HUMAN SUBJECTS RESEARCH GUIDELINES & INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION

INSTRUCTIONS

Revised 9/2022

This packet contains instructions and Federal guidelines for IRB applications.

All application forms and IRB member email addresses are available online at:
http://www.duny.edu/academic-resources/irb/

Forms are also available here:
https://my.duny.edu/ICS/Academic_Programs/Default_Page.jnz?portlet=Handouts_2011-09-23T12-13-03-408

DOMINICAN UNIVERSITY OF NEW YORK
470 WESTERN HIGHWAY
ORANGEBURG, NEW YORK 10962-1299
845-359-7800

Dominican University of New York
Institutional Review Board
Document Packet

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This packet of documents is also available from the IRB chair, your faculty advisor, or online (see cover page for address)

General Information for ALL Applicants.

POLICY STATEMENT

According to the National Institute of Health (NIH) Policy, "The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy".

In accordance with NIH policy, the Dominican University Institutional Review Board (IRB) has established a policy that states, "For any research activities involving human research subjects conducted at Dominican University, or conducted elsewhere and involving Dominican University populations, or conducted by any Dominican University agent in institutions or circumstances where an Institutional Review Board is absent, research proposals must be submitted to and approved by the Dominican University Institutional Review Board." In other words, proposals submitted to the Dominican University IRB must directly involve current students and/or faculty and/or employees as research investigators OR request the use of Dominican University and its students and/or faculty and/or employees as research subjects. Proposals submitted by research investigators who are not directly connected to Dominican University OR do not involve data collection on Dominican University property will not be considered for review by this committee. The Dominican University IRB reserves the right to accept or not an approved IRB application from an external IRB, e.g. hospital, affiliated institution, and university.

Research is defined by NIH regulations as "...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Human subjects are defined by the regulations as "...living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

Some research involving human subjects is exempt from the NIH regulations requiring IRB review. "Examples include educational testing and survey procedures where no identifying information will be recorded to link the subject to the data, and the nature of the data is such that disclosure of the data could not reasonably place the subject at risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, or reputation; and research that involves the use of existing data, documents, or specimens, where no identifying information will be recorded to link the subjects to the data."

<u>Conflict of Interest Disclosure.</u>

Dominican University maintains the maximum principles of integrity in research. A conflict of interest in research exists when an individual or institution has interests in the outcome of the research that might compromise the integrity of the research. In cases where such interests or

relationships do exist, a separate *Conflict of Interest Form* must be completed and submitted with the application.

Adapted from: Johns Hopkins Medicine Institutional Review Board, (July, 2007) Organizational Policy on Committee on Outside Interests (COI) and the JHM IRB (Policy No. 103.11). Retrieved October 18, 2007 from http://irb.jhmi.edu/Policies/103_11.html.

IRB COMMITTEE

Where to send IRB applications.
Applications are to be sent to the current chair. Investigators who have questions about forms or review procedures are asked to contact the Committee Chairperson or any member of the Committee. **See the Dominican University Website for the most up to date contact information for the chair and the rest of the committee (see cover page).**

Conflict of interests involving IRB Personnel. To avoid potential conflicts of interest between IRB members and applicants (e.g., in the case where an applicant and an IRB member/reviewer work in the same department), the following control is in place:

> Committee members from potentially conflicted departments will be recused from reviewing or voting upon relevant applications.

CRITERIA FOR INSTITUTIONAL REVIEW OF HUMAN SUBJECTS RESEARCH

University and Federal policies require that each research project involving studies on humans be reviewed with respect to:

1) rights and welfare of the individual(s);
2) appropriateness of the methods used to secure informed consent; and
3) risk and potential benefit of the investigation.

To help you decide if your research requires IRB Committee approval use the following definition: Federal guidelines define research as "a formal investigation designed to develop or contribute to generalizable knowledge" and a human subject as "an individual about whom an investigator (professional or student) conducting research obtains a) data through intervention or interaction with the person, or b) identifiable information." All research involving human subjects conducted under the auspices of Dominican University must have Committee approval before the initiation of data collection.

