to the broader community or society. Again, the benefits must be realistic and not overstated.

Question 4: *Are participants members of any of the following vulnerable populations? If yes, explain why the research is not conducted with members of less vulnerable populations, and what special protections or safeguards will be used to protect the welfare of members of a vulnerable population (see Question 4 of the HSRP Form in Appendix A).*

This question pertains to the equity of participant selection. The IRB takes into consideration the purposes of the research and the setting in which the research will be conducted. The purpose of this question is to determine whether participants are being selected from vulnerable populations, and if so, how the inclusion of those participants, rather than those from less vulnerable populations, is justified. Another purpose is to determine whether members of a vulnerable population are adequately protected in the proposed research.

The issue of concern is that members of vulnerable populations are at increased risk for coercion or undue influence than are members of less vulnerable populations. For example, when asked by a researcher to participate in a study, children are more likely to feel compelled to agree than adults. The same may be true for institutionalized individuals versus noninstitutionalized individuals.

If “yes” is checked to any of the populations listed, the applicant must clearly state why members of that group are needed for the research, versus members from a less vulnerable population, and how the rights of participants will be protected. **It is important to note that research for the benefit of vulnerable population is not to be discouraged.**

Questions 5 and 6: *Are participants exposed to deception/coercion? If so, explain how, why it is necessary, and possible risks or discomforts to subjects.*

The purpose of these questions is to determine whether participants will be exposed to deception or coercion, and if so, how they are exposed, why this is necessary, and the possible risks or discomforts to participants resulting from the deception or coercion.

Review the definitions of *coercion* and *deception* in Chapter III - Definitions and Terms of this *Manual*. An explanation is necessary only if the “yes” response is checked.

Question 7: *If either Question 5 or 6 was answered yes, explain debriefing procedures to be used to desensitize, dehoax, or otherwise inform participants of the true intent of the research and why deception and/or coercion was necessary.*

This question should be completed only if either Question 5 or 6 was answered “yes.” This question is concerned with debriefing and is used to determine if the researcher's plans for informing participants, desensitization, and/or dehoaxing are adequate in the view of the IRB. Review definitions for *debriefing*, *dehoaxing*, and *desensitization* in Chapter III - Definitions and Terms of this *Manual*.

Question 8: *What is the relationship between the researcher and the potential participants? Explain how the potential subjects will be protected from coercion during the recruitment and research processes based on this relationship.*

This question is used to determine the potential risk of coercion in the recruitment and research processes. Identify the relationship; then explain how participants will be protected from coercion.

For example, if the researcher provides nursing/therapy/educational, etc., services to participants who will be recruited, this relationship should be specified, and the researcher must explain how coercion will be prevented or reduced. In this case, the researcher may ask another person to ask subjects to participate in the research to prevent subjects from feeling compelled or obligated to participate because their nurse, therapist, or teacher is asking them to be participants in their study.

This does not mean researchers may not collect data from their patients, clients, students, employees, and so on. The researcher, however, must demonstrate they evaluated the impact of their relationship on the recruitment and research processes, based on the nature of this relationship.

Question 9: *How will participant data be maintained?*

The purpose of this question is to determine whether participant data will be maintained anonymously or confidentially. Review the definitions of *anonymity* and *confidentiality* in Chapter III - Definitions and Terms of this *Manual*.

Question 10: *How long will participant data be stored?*

In the United States, all confidential data must be stored by the researcher for three (3) years. In Canada, data must be stored for six (6) years.

Question 11: *Where and how will participant data be stored?*

Confidential data must be securely maintained in a locked file cabinet, locked desk, password-protected documents, or through some other secure method. Applicants must specify where the data will be maintained.

Question 12: *How will research findings be disseminated to participants?*

The purpose of this question is to determine how research findings will be provided to subjects. Review the *Summary of Results* definition in Chapter III - Definitions and Terms of this *Manual*. Researchers are not required to provide research participants with a summary of results, but if a summary is provided, all participants must have equitable access.

Question 13: *How will participant voluntary informed consent be obtained and documented? Specify any accommodations.*

Review Chapter VIII on Voluntary Informed Consent in this *Manual* prior to completing this question. It is not necessary to explain the consent form in the answer to this question, since IRB members use an internal document to verify that all required elements of informed consent are present in the consent form. Instead, describe the process to be used or steps to be followed to explain the study to prospective participants. The applicant may refer to a script included in the research proposal, but this script must be included with the materials submitted to the IRB (Refer to *Determining Which IRB Application to File: A Checklist* in Chapter V of this *Manual*).

The applicant must specify any accommodations made to the consent form and or consent process for special populations. For example: (a) using enlarged print on the consent form or using a Braille consent form for visually impaired participants, (b) paraphrasing the title of the study rather than using the actual title when the latter is confusing to participants, and (c) paraphrasing the purpose of the study rather than stating the actual purpose when the latter would bias performance. In this last example, the researcher must include a written debriefing procedure in the research methodology to inform participants of the deception at the completion of data gathering.

