



# UNIVERSITY OF NOTRE DAME

(For IRB use only) ND IRB Protocol #: \_\_\_\_\_

**University of Notre Dame Institutional Review Board**  
317 Main Building  
Notre Dame, IN 46556-5602  
(574) 631-1461 Fax: (574) 631-8441 Email: [irb@nd.edu](mailto:irb@nd.edu)

## IRB Application Form

<b>I. Study Title:</b>  (If Funded must match the sponsored title)	<b>Date:</b>
<b>II. Principal Investigator Information</b>	
Name of Principal Investigator	A. <u>Are you? (Please check)</u> <input type="checkbox"/> Faculty <input type="checkbox"/> Staff <input type="checkbox"/> Undergraduate Student <input type="checkbox"/> Graduate Student <input type="checkbox"/> Postdoctoral fellow <input type="checkbox"/> Other:
B. Mailing Address:	
C. Department:	
D. E-mail Address:	
E. Primary Phone Number:	F. Alternate Phone:
G. Faculty Advisor's Name:	H. Faculty Advisor's Phone:
I. Faculty Advisor's Email:	
<b>III. Funding</b>	
A. <input type="checkbox"/> None ( <b>Go to Section IV</b> ) Do you plan to apply for funding in the future? <input type="checkbox"/> Yes * <input type="checkbox"/> No* Please explain:	
B. <input type="checkbox"/> University Funded: List Source:	
C. <input type="checkbox"/> External*: List source and grant number:	
D. <input type="checkbox"/> Federal*: List agency, department:	
*Wait until you have been notified that your project will be funded before seeking IRB approval unless otherwise instructed by funding source. Submit documentation of funding status with application and <u>a complete copy of the grant with your IRB application.</u>	
E. Is ND the primary awardee for the grant? <input type="checkbox"/> Yes <input type="checkbox"/> No* If No Please list Primary Awardee: _____	
F. Are there subcontracts? <input type="checkbox"/> Yes* <input type="checkbox"/> No If Yes Please list sub-contractors: _____	

#### IV. General Study Information

A. Participant Recruitment Numbers

Females:                      Males:

B. Participant Ages (please check)

- 0-7 (parental consent or oral child assent)
- 7-11 (parental consent and child written consent)
- 12-18 (parental consent and written consent)
- 18-65
- 65+

C. Estimated Project Duration

Start Date:                      End Date:

D. Why is this Project being conducted? (please check)

- Faculty/Staff Research
- Undergraduate Coursework
- Master's Thesis
- Doctoral Dissertation
- Other:

E. Special Study Populations (check of applicable)

- Minors (under 18 years) If including minors, also complete **ND Research with Minors Form**
- Pregnant Women/Fetuses or products of labor & delivery
- Prisoners
- Physically or mentally challenged
- Diminished capacity for consent
- Other:

#### V. Research Risk

\*Research must present no more than a minimal risk to human participants in order to qualify for expedited review. Minimal risk means that 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 test." (45 CFR 46.102).

**A. Does the research propose greater than a minimal risk to participants?**  Yes\*  No

\*If yes, skip to part C of this section

**B. Does the research include prisoners?**  Yes\*  No

\*If research includes prisoners, the application must be reviewed by the full board

**C. Check all procedures that apply to the research:**

- (1) Clinical studies of drug and medical devices.
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.

- (3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: hair and nail clippings; saliva, deciduous teeth at time of exfoliation or extracted during routine care; excreta and external secretions (including sweat); un-cannulated mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; sputum collected after saline mist nebulization.
- (4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Examples: 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 participant or an invasion of the participants privacy; 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; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- (5) 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).
- (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- (7) 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 survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
- (8) Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research related interventions; and (iii) the research remains active only for long-term follow-up of participants; or (b) where no participants have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
- None of the about categories apply.

For a comprehensive list of Expedited Categories see:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

**D. Does this study involve any of the following? (Check all that apply)**

- Deception or Punishment
- Use of drugs
- Covert observation
- Induction of mental and/or physical stress
- Procedures which may risk physical/mental harm to the participant
- Materials/issues commonly regarded as socially unacceptable
- Information relating to sexual attitudes, preferences, or practices
- Information relating to the use of alcohol, drugs or other additive products
- Procedures that might be regarded as an invasion of privacy
- Information pertaining to illegal conduct
- Genetic information that may be linked to a participant's health status, such as genetic markers for cancer, heart disease, etc.
- Information normally recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination
- Information that if released could reasonably damage an individual's financial standing, employability, or reputation within the community.

Please submit responses to Section VI: Research Design in a separate document.