The principal investigator has the responsibility for asking the institution in which the research will be collected whether it has an Institutional Review Board (IRB). If the institution does have an IRB, the investigator must submit the application to that Institution's review board and submit the approval documentation to Dominican University's IRB. If the institution declines, the Dominican University's IRB must withdraw from the review process. The principal investigator should attach all supporting facility approval forms, on appropriate letterhead, to the application.

GUIDELINES:

All research proposals to conduct human subjects research will be evaluated by the IRB Committee of the University using the following Criteria.

1. RISK TO THE SUBJECTS - Does the proposed research pose a chance of physical, psychological or social harm?

2. VOLUNTARY PARTICIPATION - Are the subjects freely participating in the study? (e.g., they are aware of the study and are not acquiescing to a teacher's presence). Are they making an informed choice? In the case of deception, have they been told what they can be told? (Nothing is hidden from them that, if known, would keep them from participating. There is no risk in what is withheld.) Are the subjects free to withdraw at any point without question by the experimenter?

3. DEBRIEFING - Are there assurances that subjects will be debriefed? Is the debriefing complete as possible? In the case of deception, will subjects be reassured that it is normal to be deceived and that it is not a personality trait of theirs?

4. CONFIDENTIALITY - Is it possible for subjects to remain anonymous? Is their confidentiality protected?

5. AGE - Are all subjects at least 18 years old? If not, are the appropriate consents from legal guardians being obtained (and teachers, etc. when appropriate).

6. CONSENT - All risk research requires written consent of subjects.

7. CONFLICT OF INTEREST – All research is reviewed for conflict of interest, including conflict of financial interest if research is sponsored or funded by an outside entity (a company or institution other than Dominican University).

DESCRIPTION OF TYPES OF RESEARCH

There are three different applications: exempt, minimal risk and full review. Please use the information below to determine which application to complete.

EXEMPT RESEARCH

The Institutional Review Board (IRB) of Dominican University has adopted the following exemption policy criteria (in line with Title 45 Code of Federal Regulations "45CFR") in order to maintain high standards for conducting research and in supporting the guiding principle of "do no harm."

The following research types are generally exempt from IRB review, unless otherwise called for review by a committee representative. Please note, however, that ONLY the IRB may decide if research is exempt. If you believe your research satisfies the following criteria, you must complete the appropriate paperwork available at our website (see cover page for address).

§46.104(d)(1)
Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.
Examples include:

a. teaching techniques
b. curricula
c. classroom management

§46.104(d)(2)
Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in a way the identity of the subjects cannot be ascertained;
(ii) Any disclosure of the human subjects' responses outside the research would not place the subjects at risk of criminal or civil liability or could be damaging to the subjects' financial standing, employability, educational advancement or reputation; or
(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

§46.104(d)(3)

(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
   (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained;
   (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement or reputation; or
   (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. (This description is omitted intentionally in Dominican's application.)

(iii) If the research involves deceiving the subjects regarding the nature/purpose of the research, this exemption is not applicable unless the subject authorized the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

§46.104(d)(4)

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of several criteria are met including the identifiable private information or biospecimens are publicly available; identify of human subjects cannot be readily ascertained & the investigator does not contact the subjects; or the research uses identifiable health information regulated under 45 CFR parts 160 and 164, for health care operations or research. **Please review the full required criteria at this link since the above is a summary:**
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(4)

§46.104(d)(5)

Researching public services for the purpose of change, and having agency approval. **Full explanation and criteria are at this link:**

https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(5)

§46.104(d)(6)
Taste and food quality evaluation and consumer acceptance studies where the food that does not have additives, or food has a food ingredient deemed at or below safe levels by the FDA or APA or Food Safety and Inspection Service of the U.S. Dept. of Agriculture.

§46.104(d)(7)
Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

§46.104(d)(8)
Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met (see info at following website):
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(8)

To view §46.111(a)(7) (limited review information referenced above) go to https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.111#p-46.111(a)(7)

SUBMISSION: An electronic copy of the Exempt application may be submitted to the IRB provided you have original signatures (e.g., you print and sign the completed application, scan it and email it to the chair). Alternatively, you may use electronic signatures. Otherwise, please sign and forward TWO completed copies to the IRB chair via interoffice mail or regular postal mail.