CHAPTER VII - IRB DISPOSITIONS

Four dispositions are possible from the IRB committee review: Full Approval, Approval with Recommendations, Approval with Conditions, or Disapproval.

FULL APPROVAL

Upon notification of Full Approval, the applicant may begin formal application as needed to other IRBs at the facilities/agencies in which data are to be collected.

The applicant is required to notify immediately the IRB for further review of the research in the event ANY of the following occurs:

- a major change in the method of data collection
- unanticipated problem or unanticipated adverse effects on the human subjects
- unanticipated difficulties in obtaining informed consent or maintaining confidentiality

APPROVAL WITH RECOMMENDATIONS

Upon notification of Approval with Recommendations, the applicant may begin formal application as needed to other IRBs at the facilities/agencies in which data are to be collected. Note, however, that while the IRB has approved the research, the IRB has chosen to make recommendations to the applicant regarding possible improvements to the research plan or appearance of written materials to be used in the research. These recommendations should be addressed prior to application to other IRBs as needed.

The applicant is required to immediately notify the IRB for further review of the research if ANY of the following occurs:

- a major change in the method of data collection
- unanticipated adverse effects on the human subjects
- unanticipated difficulties in obtaining informed consent or maintaining confidentiality

APPROVAL WITH CONDITIONS

If Approval with Conditions is granted, the letter from the IRB committee specifies what conditions must be met before Full Approval will be granted. The applicant, in consultation with the graduate research director, must address each of the conditions and report in memo format back to the IRB via irbhelp@dyc.edu.

When submitting revised materials, the applicant must include: **(a) a memo signed by the research director indicating the changes have been approved by the director, (b) a copy of the approval with conditions letter the applicant received from the IRB after the previous IRB review, and (c) all supporting documentation providing evidence of the revisions in final form.**

Upon subsequent review, the application may be granted any of the four possible dispositions. The proposed research may not begin until Full Approval or Approval with Recommendations has been granted by the IRB.

DISAPPROVAL

If the IRB disapproves of the research, the applicant (and for students, the Research Director) is notified of the specific reasons for disapproval. (Student applicants should then schedule a meeting with their Research Director to discuss what actions need to be taken to remediate the problems). When an application is disapproved by the IRB, the applicant must submit a new application with supporting materials to the IRB for the application to be reviewed again. When submitting the new application, the applicant must include a copy of the disapproval letter the applicant received from the IRB after the first review of the application by the IRB. The proposed research may not begin until Full Approval or Approval with Recommendations has been granted by the IRB.

CONTINUING APPROVAL

If the research is not completed within 12 months of the notice of approval from the IRB, the applicant must notify the IRB of the status of the project. The Researcher(s) must provide a formal letter notifying the IRB of the progress of the research, and the reasons and rationale for requesting the extension.

COMMON REASONS FOR CONDITIONS RATHER THAN FULL APPROVAL

The following are common reasons research applications receive approval with conditions rather than full approval from the D'Youville IRB. The applicant is responsible for reviewing the application to ensure that none of the following scenarios will prevent full approval of the submitted research.

1. Missing proper signatures on IRB forms, or for students - failing to have on file fully approved and signed graduate forms.
2. Failure to proofread materials; missing page numbers; missing appendices, missing supporting documents, etc. There should be no spelling errors or grammatical errors in Recruitment scripts or on Informed Consent Forms.
3. The Informed Consent Form and Informed Assent Form included in Appendix B of this *Manual* and not exactly followed.
4. Failure to provide complete details of research procedures, such as missing steps in the procedures, or inconsistencies in different section(s) of submitted materials.
5. Inconsistencies on Recruitment script(s) or in the explanation of the study. Different sections of supplied materials make conflicting statements, such as varying time commitments of 15 minutes at Recruitment and 30 minutes on Informed Consent.
6. Failure to provide complete details on how participants will be contacted, what will be said to them - missing scripts.
7. Failure to provide complete details on recruitment for participation.
8. Terminology in participant recruitment or instruction scripts not easily understandable by the target group.
9. Failure to specify accurately how long data will be securely maintained. The U.S. requires 3 years; Canada requires 6 years.
10. Confusion regarding anonymity vs. confidentiality. Face-to-face contact with participants, or signatures on Consent Forms often make it impossible for data to be collected anonymously.
11. Not giving a name and title of a contact person (other than the researcher) and providing a phone number or address at which he or she may be contacted. Do not include personal or home phone numbers.
12. Not clearly specifying withdrawal procedures and/or the time frame within which the withdrawal option may be exercised by participants. Avoid language that suggests participants may withdraw "at any time," as this suggests participants may withdraw after the study has been completed.
13. Coercive recruitment procedures or script. For example, a therapist recruits participants for research and even states participation is voluntary but implies the patient/client should participate in order to help the therapist.
14. Requiring more than one yes or no answer on a screening tool or health questionnaire (see an example in Appendix B of this *Manual*). The screening criteria should be presented as a list, asking potential participants to answer only one yes-or-no question about whether **any** of the exclusion criteria apply.
15. Not specifying participant duration of commitment (such as two 45-minute sessions a week for 6 weeks).
16. Not including the *no loss of benefits* phrase on the consent form when necessary.
17. Not clearly stating how data will be securely maintained (e.g., use of participant ID numbers and a master ID number/name coding list), or where data will be stored (e.g., locked file cabinet).
18. Insufficient sample size to detect a hypothesized effect. Small effects cannot easily be detected by small samples; this raises the question of whether the time of participants is being wasted in a study that cannot detect the effect under investigation.

