Touro University Nevada

Institutional Review Board

Application Form: Full Board or Expedited Review

*****PLEASE NOTE THAT RESEARCH CANNOT BEGIN UNTIL YOU HAVE OFFICIAL IRB APPROVAL DOCUMENTATION*****

EXPERIMENTAL/SOCIAL/ BEHAVIORAL/EDUCATIONAL RESEARCH
PROTOCOL APPLICATION for Human Subjects Research

All materials (new applications and requested resubmissions) must be received electronically by the IRB Chair no less than 10 business days prior to the next meeting. Please see the schedule of IRB meetings posted in Blackboard.

Materials will be reviewed as time permits in the order received. Submit materials early to best ensure timely review and response by IRB. Depending on the volume of submissions, please be aware that your application may be reviewed at the subsequent meeting.

Date of Submission to IRB: _____

Date Received by IRB: _____

IRB Assigned Protocol Number: _____

Touro University Nevada Affiliation:

- ☐ F/T Faculty
- ☐ P/T Faculty
- ☐ Adjunct Faculty
- ☐ Other _____

Research Risk and Level of Review Required:	**Type of Review Requested**
Research participants will be placed at as defined below: ☐ No risk (exempt review) ☐ No more than minimal risk *(expedited review)* ☐ More than minimal risk *(full board review)* ***Minimal risk*** means that 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 [45 CFR 46.102(i)]	Expedited ☐ Full Board ☐
Project Title:	
Please complete the following for each person involved as Principal Investigator or Co-Investigator. Use additional pages if necessary.	

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Principal Investigator :	
Name/Degree:	Title:
Campus Address:	Telephone #:
Department:	Email Address:
Co-Investigator(s):	
Name/Degree:	Title:
Campus Address:	Telephone #:
Department:	Email Address:
Name/Degree:	Title:
Campus Address:	Telephone #:
Department:	Email Address:
Name/Degree:	Title:
Campus Address:	Telephone #:
Department:	Email Address:
Name/Degree:	Title:
Campus Address:	Telephone #:
Department:	Email Address:

HUMAN SUBJECTS PROTECTION TRAINING

All Key personnel who will be involved in obtaining consent from participants, otherwise interacting with human subjects or who will be working with project data must complete and/or verify current Human Subjects Protection Training. Initial training or renewed certification must be current within three years prior to the date of application submission.

All Key Personnel must complete Human Subjects Protection Training as a condition of Federal Wide Assurance. Online training is provided via the Collaborative Institutional Training Initiative (CITI) at https://www.citiprogram.org . The registration page will have a pull-down list of participating institutions; select "Touro University Nevada" and then complete the remaining steps for registration.

KEY PERSONNEL

Name	Department	Date Human Subjects Training completed

Please attach the training certification verification sheet for each individual.

Type of Funding:	**Source of Funding:**
☐ **None**	☐ **TUN**
☐ **Grant/Contract** ☐ **Subcontract**	☐ **Federal Government** ☐ **Industry**
☐ **Departmental**	☐ **Not applicable**
☐ **Other:**	☐ **Other:**

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NOTE: Funding Sources – *Include One Copy of Federally Funded Grant*

Location Where Research Is To Be Conducted:	☐ TUN Campus ☐ TUN Clinic ☐ TUN Center for Autism and Developmental Disorders ☐ Elementary/Secondary Schools (complete Supplemental Form 1) ☐ Other: specify _____ ***NOTE****: If other, attach approval letter from external site*

Potential Conflict of Interest – The *Touro University Nevada IRB Conflict of Interest Policy and Statement* must be read and completed by the principal investigator, and the signed document must be attached to this application.

I have read and completed the *Touro University Nevada IRB Conflict of Interest Policy and Statement* and the signed document is attached. ☐ Yes ☐ No

Recruitment/Compensation:	1. Describe the process you will use to recruit participants and inform them about their role in the study {attach copies of any recruitment materials} _____ 2. Will you give subjects gifts, payments, compensation, or reimbursement? ☐ Yes ☐ No **If yes**, describe: _____ 3. Check all the following to be used:

☐	Internet/Email *(attach copy)*
☐	Newspaper/radio/TV *(attach copy)*
☐	Poster/brochure/letters *(attach copy)*
☐	Other: specify _____ *(attach copy)*

SUMMARY OF ACTIVITIES

Describe the objective(s) of the proposed research including **purpose, research question, hypothesis and relevant background information:** _____

_____

_____

Describe the tasks subjects will be asked to perform. *Attach surveys/instruments/interview questions/focus group questions, etc. Describe frequency and duration of procedures, tests and experiments; including screening, intervention, follow-up:*

_____

_____

_____

What is the expected duration of the study through data analysis? (Include a timeline, if applicable) _____

_____

_____

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CONSENT PROCESS – PLEASE ATTACH COMPIES OF CONSENT FORMS TO BE USED

Describe how consent will be obtained, who will obtain the consent and the time frame between informing the subject and soliciting a decision to subject:

_____

Describe how subjects will be recruited (e.g., brochures, advertisements, websites):

_____

Will more project specific instruments be used in the consenting process?