A written decision letter will be sent to research participants whether your research meets exempt criteria.

MINIMAL RISK & FULL REVIEW RESEARCH

The following is a checklist to indicate whether research is minimal risk or full review research.

- If all the following can be checked "no," then your research qualifies as no more than minimal risk and a minimal risk application should be submitted.
- If any "yes's" are selected, your research must be submitted as a full review application.

Please see our website (see cover of this document for address) to download all application forms.

RISKS

The purpose of this section is to determine whether human subjects involved in the proposed research project will be placed "AT RISK," i.e., "if they may be exposed to the possibility of harm - physical, psychological, sociological, or other - as a consequence of any activity which goes beyond the application of those established and accepted methods necessary to meet their needs."

Does the research planned in this project involve:		Yes	No
1	Possible invasion of privacy of subject or family, including use of personal information or records?	☐	☐
2	The administration of physical stimuli other than auditory and visual stimuli associated with the subject's normal situations or during the performance of routine physical or psychological examinations or tests?	☐	☐
3	Deprivation of physiological requirements such as nutrition or sleep; manipulation of psychological and/or social variables, e.g., sensory deprivation, social isolation, psychological stresses?	☐	☐
4	Any probing for information which an individual might consider to be personal or sensitive, (beyond standard questions that may be posed in physical or psychological examinations or tests)?	☐	☐
5	The presentation to the subject of any materials which they might find offensive, threatening or degrading?	☐	☐
6	The requirement of physical exertion beyond the subject's normal situations?	☐	☐
7	Other risk (e.g., use of vulnerable populations, such children)?	☐	☐

Again, if any of the above can be checked as "yes," you must submit a "full review" application. All applications are available at the IRB website.

Application Submission Requirements

The Dominican University Institutional Review Board has the following requirements of research applications submitted for review:

1. Format. Applications must be in a format that is reader friendly (e.g., APA style, paginated, and without abbreviations).
2. Form. Applications must be submitted using the Dominican University IRB application form.
3. Where to Send & Number of Copies. Applications are to be prepared and forwarded to the IRB Chair (see committee list and emails at our website (see cover for address).
    a. Full review applications – A single electronic copy must be forwarded to the Chair. It ***must*** contain an original signature. Full proposals must be received a minimum of two weeks prior to the monthly committee meetings for dissemination and review.
    b. Minimal risk and exempt applications.
        i. A single electronic copy must be forwarded to the Chair and it ***must*** contain an original signature.
        ii. If it is determined that a minimal risk or exempt proposal has potential risk, the proposal will be subject to a full committee's review and must be resubmitted following full review guidelines.
4. Ethics Tutorial. Applications must provide evidence of completion of an IRB ethics tutorial (see box below).
5. **ORDER OF APPLICATION MATERIALS:**
    a. **Except for exempt research, proposals *must* be submitted in the following order:**
        i. **Application to Human Research Review Committee**
        ii. **Appendixes**
            1. **Informed Consent**
            2. **All participant documents (surveys, letters, questionnaires)**
            3. **All approval documents from outside institutions (if applicable)**
            4. **Any other relevant documents**
        iii. **IRB ethics tutorial certificate (see box below)**
        iv. **Conflict of Interest Form (if needed)**

Ethics tutorials are available as free web-based courses which also provide evidence of completion or a certificate of completion. The following website is recommended. Follow instructions to Ethics Tutorial Certificate:

http://www.duny.edu/academic-resources/irb/

All proposals will be reviewed by the committee based upon when they are received in the office of the Chairperson (criteria: the time and day) in order to be fair to all applicants.

INFORMED CONSENT CRITERIA & INSTRUCTIONS

Written consent as outlined below is required when there is a definite physical, social or psychological risk to the subject. Oral consent only (#3 below) may be sufficient in the case of minimal risk to the subject. In all cases, language of the consent must be comprehensible to the normal participant population and cannot exceed an eighth grade reading level.