CHAPTER VIII - VOLUNTARY INFORMED CONSENT

Except for Exempt research, no researcher may involve a human being as a subject in a research study unless the researcher has obtained the legally effective informed consent of the participant or their legally authorized representative (e.g., guardian). Informed consent is not just a form or signature, but a process of information exchange. Information must be presented to enable persons to decide voluntarily whether to participate as a research subject. It is a fundamental mechanism ensuring respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate prospective participants in terms they can understand. Therefore, the language and its documentation (especially the explanation of the study's purpose, duration, experimental procedures, alternatives, risks, benefits, and so on) must be written in simple language that is fully understandable to the people being asked to participate. The written presentation of information is used to document the basis for consent and for future reference.

The Informed Consent Form and Informed Assent Form are included in Appendix B of this *Manual*. If necessary for the research, these exact forms must be used, with no changes.

Appendix A

IRB Application Forms

All IRB application forms are fillable PDFs located on the [IRB Webpage](#). Please click the link for the appropriate form:

[Exempt Application Form](#)

[Expedited Application Form](#)

[Standard Application Form](#)

[Human Subjects Research Proposal Form](#)

Appendix B

INFORMED CONSENT, ASSENT, and SCREENING TOOL TEMPLATES

INFORMED CONSENT [TEMPLATE]

The purpose of this form is to assure you are given enough information to make an informed decision as to whether you will agree to be a subject in research.

Study Title: *Insert study title*

Length of participation: *Insert dates that correspond to the dates of submission to the IRB*

Name and credentials of Study Investigator(s): *Insert name(s) and credential(s) of Investigator(s)*

Address of Study Investigator(s): *Insert institutional address of Investigator(s)*

Phone number of Study Investigator(s): *Insert institutional phone number of Investigator(s)*

Name and credentials of Study Co-Investigator(s): *Insert name(s) and credentials of Co-Investigator(s)*

Address of Study Co-Investigator(s): *Insert institutional address of Co-Investigator(s)*

Phone number of Study Co-Investigator(s): *Insert institutional phone number of Co-Investigator(s)*

Name and credentials of Study Coordinator: *Insert name and credentials of Coordinator*

Email of Study Coordinator: *Insert email address of Coordinator*

Phone number of Study Coordinator: *Insert institutional phone number of Coordinator*

Present key information about this study that will assist a potential subject in understanding reasons one might or might not want to participate.

This section must be organized and presented in a way that facilitates understanding of the proposed research and ensures potential subjects how their data and biospecimens may be used.

EXAMPLE:

Please take the time to read this document carefully. This document will provide you with important information about your participation in research on *[in a concise and focused way describe what the study is about. Also include reasons for conducting the research, and why the potential subject is being asked to participate. If applicable, state who is sponsoring the research. If the project involves biospecimens, include statements indicating whether biospecimens may be used for commercial profit and if the subject will share in that profit].*

Discuss the voluntary nature of this study and the importance of the subject asking questions.

The section must emphasize the voluntary nature of the research and encourage subjects to ask questions before they agree to participate.

EXAMPLE:

Participation in this study is voluntary and you can change your mind and withdraw from the research at any time before the study is completed and your decision will not be held against you. Please ask any questions you may have before you agree to take part in the research. If you decide to take part in this study, you will be asked to sign this form and comply with the study procedures as described below.

Will this study involve experimental procedures?

Explain in lay terms if the study involves experimental procedures (including experimental drugs and/or devices) and clearly differentiate the experimental procedures from standard of care procedures.

EXAMPLE:

The procedures in this study *[are] [are not]* considered experimental. *[If experimental, describe what is experimental].*

What will happen to me if I decide to participate in this study?

