DYOUVILLE

Institutional Review Board (IRB) Manual for the Researcher

Last Revised: April 2026

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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 D'Youville's Graduate Handbook by Dr. James Klyczek well before 1995, with the IRB developed initially at the D'Youville 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 across D'Youville. On or about 2005, Dr. Fiedler handed the responsibilities over to Dr. Mark Garrison, and then Dr. Catherine Lalonde headed 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 D'Youville, prompted a final review that has resulted in the current 2017 *IRB Manual for the Researcher* (*IRB Manual*).

Researchers across D'Youville 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 the years, this *Manual* has been supported by several members of the IRB at DYU, without whom our IRB could not function. The IRB is a purely voluntary service by these folks, and D'Youville 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), Dr. Eric Miller (10), and Dr. Julia Hall (8).

CHAPTER I - INTRODUCTION

The Institutional Review Board (IRB) of D'Youville University 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 upholding 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 permission 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.

IRB Reliance

We have a shared IRB with the Catholic Health System [CHS] and Roswell Park Cancer Institute. This means they will accept the decisions of the DYU IRB and allow DYU to be responsible for research where the project is taking place at DYU or with DYU students as the subjects. And DYU will accept the decisions of their decisions and allow them to be responsible for studies where the research is taking place at these institutions or with their patients, staff, or medical records. 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 that 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/ohrpregulations.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 a 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 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 harm. 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 University 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 University 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 Final is acceptable. See more details at: https://www.uniformlaws.org/committees/community-home/librarydocuments?communitykey=015e18ad-4806-4dff-b011-8e1ebc0d1d0f&LibraryFolderKey=&DefaultView=&5a583082-7c67-452b-9777-e4bdf7e1c729=eyJsaWJyYXJ5ZW50cnkiOiIzODAxNWQ1YS1iY2VmLTQ5NDQtOWU0OS01NTVmZmJkMjFjMzcifQ%3D%3D

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 D'Youville 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 D'Youville 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 IRB at D'Youville operates under the *Common Rule*, the federal policy for the Protection of Human Subjects.

Additional Readings

- Declaration of Helsinki: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- The Federal Policy and 45 CFR 46: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
- 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 has 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).

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 the 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 was unusually large. Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation.

Confidentiality

Confidentiality refers to the 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

When a 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). DIRB-006 Informed Consent Form, is located under the IRB Application forms. **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 has 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 that 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 is 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 D'Youville.

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 D'Youville 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. The 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 in 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 University's IRB Website (https://www.dyu.edu/academics/schools-and-departments/center-doctoral-studies-research/research/institutional-review) 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 be the most 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@dyu.edu.

   IRB Review Applications are found under the IRB Application forms in the University's IRB Website.

   - Exempt form
   - Standard form
   - Any supporting documentation
   - D'Youville Informed Consent Form and Assent Form, with No Changes (if necessary for the research)
   - Expedited form
   - Modification form
   - CITI certificate of completion

Completed electronic applications and documentation should be attached and sent to irbhelp@dyu.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/physicians/physician-resources/boards-committees/

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 DYU letterhead to irbhelp@dyu.edu.

- SEE THE IRB WEBPAGE for our DIRB-014 FILLABLE STUDY CLOSURE FORM, under IRB Application forms. 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@dyu.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 irbhelp@dyu.edu.

- If applicable, The DYU 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 FURTURE 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.

Site Approval and IRB Requirements for External and D'Youville Locations

Applicants must submit a Site Approval Letter from each location where they will collect data, including the D'Youville University campus, authorized off-campus clinics, academic sites, or any external institutions. They must include this documentation in their IRB submission packet to the D'Youville IRB Office. For research conducted at D'Youville University, applicants must obtain site approval from the Chief Mission Officer by contacting **dirienzd@dyu.edu** before submitting their IRB application.

If the research occurs at an external site with its own Institutional Review Board (IRB), applicants must confirm whether that site requires IRB approval. If needed, applicants must apply to the external IRB. After receiving approval from the external IRB, they must submit the external IRB approval letter to the D'Youville IRB Office.

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	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. 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.

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.

EXPEDITED 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 gum base 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 visually 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.

Choose Exempt Review if you answer yes to the following questions.

Y/N 1. Research which does not utilize human subjects.

Y/N 2. Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, from publicly available sources or if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects such as in content or secondary data analyses.

Y/N 3. Research conducted in established or commonly accepted educational settings, involving 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.

Y/N 4. Research involving 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

Y/N 4. 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.

Y/N 5. 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.

Y/N 6. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey or interview procedures, or observation of public behavior and the subjects are elected or appointed public officials or candidates for public office.

Y/N 7. 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.

Choose Expedited Review if you answer YES to the following questions:

Y/N 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.

Y/N 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). 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, magnetic resonance imaging, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography.

Y/N 3. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Y/N 4. 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).

Y/N 5. Collection of data from voice (such an investigation of speech defects), video, digital, or image recordings made for research purposes.

Y/N 6. Clinical studies of drugs or devices only when an IND or IDE are not required.

Y/N 7. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from adults, considering amounts drawn, and the age, weight, and health of the subjects.

Y/N 8. Prospective collection of biological specimens for research purposes by noninvasive means, such as hair and nail clippings in a non-disfiguring manner; deciduous or permanent teeth if routine patient care indicates a need for extraction; excreta and external secretions (including sweat); uncannulated saliva; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; supra- and subgingival dental plaque and calculus, provided the collection procedure is not invasive and the process is in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; or sputum collected after saline mist nebulization.

Y/N 9. Continuing review of research previously approved by the convened IRB.