Documentation of consent is necessary in all cases and will employ one of the following forms:

1) Provision of a written consent document embodying all of the basic elements of informed consent as outlined below. This may be read to the participant or his/her legally authorized representative (e.g., parents in the case of minors), but in any event she/he or her/his legally authorized representative must be given adequate opportunity to read it. This document is to be signed and dated by the participant or authorized representative. A sample copy of the consent form must be submitted to the Committee and a copy of this approved document will be retained in the Committee files.

2) Provisions for a "short form" written consent document indicating that the basic elements of informed consent have been presented orally to the participant or her/his legally authorized representative. Written summaries of what is to be said to the participant are to be approved by the Committee. The short form is to be signed and dated by the participant or her/his legally authorized representative and by an auditory witness to the oral presentation and to the participant's signature. A copy of the approved summary annotated to show any additions, is to be signed by the person(s) officially obtaining the consent and by the auditory witness. A sample copy of the consent form and of the summary must be submitted to the Committee and a copy of each as approved by the Committee will be retained in Committee files.

3) Provision for oral or written presentation and consent, in which the participant is informed of those basic elements of consent which are applicable to Low-risk procedures. No signed document is necessary on the part of the participant. However, a sample copy of the presentation must be approved by the Committee and a copy retained in the Committee files. (This method of obtaining consent is usually approved only for very low-risk research procedures.)

The basic elements that *must* be included in informed consent are:

Study Title (must match IRB application) _____

Principal Investigator's Name _____

I. Background & Purpose of Study.
   Should include a statement that the study involves research.
   Why it is being conducted.
   If the study involves review of patient records, the statement must say that researchers will review patients' records;

II. Qualification to Participate and Right to Refuse or Discontinue.
   A statement concerning how participants were chosen for possible participation and that participants may choose to discontinue participation at any time during the study without

penalty from Dominican (or whatever institution/agency may be sponsoring the research).

III. Study Procedures.
Must include a description of the procedures to be followed, including an identification of any procedures which are experimental (including possible random assignment to treatment and control groups if study is health related (e.g., Nursing, O.T. or P.T. studies).
A description in layperson's terms of any medical terms/procedures.
Length of study;

IV. Possible Physical or Psychological Risks & Benefits (or none).
A description of the associated discomforts and risks reasonably to be expected.
If no risks or benefits to the participant are expected, this should be stated;

V. Confidentiality.
A statement describing the extent to which confidentiality of records identifying the participant will be maintained;

VI. Alternative Methods of Treatment (generally medical studies only).
A disclosure of appropriate alternative procedures that might be advantageous for the participant if he or she chooses not to participate;

VII. Illness or Injury (medical studies only).
IF RESEARCH INVOLVES PSYCHOLOGICAL OR MEDICAL RISK, a statement indicating that Dominican University will not be responsible for any treatment if participant is injured or becomes ill and that participant is responsible for any treatment.
If any participating agency/institution chooses to provide medical treatment in the case of injury, indicate so;

VIII. Compensation (remuneration).
A statement on compensation indicating the type and amount if there is compensation (e.g., research credits for research participation);

IX. Contact Information.
A statement concerning who to contact with questions or problems that includes the names, titles (e.g., undergraduate student or Ph.D.) and contact information for researchers and faculty advisors.
An offer to answer any questions about the procedure.
A statement that participant will receive a copy of the informed consent to keep (for written consent forms only);

X. Separate Signature Area.
A statement that signature indicates participant is making a decision to participate.
That the signature indicates he or she has read the consent, decided to participate, and questions have been answered.

If potential participants may be minors, as in the case of undergraduate students, there must be a statement that participant's signature indicates he or she is also at least 18 years of age.
A statement that, although the participant may sign the form, he or she may withdraw at any time without penalty.
An area for participant's written name, signature and date.

In addition, the agreement, written or oral, entered into by the participant, should include no exculpatory language through which the participant is made to waive, or to appear to waive, any of his legal rights, or to release the institution or its agents from liability for negligence.

Please see IRB website where you can download a copy of the Informed Consent Template (in the format shown above).