Provide a clear, concise description of the protocol to be followed and the number of study visits and procedures to be performed, in a language understandable to the subject. This section should explain exactly what the subject's participation would involve. Describe the procedures to be employed, screening or exclusion tools, tests and/or treatments to be administered, review of medical records, forms to be completed, etc.

EXAMPLE:

Your participation will involve [#] session(s) for [#] minutes, [#] time(s) per _____ for [#] _____ (s). As a subject, you will be asked to *[describe procedures to be employed, screening or exclusion tools, tests and/or treatments to be administered, review of medical records, forms to be completed, etc.]*.

How many people will take part in this study and how long will this study last?

Discuss the length of the subject's participation and total number of subjects participating in the study. Explain if subjects will be recruited from multiple locations, the total number of subjects at each location, and total number of subjects recruited for the entire study.

EXAMPLE:

If you decide to take part in the study, you will be one of *[insert number]* people involved in the research. Your participation will begin and last up to *[insert time frame]*.

What are my responsibilities if I decide to participate in this study?

Clearly describe any responsibilities of the subject. Explain what the subject is expected/not expected to do.

EXAMPLE:

If you take part in this research, your responsibilities as a study participant will be to *[explain any responsibilities of the subject]*.

What other options do I have if I decide not to take part in this study?

Describe the alternatives and include the risks/benefits of those alternatives, if known. Always include the option for the subject not to participate in the study.

EXAMPLE:

You are not required to take part in this study. If you decide not to take part in this research, there may be other options available to you *[list other options, if applicable]*. *[Enter Researcher's name]* will discuss alternative options with you.

What happens if I decide not to participate in this study OR if I change my mind after I decided to participate in this study?

Clearly state what will happen if the potential subject decides not to participate or decides to terminate participation in the study after signing the Consent Form.

EXAMPLE:

Taking part in this research is voluntary and your choice. You may say no if you do not want to take part in the study. You will not be treated differently if you choose not to take part in the research. If you decide to take part in the study, you may change your mind at any time during the research timeframe and withdraw your consent. If you decide to withdraw before the end of the study, there *[may be]* *[may not be]* risks associated with this decision. Therefore, you are encouraged to notify *[Name of Person]* at *[phone #]* as soon as possible. You will not be treated differently if you later decide to stop taking part in the study.

There is no penalty or loss of benefits to which you are otherwise entitled if you withdraw from the study, or if you choose to not participate. You do not need to give a reason.

However, whether you formally withdraw from the study or fail to appear for scheduled study visits for unforeseen reasons, the information already collected for research purposes will be retained and analyzed.

What are some possible risks or discomforts if I decide to participate in this study?

If there are known possible risks (e.g., physical, legal, psychological, financial, social, confidentiality), clearly identify them. If the research does not involve more than minimal risk, clearly explain this to the subject.

EXAMPLE:

There are no more risks or discomforts associated with the procedures involved in this study than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

OR

The currently known possible risks are *[list the risks and their probability to occur if know and their magnitude]*.

What will happen if I get sick or hurt as a result of my participation in this study?

Define if research provides reimbursement for study-related injuries.

EXAMPLE:

If you think you have been injured as a result of taking part in this research, tell the person in charge of the study as soon as possible. The researcher's name and phone number are listed on this consent form. The researcher and D'Youville assume no liability for any discomfort or injury you may incur as a result of your participation in this study. You do not give up your legal rights by consenting to this form.

What are some possible benefits if I decide to participate in this study?

If there are known possible benefits clearly identify them. If there are no direct benefits to the subject or others, clearly explain this to the subject.

EXAMPLE:

There may be no direct benefits to you or others for participating in this research, but your participation could be helpful in *[describe realistic possible benefits such as testing current or new tests and treatments, developing new tests and treatments, etc.]*.

OR

The possible benefits of the study are *[list expected benefits]*.

Can the researcher remove me from this study?

Describe the reasons for terminating a subject's participation in the research.

EXAMPLE:

The researcher may decide to remove you from the study without your approval for the following reasons *[list reasons such as, subject does not keep appointments, does not follow study instructions, developed a condition that makes the participation in the study unsafe]*.

Will participating in this study cost me anything?

Clearly indicate costs to the research subject and state whether additional costs may result from participation in the research.

EXAMPLE:

You will be responsible for the costs of transportation to participate in the study.

OR

Participating in this research study will not cost you anything.

Will I be compensated for taking part in this study?

Describe whether the subject will be paid for participation or for reimbursement of expenses. If so, detail method of payment, how much, and when. Indicate if the payment or reimbursement is prorated, paid at each visit, or paid upon completion of the study.

EXAMPLE:

You will receive no payment or reimbursement for participating in this study.

OR

It is recognized you will incur travel costs, use of your time, and a measure of inconvenience to participate in this study. To help cover expenses associated with your participation, you will receive a total of *[\$....]* which will be divided as follows: *[\$...]* for attending Visit *[#]*; *[\$...]* for Visit *[#]*. In the event you do not complete all visits, you will be reimbursed only for the visits you completed.