**VI. Research Design:**

Please describe the research design, paying close attention to the topic sections below

**A. Introduction and Background:**

1. State the problem and hypothesis
2. Provide the scientific or scholarly reason for this study and background on the topic

**B. Specific Aims/Study Objectives:**

1. List the purpose(s) of the study (what are you hoping to learn as a result of the study)

**C. Materials, Methods and Analysis (quantitative and qualitative):**

1. Describe data collection methods (Procedures) be specific
2. Describe the specific materials or tools that will be used to collect the data- be specific

**D. Research Population & Recruitment Methods:**

Describe:

1. Inclusion and Exclusion Criteria (what participant traits are needed to be included, what traits exclude participants?)
2. What is the scientific or scholarly justification for the number, gender, age, or race of the population you intend to recruit?
3. How did you choose the source of participants or data? (census records, ND students, other records, etc.)
4. Recruitment procedure (if applicable) including who will recruit participants
5. Tools that will be used to recruit (payment, advertisements and flyers attach copies to this application)

**E. Informed Consent Procedures:**

Describe:

1. Who will perform the informed consent procedure?
2. How will that person be trained? (previous related coursework, previous experience, one-on-one training with PI or faculty, etc.)
3. How will the prospective participant's competence or understanding of the procedures be assessed; will participants be asked questions about the procedures, or encouraged to ask questions?

**F. Confidentiality:**

Describe the Provisions for participant and data confidentiality:

1. Where the data will be stored, and who will have access to the data and the area?
2. How will the data be stored, and in what format (hard or electronic copy, identifiable or deidentified)
3. Will the participant's identity be coded? Will the codes to identify participants be stored with the data? (**Note:** If you are working with a Hospital or Clinic, please see information on HIPAA and Research)

**G. Potential research risks or discomforts to participants:**

1. Indicate the type of risk that may result from participation. Consider psychological or emotional risks, social stigma, change in status or employment, physical risks or harms, information risks- breach of confidentiality and any effect loss of confidentiality may have on status, employment, or insurability. If the protocol involves treatment, what are the risks compared to other treatments in terms of "standard of care"?
2. Consider the likelihood and magnitude of the risks or discomforts occurring? Are they unlikely, or likely to occur and what effect would the discomforts or risks have on the individual should they occur?
3. How will you minimize risks? Some examples include informed consent, adequate staff training and experience, debriefing, and monitoring adverse effects on participants.

**H. Potential research benefits to participants:**

1. Indicate the type of benefit that may result from participation. Consider psychological or emotional benefits, learning benefits, mental benefits, or physical benefits and discuss if participant will benefit directly or if the benefit is largely to gather generalizable knowledge or provide scientific or social information on a topic that may benefit society. **DO NOT OVERSTATE** the benefit.
2. Consider the likelihood of the benefits. Will all or some participants benefit? (Note: Monetary compensation is not a benefit of participation, it is a recruitment tool)

**VII. Informed Consent and Waiver of Elements of Informed Consent or Documentation**

- A statement that the study involves research
- The purpose of the research in lay terms (language understandable to the participant)
- A statement that they are being asked to participate in research, and how they were selected to participate
- The expected duration of the participant’s participation “You will be asked to complete a survey every month for 1 year”
- The total time commitment of participation in the procedures “the survey will take 20 minutes to complete”
- A brief but complete description of all procedures to be followed (if research includes treatment, describe which procedures are experimental and alternatives to those procedures)
- The risks or discomforts that are reasonably expected from the research, and a statement that “There may be unknown risks”
- The benefits to the participant or others that are reasonably expected from the research
- A statement that participation is entirely voluntary and may be discontinued at any time
- A statement that withdrawal from participation will not result in denial of entitled benefits
- Invasive biological, clinical or behavioral interventions require specific descriptions of the procedure
- The consent form must be signed and dated, or oral consent must be witnessed and signed and dated by the witness
- A statement and check box that includes the participants have a copy of the informed consent document

Note: Individuals with added protections require both permission of a legal representative and assent of the the individual.

**A. In some instances the IRB may consider altering the informed consent requirements. To be considered for an alteration or waiver of the required elements of informed consent, one of the following must apply in accordance with (45 CFR 46.116 (d)) or 45 CFR 46.117 (c)**

Are you requesting an alteration or waiver?  Yes\*  No

\*Please send this form as an attachment to [tposton@nd.edu](mailto:tposton@nd.edu)

**DO NOT WRITE BELOW THIS LINE**

Approved  Deferred  Not Approved  Full Committee Review

Executive Secretary of IRB Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Federal-Wide Assurance Number: A00002462  
IRB Registration Number: IRB00000329

Approved  Deferred  Full Committee Review

IRB Chair Signature: \_\_\_\_\_ Date: \_\_\_\_\_