Additional Information

VIDEO/AUDIO Recordings:
Please note we require a second informed consent if you will be videotaping or audiotaping your participants.

FORMS ON NEXT 2 PAGES:

(1) Sample Consent Form (see website to download this standard template)

(2) Audio/Video Recording Consent Form Template

SAMPLE CONSENT FORM

Study Title: Attitudes toward others.

Principal Investigator's Name:
Marian Aribe, Undergraduate Psychology Student

I. Background & Purpose of Study.
This study involves research into attitudes. Specifically, the purpose is to examine how photographs of males and females differently influence our attitudes toward the persons in the photos.

II. Qualification to Participate and Right to Refuse or Discontinue.
You were chosen as a possible participant because you are a male over 18 and a student in undergraduate psychology courses. You have the right to decline participation. However, even though you may choose to participate initially, you may stop participation at any time during the study without penalty from Dominican University or your psychology professor.

III. Study Procedures.
During this study, you will view 6 photographs of both men and women, after which you will answer a brief questionnaire concerning your attitudes toward the individuals in the photographs. This entire study will take less than 60 minutes.
If you have any questions about the procedure or study, please feel free to ask them at any time.

IV. Possible Physical or Psychological Risks & Benefits.
There are no known risks or benefits to participating in this study.

V. Confidentiality.
Your name will not be associated with your data. Further, all records will be destroyed after three years.

VI. Alternative Methods of Treatment (generally medical studies only).
(*This section would be omitted in this IRB application)*

VII. Illness or Injury (medical studies only).
(*This section would be omitted in this IRB application)*

VI. Compensation.
(Note that the item was RENUMBERED because this is not a medical study and the last couple headings/sections were skipped)
You will receive one research credit for participating in one hour of research. This is not an academic credit.

VII. Contact Information.

Again, if you have questions, please ask. If you have questions or problems later, please contact Marion Aribe, Undergraduate student at (845) 111-2222, Marion.Aribe@duny.edu, or faculty advisor, Abel Bond, Ph.D., Professor of Psychology, (845) 222-3333, Abel.Bond@duny.edu.

You will be offered a copy of this form to keep.

You are making a decision whether to participate. Your signature indicates that you have read the information above, have decided to participate, and that your questions, if any, have been answered**.** ***(If potential participants may be minors, as in the case of undergraduate participants, you must include a statement that participant's signature indicates he/she is also at least 18 years of age, e.g., "Your signature indicates that you are at least 18 years of age.")*** Although you have signed this form, you may withdraw at any time without penalty, should you choose to discontinue participation in this study.

_____ _____

Printed Name Date

_____

Signature

_____ _____

Signature of Parent or Guardian Date

(This line should not appear on forms that will be given to subjects consenting for themselves.)

_____ _____

Signature of Witness
(when appropriate)

Signature of Investigator
(when appropriate)

CONSENT FORM TEMPLATE FOR AUDIO/VIDEO RECORDINGS ONLY!

*(This is an **additional** consent form required when audio or videotaping research participants)*