How will the researcher protect my privacy and keep my personal information confidential?

Explain the extent (if any) to which confidentiality of records will be maintained.

EXAMPLE:

Any information you provide during the study will be recorded in such a way that your identity will remain *[confidential]* or *[anonymous]*. (If confidential) This means number codes will be used to record your information, only the researcher will have access to the information, and it will be securely stored. Your identity will never be revealed and information about the study will be reported in group form only. (If anonymous) This means your name will not be associated with your information, no one will be able to identify you, and information about the study will be reported in group form only.

All reasonable efforts will be used to protect the confidentiality of your individually identifiable information. Information related to you will be treated in strict confidence to the extent provided by law. Your identity will be assigned a code number and will not be associated with any published results. Your code number and identity will be kept in a locked file of the researcher. In order to monitor this study, representatives from federal agencies such as the National Institutes of Health and the Office of Human Research Protection or representatives from the D'Youville Institutional Review Board may inspect the research records which may reveal your identity. Therefore, we cannot promise complete confidentiality.

If I take part in this study, what confidential information about me will be collected, used, and shared with others?

EXAMPLE:

If you agree to be in this study, *[insert appropriate names]* will collect health information that identifies you such as *[insert type of information]*. We may collect the results of tests, questionnaires, and interviews, such as *[insert specific examples]*. We may also collect information from your medical record, such as *[insert specific examples]*. We will collect only information needed for the research.

If you sign this form, you are giving us permission to collect, use, and share your information. This permission is called authorization.

Who can I talk to if I have questions about this study?

Provide contact information for the research team and for the person responsible to answer questions related to subject research rights.

EXAMPLE:

If during the study you have questions about the research, tasks, or activities you are asked to perform or complete, or think the research has hurt you, you may contact *[Name and Title of the researcher]* at *[phone #]*, and all your questions will be answered.

If you have questions about your rights as a research subject, you may contact *[Name and Title of Contact Person other than the researcher]* at *[phone #]*.

You are receiving two copies of this form. Return the signed copy to the researcher and keep the other for your future reference. If you would like to receive a summary of the results of the study upon its completion, record your full address on the reverse side of this form.

STATEMENT OF CONSENT

I have read this form and the information in it was explained to me. I agree to take part in this research. All my questions were answered. My taking part in the study is completely voluntary. I will receive a copy of this document for my records. I am not giving up my legal rights by signing this form. My signature below also indicates I understand the procedures to be employed in this study, and I also agree to allow the researcher to present his or her findings publicly or privately, for educational purposes, and orally or in written form.

Subject's Signature

Date

Subject's Printed Name

Person Obtaining Consent Signature Date

Person Obtaining Consent Printed Name

Legally Authorized Representative or Parent/Legal Guardian's Signature Date

Legally Authorized Representative or Parent/Legal Guardian's Printed Name

ASSENT FORM [TEMPLATE]

Let us tell you who we are.

EXAMPLE:

My/Our name(s) is/are *[Researcher's Name(s)]*, and I/we want to tell you about a study I/we am/are doing on *[clearly and concisely describe the research in a way that is understandable to the participant]*.

It is OK for you to ask questions about anything we are telling you. You can ask us questions now and anytime while the research is taking place.

Why are we doing this study?

EXAMPLE:

A study is a way to find out how things work or to learn information about something. We are conducting this study because *[provide in lay terms the reasons why you are conducting this research]*.

Why are we asking you to participate in this study?

EXAMPLE:

Like other children, we are asking you to be in this study because *[provide in lay terms the reasons why you are asking the child to participate in this research]*. However, for you to be in this study we would also need to have your parent's or legal guardian's permission.

You do not need to be in this study if you do not want to and no one will be upset about your decision. Also remember you can say OK now and then change your mind later while the study is taking place. Just tell us or your parent or guardian if you want to stop being in the study.

What will we ask you to do if you decide to participate in this study?

Use simple terms to describe procedures to be employed, screening or exclusion tools, tests and/or treatments to be administered. Provide simple, easy-to-read and easy-to-understand examples.

EXAMPLE:

If you decide to be in this study and your parent or guardian also says yes, this is what we will ask you to do:

You may choose to be in the study or not. You may choose to do, or stop doing, the activities described any time you want to.

What may happen to you if you decide to be part in this study?

Clearly state the risks and benefits for being part of this study. If no risks or benefits are expected, please state so.

EXAMPLE:

There is a chance during the study you could *[clearly state what it may happen to the child]*.