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 to 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 University's policy may be located at:
the IRB webpage, under the IRB applications, DIRB013 Conflict of Interest-DYU form. 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 1- 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@dyu.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 email 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.
- ☐ Site Approval Letter (if the study is being conducted within an institution).
- ☐ 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 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 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
- ☐ Site Approval/Support Letter (if the study is being conducted within an institution)

Criteria to Review All Research Proposals Submitted to the IRB:

The criteria listed below are used by the IRB to evaluate the plan for the protection of human subjects as described on the Human Subjects Research Proposal Form (see Appendix A) and other documentation submitted with the application. The Criteria Form here is an internal IRB document that may be used by the IRB Members to review any IRB applications. It is included in the *Manual* to relay exactly what criteria the IRB utilizes to review all proposed research. Applicants may utilize the form as a "double check" to ensure the application is clear, consistent, and complete.

<u>This form is NOT completed by the applicant</u>!

YES	NO	N/A	
			1. Risks to subjects are minimized by using procedures which:
			a. are consistent with sound research design.
			b. do not unnecessarily expose subjects to risk (pregnant women excluded from exercise).
			c. when appropriate, are already being performed for diagnostic or treatment purposes.
			2/3. Risks to subjects are reasonable in relation to anticipated benefits.
			4. Selection of subjects is equitable and subjects will be selected from the least vulnerable population possible given the nature of the planned research.
			5. Risk/benefit ratio of exposure to deception is acceptable.
			6. Risk/benefit ratio of exposure to coercion is acceptable.
			7. Plan for desensitization and/or dehoaxing is acceptable.
			8. Subjects are protected from coercion related to researcher-subject relationship.
			9/10. Procedures for maintenance of subjects' data are acceptable for the planned design.
			11. All subjects have equitable access to research findings.
			12. Required elements of INFORMED CONSENT:
			a. statement that the study involves research.
			b. name of primary researcher.
			c. title of research or general topic of research.
			d. explanation of the purposes of the research.
			e. expected duration of the subject's participation.
			f. description of the procedures to be followed.
			g. identification of any experimental procedures to be used.
			h. description of possible risks and/or discomforts.
			i. Description of realistic benefits to the subject or others.
			j. disclosure of appropriate alternate procedures and/or treatments, if any, that might be advantageous to subjects.
			k. extent to which confidentiality or anonymity will be maintained.
			l. Statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which subject is otherwise entitled.
			m. statement that subject may withdraw participation and when and how subject can do so.
			n. contact person for questions about research and subject's rights. In studies of more than minimal risk or questionable liability:
			o. explanation as to whether compensation is provided and what it consists of.
			p. name, title, and phone number or address of contact person in event of research-related injury.
			q. explanation as to whether medical treatments are available if injury occurs and what they consist of, or where further information may be obtained.
			r. consent is documented/dated with signature of subject or subject's legal representative.
			13. Required elements of IMPLIED CONSENT (when coding mechanisms are used):
			a. subjects are informed that coding is being used.
			b. researcher destroys coding mechanism at completion of data collection.
			c. subjects are informed of date on which coding mechanism is to be destroyed.

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@dyu.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) DIRB-012 Response to Comments form located on the IRB University page under the IRB application forms, 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 the DIRB-012 Response to Comments form, located in the IRB University page, under the IRB application forms 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.

How to Respond to Reviewers' Comments

Obtain the Comments Responses Form

- On the IRB University page, under the IRB application forms, download or access the DIRB-012 Response to Comments form provided by the IRB.

Review and Understand the Form

- It's crucial to carefully read and understand the instructions provided on the form by the IRB. This will guide you in completing the form properly.

Organize and List Comments

- Transfer each comment from the reviewers onto the form.
- Use the designated space or section provided for each comment.

Provide Point-by-Point Responses

- Respond to each comment directly on the form.
- Ensure your responses are clearly labeled and correspond to the comment numbers.
- Provide concise but detailed responses to each comment.
- Include all necessary information or justifications as required.
- Indicate any revisions or changes you have made to the application in response to each comment. This might include referring to specific sections of your revised application document.

Use Additional Attachments if Necessary

- If the form allows or if requested, attach additional documents or revised sections of your application.
- Ensure these attachments are clearly labeled and relevant to the comments addressed.

Submission

- Email your response to the comments form and other relevant documents to the IRB at irbhelp@dyu.edu

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 templates 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.

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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 re reference.

The DIRB-006 Informed Consent Form can be found on the IRB University page, under the IRB application forms.

If necessary for the research, this exact form must be used, with no changes.

Appendix A

IRB List of Application Forms

All IRB application forms are fillable PDFs located on the IRB Webpage, under the IRB Application forms area.

DIRB-001 HSRPF Exempt form

DIRB-002 HSRPF Expedited form

DIRB-003 HSRPF Standard form

DIRB-004 HSRPF Modification form

DIRB-005 Class Project Consent form

DIRB-006 Consent form

DIRB-007 Consent Form-Biomedical Research Form

DIRB-08 Recruitment Email Template

DIRB-009 Worksheet Exemption Determination form

DIRB-010 Worksheet Expedited Review Determination form

DIRB-011 Worksheet Standard Review Determination form

DIRB-012 Response to Comments form

DIRB-013 Conflict of Interest-DYU form

DIRB-014 DYU IRB Study Closure form

DIRB-015 Incident Report form

DIRB-016 IRB Confidentiality Agreement form

DIRB-017 PHS FCOI Disclosure form

DIRB-018 Data-Use-Agreement

IRB Guidance for Student Research and Class Projects-https://www.dyu.edu/sites/default/files/2024-07/IRB%20Guidance%20for%20Student%20Research%20and%20Class%20Projects.docx

Misconduct Policy-https://www.dyu.edu/sites/default/files/2024-07/Misconduct%20Policy.docx