CONSENT FORM FOR AUDIO/VIDEO RECORDING

STUDY TITLE: _____

PRINCIPLE INVESTIGATOR(S): _____

TELEPHONE #: _____

E-MAIL: _____

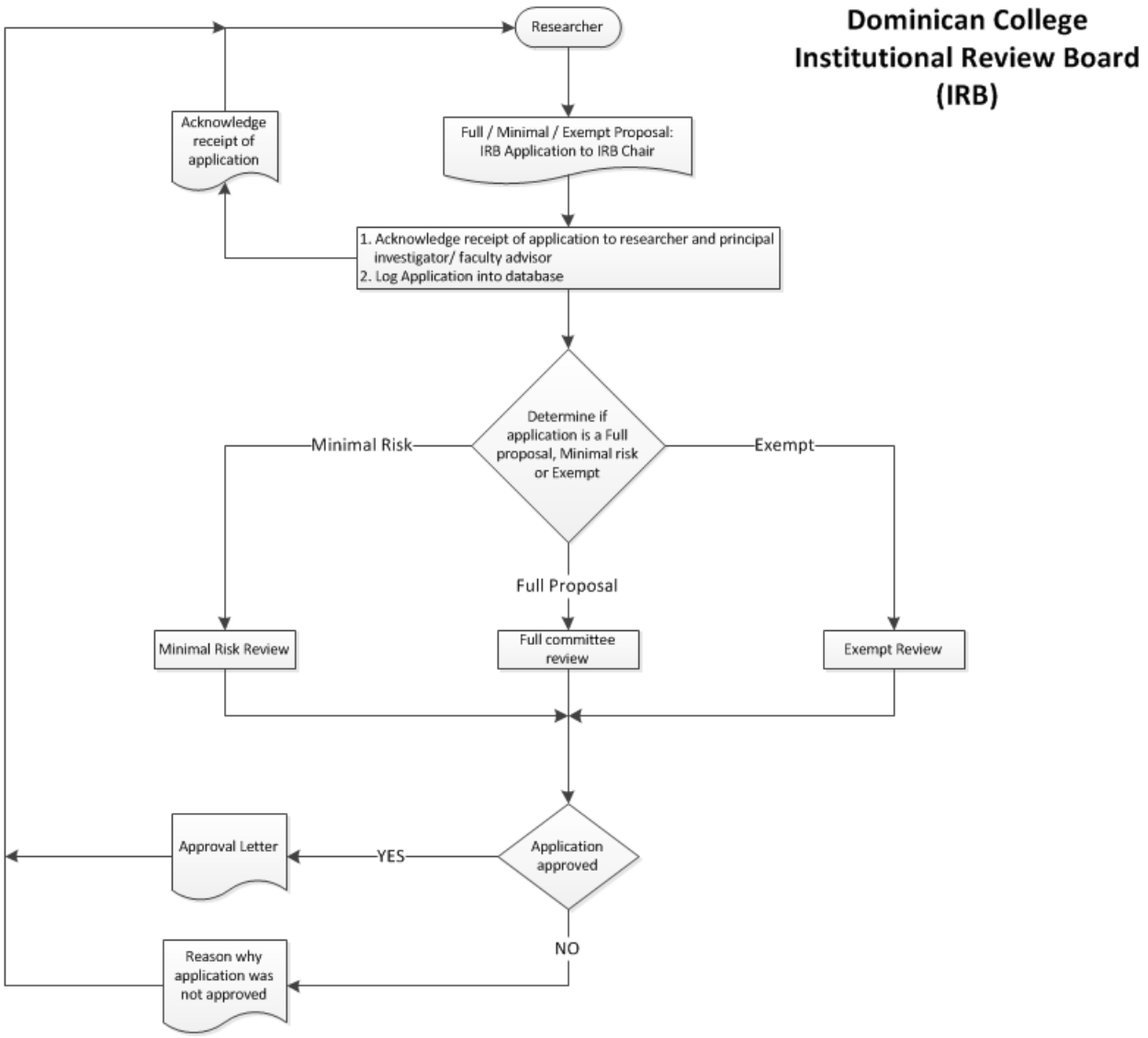
You have been invited to participate in this research study entitled [name of study]. If you decide to participate your responses will be recorded during the interview to assure quality and accuracy of interpretation. This audio/video tape will be transcribed by the principle investigator, [investigator(s) name(s)]. The tape will be kept securely by and in the principle investigator's locked office file cabinet. No other individual will have a key to access the locked file. This tape will be kept for 3 years for regulatory purposes and then destroyed. The tapes will be transcribed in a closed room to maintain confidentiality during transcription. Your name will not appear on the transcripts. The transcripts will be numerically coded to maintain your confidentiality.

Your signature indicates that you have read and agree with the information above and consent to be taped. You have been told these recorded materials will be used only for research, educational or regulatory purposes and your questions, if any, have been answered. Although you have signed this form you may withdraw at any time without penalty, should you choose to discontinue participation in this study.

You will be offered a copy of this form to keep.

_____
Print Name

_____ _____
Signature Date



Process Diagram