Do you want to be in the study? (Check "Yes" or "No," or Circle the face)

Yes

No



Did we answer all your questions? (Check "Yes" or "No")

Yes

No

Child's Signature

Date

Child's Printed Name

Person Obtaining Consent's Signature

Date

Person Obtaining Consent's Printed Name

The child was capable of reading and understanding this form and has signed above as documentation of assent to take part in this study.

The child was not capable of reading this form, but the information was verbally explained to the child. The child signed above as documentation of assent to take part in this study.

SCREENING TOOL [TEMPLATE]

To determine the eligibility of all potential subjects who might wish to participate in the study, the following list of statements will help to identify whether you are eligible or not to participate in the study.

Anyone who can answer **NO** to **ANY of the questions** below will **NOT** be eligible to participate in the study.

Are ALL of the following statements true about you?

1. I am over the age of 18.
2. I am currently employed.
3. I am able to swim.
4. I am unable to walk without support from another or without an assistive device for more than 100 feet.
5. I am a veteran.
6. I am currently enrolled at a college as a student.
- 7.

[etc.]

Please answer by checking **only one choice**;

NO, at least one of the statements is NOT TRUE about me,

YES, ALL of the statements are true about me.

Appendix C

MODEL and PHOTO RELEASE FORM TEMPLATES

MODEL RELEASE FORM [TEMPLATE]

Any person who is not at least 18 years of age must have a parent or legal guardian to sign this form.

I understand that [Researcher's full name] is a graduate student in [Researcher's department] at D'Youville and [they] are conducting [research/project] on [purpose of research/project]. I understand [Researcher's name] intends to include photographs and slides of me in [their] work [describe where photographs will appear in the materials]. I understand I am not the subject of the study, and my name, address, and phone number will remain anonymous. I understand I can obtain a copy of the [research/project] by contacting [Researcher's name] at [contact information].

I hereby irrevocably consent to, and authorize, the use and reproduction by [Researcher's name] of any and all photographs and slides, which have been taken of me by [Researcher's name]. This encompasses the absolute right and permission to copyright and use, reuse and publish, advertise and disperse in whole or in part without restriction, including the use of any printed matter and including release over the Internet in conjunction therewith for any D'Youville purpose whatsoever, without compensation to me. All negatives, positives, or digital disk materials, together with the prints, shall constitute the property of [Researcher's name], solely and completely forever more.

I hereby waive any right I may have to inspect or approve the finished product that may be used in connection with this there with [research/project]. I also hold [Researcher's name] and D'Youville harmless from any liability for any reproduction difficulty arising during the process of printing such photos.

Model's Name _____

Address _____

City _____ State _____ Zip _____

Telephone #: (____) _____ - _____

I certify I am of full age (18) and am possessed of full legal capacity to execute the foregoing authorization and have read and agree to the above.

Model's Signature _____

Witness's Signature _____

Relationship to Model _____

I certify I am NOT of full age (18) and have read and agree to the above. My parent(s) or legally authorized representative/ legal guardian must also sign this form.

Model's Signature _____

Witness's Signature _____

Relationship to Model _____

Legally Authorized Representative or Parent/Legal Guardian's Signature Date

Legally Authorized Representative or Parent/Legal Guardian's Printed Name

PHOTO RELEASE FORM [TEMPALTE]

I understand [Researcher's full name] is a graduate student in [Researcher's department] at D'Youville and [they] are conducting [research/project] on [purpose of research/project]. I understand [Researcher's name] intends to include the following photographs and slides in [their] work [describe where photographs will appear in the researcher's materials]. I understand I am not the subject of the study, and my name, address, and phone number will remain anonymous. I understand I can obtain a copy of the research material by contacting [Researcher's name] at [contact information].

I hereby irrevocably authorize the use and reproduction by [Researcher's name] of all photographs and slides, which are listed above, the absolute right and permission to use, re-use and publish, advertise, and disperse in whole or in part without restriction. This encompasses including the use of any printed matter and including release over the Internet in conjunction therefore for any D'Youville purpose whatsoever, without compensation to me.

I hereby waive any right I may have to inspect or approve the finished product that may be used in connection therewith. I also hold [Researcher's name] and D'Youville harmless from any liability for any reproduction difficulty arising during the process of printing such photos.

I certify I am of full age (18) and am possessed of full legal capacity to execute the foregoing authorization and have read and agree to the above.

Model's Name _____ Address _____ City _____ State _____ Zip _____ Telephone #: (____) _____ - _____
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I certify I am of full age (18) and am possessed of full legal capacity to execute the foregoing authorization and have read and agree to the above.

Model's Signature _____

Witness's Signature _____

Relationship to Model _____

I certify I am NOT of full age (18) and have read and agree to the above. My parent(s) or legally authorized representative/legal guardian must also sign this form.

Model's Signature _____

Witness's Signature _____

Relationship to Model _____

Legally Authorized Representative or Parent/Legal Guardian's Signature

Date

Legally Authorized Representative or Parent/Legal Guardian's Printed Name

Appendix D

**POLICIES AND PROCEDURES ON
MISCONDUCT IN SCIENCE**

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D'Youville Policies¹ on Allegations of Scientific Misconduct

¹DETERMINATION OF POLICY A or B:

The D'Youville investigating official must first determine whether the research involves financial support by the Office of Public Health and Science (OPHS) or not. If it does, in whole or in part, the College investigating official must proceed pursuant to Policy "A" contained under separate cover. If the research does not involve OPHS support, the College investigating official must proceed according to Policy "B" described herein.

I. INTRODUCTION

A. General Policy

The College is committed to the principle that the professional conduct of the faculty, administration, staff, and students must conform to the highest ethical standards in all phases of research and teaching. To ensure that this principle is strictly honored, a policy has been established to address promptly and fairly allegations of scientific misconduct.

B. Scope

This policy and the associated procedures apply to all individuals at D'Youville engaged in research that is not supported by OPHS. This policy applies to any person paid by, under the control of, or affiliated with the institution, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at D'Youville.

This policy and associated procedures will normally be followed when an allegation of possible misconduct in science not involving OPHS funded research is received by an institutional official. Circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of D'Youville and any outside funding agency, in the absolute discretion of D'Youville. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the Research Integrity Officer (RIO) of D'Youville. The current RIO is the Vice President for Academic Affairs.

II. DEFINITIONS

A. Allegation means any written or oral statement or other indication of possible scientific misconduct made to an institutional official.

B. Conflict of interest means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

C. Deciding Official means the institutional official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions. At D'Youville, the Deciding Official is the College President.

D. Good faith allegation means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

E. Inquiry means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.

F. Investigation means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.

G. Research Integrity Officer means the institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

H. Research record means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal

facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

I. *Respondent* means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

J. *Retaliation* means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

K. *Scientific misconduct* or *misconduct in science* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

L. *Whistleblower* means a person who makes an allegation of scientific misconduct.

III. RIGHTS AND RESPONSIBILITIES

A. Research Integrity Officer

The Vice President for Academic Affairs will serve as the Research Integrity Officer who will have primary responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer will be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The Research Integrity Officer will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained.

The Research Integrity Officer will assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

B. Whistleblower

The whistleblower will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation.

Also, if the Research Integrity Officer has determined that the whistleblower may be able to provide pertinent information on any portions of the draft report, these portions will be given to the whistleblower for comment.

The whistleblower is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of any non-lawyer advisor.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of scientific misconduct, the RIO and the deciding official shall determine what measures, if any, are appropriate to assist in restoring the respondent's reputation.

D. Deciding Official

The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the whistleblower on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and will determine whether to investigate, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions [see section X].

IV. GENERAL POLICIES AND PRINCIPLES**A. Responsibility to Report Misconduct**

All employees or individuals associated with D'Youville should report observed, suspected, or apparent misconduct in science to the Research Integrity Officer or to their appropriate department/program chairs. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the Research Integrity Officer at (716) 829-7556 to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an employee or individual associated with D'Youville may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer or their appropriate department/program chairs and will be counseled about appropriate procedures for reporting allegations.

B. Protecting the Whistleblower

The Research Integrity Officer will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action.

Employees or individuals associated with D'Youville should immediately report any alleged or apparent retaliation to the Research Integrity Officer.

Also, the institution will protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the whistleblower requests anonymity, the institution will try to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The whistleblower will be advised that if the matter is referred to an investigation committee and the whistleblower's testimony is required, anonymity may no longer be guaranteed.

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.

Institutional employees or individuals associated with D'Youville accused of scientific misconduct may consult with a non-lawyer advisor (who is not a principal or witness in the case) to seek advice.

D. Cooperation with Inquiries and Investigations

Institutional employees or individuals associated with D'Youville will cooperate with the Research Integrity Officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees or individuals associated with D'Youville have an obligation to provide relevant evidence to the Research Integrity Officer or other institutional officials on misconduct allegations.

E. Preliminary Assessment of Allegations

Upon receiving an allegation of scientific misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, and whether the allegation falls under the definition of scientific misconduct under this policy.

V. CONDUCTING THE INQUIRY

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up and meets the definition of scientific misconduct under this policy, he or she will immediately initiate the inquiry process. In initiating the inquiry, the Research Integrity Officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

B. Sequestration of the Research Records

After determining that an allegation falls within the definition of misconduct in science under this policy, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are immediately secured.

C. Appointment of the Inquiry Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint a standing inquiry committee and committee chair that will meet within 10 days of the initiation of an inquiry. The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution.

The Research Integrity Officer will notify the respondent of the committee membership in 10 days. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 days, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to Committee and First Meeting

The Research Integrity Officer will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation as required by the PHS regulation. The purpose is not to determine whether scientific misconduct definitely occurred or who was responsible.

At the committee's first meeting, the Research Integrity Officer will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee.

E. Inquiry Process

The inquiry committee will normally interview the whistleblower, the respondent, and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

VI. THE INQUIRY REPORT

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. The Research Integrity Officer may consult with the deciding official, and/or the latter's representative, as to sufficiency of the committee's report.

B. Comments on the Draft Report by the Respondent and the Whistleblower

The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the whistleblower, if he or she is identifiable, with portions of the draft inquiry report that address the whistleblower's role and opinions in the investigation.

1. Confidentiality

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report.

2. Receipt of Comments

Within 14 calendar days of their receipt of the draft report, the whistleblower and respondent will provide their comments, if any, to the inquiry committee. Any comments that the whistleblower or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

1. Decision by Deciding Official

The Research Integrity Officer will transmit the final report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible scientific misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

2. Notification

The Research Integrity Officer will notify both the respondent and the whistleblower in writing of the Deciding Official's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The Research Integrity Officer will also notify all appropriate institutional officials of the Deciding Official's decision.

D. Time Limit for Completing Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the Research Integrity Officer no more than 60 calendar days following its first meeting, unless the Research Integrity Officer approves an extension for good cause. If the Research Integrity Officer approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent also will be notified of the extension.

VII. CONDUCTING THE INVESTIGATION

A. Purpose of the Investigation

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records

The Research Integrity Officer will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint a standing investigation committee and the committee chair to meet within 10 days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The Research Integrity Officer will notify the respondent of the proposed committee membership within 5 days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to Committee and First Meeting

1. Charge to the Committee

The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the Research Integrity Officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The Research Integrity Officer, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions.

E. Investigation Process

The investigation committee will be appointed, and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the whistleblower(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations. Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

VIII. THE INVESTIGATION REPORT

A. Elements of the Investigation Report

The final report must describe the policies and procedures under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed, and administrative actions taken by the institution.

B. Comments on the Draft Report

1. Respondent

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 3 days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

2. Whistleblower

The Research Integrity Officer will provide the whistleblower, if he or she is identifiable, with those portions of the draft investigation report that address the whistleblower's role and opinions in the investigation. The report should be modified, as appropriate, based on the whistleblower's comments.

3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and whistleblower, the Research Integrity Officer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the Research Integrity Officer may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

C. Institutional Review and Decision

D. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, and submitting the report to the Deciding Official for approval.

IX. INSTITUTIONAL ADMINISTRATIVE ACTIONS

D'Youville will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Officer. The actions may include:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found.
- removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment, or dismissal from the College;
- restitution of funds as appropriate.

X. OTHER CONSIDERATIONS

A. Termination of Institutional Employment or Resignation, or withdrawal from the College Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, or withdrawal from the College before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the respondent, without admitting to the misconduct, elects to resign his or her position or withdraws from the College prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation or withdrawal, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation

If the institution finds no misconduct, after consulting with the respondent, the Research Integrity Officer will determine what steps, if any, are appropriate to assist in restoring the respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer should

consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of scientific misconduct was previously publicized, or expunging all reference to the scientific misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Whistleblower and Others

The Research Integrity Officer will undertake reasonable efforts to protect whistleblowers who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Deciding Official will determine, after consulting with the whistleblower, what steps, if any, are needed to restore the position or reputation of the whistleblower. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the whistleblower.

D. Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine whether the whistleblower's allegations of scientific misconduct were made in good faith. If an allegation was not made in good faith, the Deciding Official will determine whether any administrative action should be taken against the whistleblower.

E. Interim Administrative Actions

Institutional officials will take interim administrative actions, as appropriate, to protect grant funds and ensure that the purposes of the grant programs are carried out.

XI. RECORD RETENTION

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. Personnel of the Office of Public Health and Science (OPHS) will be given access to the records upon request.

FREQUENTLY ASKED QUESTIONS

1. *What about a NYC faculty member who is not a principal investigator for a submission made to another IRB?*

Formal submission to other institution IRBs may not be initiated until approval from the D'Youville IRB has been received if a faculty/student is the principal investigator. This does not apply to faculty (particularly those who regularly conduct clinical rotations at hospitals in western New York) who are not principal investigators but who are part of the research team (e.g., hospital-based) IRBs.

2. *What happened to the NIH Training?*

We're not sure. For a while, the link to the NIH tutorial indicated that the tutorial would be returning at some point, but later led to a 404 error. At this time, it is still unavailable. Please follow the instructions for CITI training instead.

3. *What if I'm conducting cadaver research? Do I have to apply to the IRB and take NIH training?*

Yes, researchers working with cadavers must apply for exempt status and undergo CITI training.