☐ Yes ☐ No

RISKS
What are the potential risks of the research to the subject participants? {check all that apply} ☐ physical harm ☐ use of deceptive technique *(complete Supplemental Form 2)* ☐ release of confidential information ☐ legal ☐ presentation of materials which subjects may consider sensitive, offensive or degrading ☐ psychological harm ☐ other: specify: _____
Describe any potential risks to human subjects and the steps that will be taken to reduce the risks. Include any risks to the subject's well-being, privacy, emotions, criminal and legal status. *NOTE: The described risks/harms must be fully disclosed in the consent form*
BENEFITS
What are the anticipated benefits to the subject, if any, as a result of being in the study? _____ _____
What are the anticipated benefits of this research for society, if any, and explain how the benefits outweigh the risks. _____ _____

SUBJECT POPULATION(S)		
Age range: _____	Gender: ☐ Males ☐ Females	Total Number of Participants Planned for Enrollment: _____

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Type of Subjects: (Check all that apply) NOTE: the subjects below are considered to be vulnerable and are reviewed at higher risk level.	
☐ Minors under 18 years of age:	☐ Subjects Unable to Consent
☐ Pregnant Women :	☐ Subjects with Diminished Capacity to Consent
☐ Fetuses ☐ Neonates:	☐ Subjects unable to Read, Speak, or Understand English
☐ Prisoners :	

DATA CONFIDENTIALITY and SECURITY

NOTE: The Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rule provides additional protection for protected health information (PHI), which is defined as "individually identifiable health information" including demographic information collected from an individual

Does your research use health information that contains **ANY** of the following identifiers *(check all that apply):*

- ☐ Names
- ☐ Geographic subdivisions smaller than a State
- ☐ Elements of dates (except year) related to an individual
- ☐ Device identifiers and serial number
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Social security numbers
- ☐ Medical record numbers
- ☐ Health plan beneficiary numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identifiers and serial numbers
- ☐ Biometric identifiers
- ☐ Web universal resource locators (URLs)
- ☐ Email addresses
- ☐ Internet protocol address numbers
- ☐ Full-face photographic images
- ☐ Any other unique identifying number (codes are not identifying as long as the researcher cannot link the data to an individual)
- ☐ **None**

If yes, explain why it is necessary to record findings using these identifiers. Describe the method you will use to protect against disclosure of these identifiers: _____

Do you plan to maintain electronic identifiable health information specific to this study? *(e.g., research databases, spreadsheets, computing applications)*

☐ Yes ☐ No

Where, how long and in what format (e.g., paper, digital, electronic media, video, audio or photographic) will data and identifiers be kept? _____

_____

Data Security :

Please indicate how study data will be kept secure. Check all that apply:

- ☐ Data coded; data key is destroyed at end of study
- ☐ Data coded; data key is kept separately and securely

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- ☐ Data kept in locked file cabinet
- ☐ Data kept in locked office/suite
- ☐ Electronic data protected with a password
- ☐ Data stored on a secure network
- ☐ Portable storage (e.g., laptop, flash drive)

Describe how data will be protected for any portable device: _____

_____

☐ Other: _____

If the data collected contains information about illegal behavior, subjects' sexual attitudes, genetic information, visit the NIH Certificates of Confidentiality Kiosk (http://grants.nih.gov/grants/policy/coc/) for information.

Will you obtain a Federal Certificate of Confidentiality for this research?

☐ Yes ☐ No

If yes, submit documentation of application (and a copy of certificate if granted) with this application form.

You are: *(check applicable box)*

☐ Obtaining Subject Authorization to use the health information in research

(Include Subject Authorization to Use/Disclose PHI in the confidentiality section of the informed consent document)

☐ Requesting a Waiver of Subject Authorization

(Attach Request for Waiver of Subject Authorization Form)

☐ HIPAA does not apply to this human subjects research study

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SIGNATURE FORM

Project Title

Principal Investigator

Department/Campus Address

My signature, as Principal Investigator, certifies that I will:

►Conduct all aspects of the project as approved by the IRB,

►Promptly report any revisions or amendments to the research activity for review/approval by the IRB prior to commencement of the revised protocol, with the only exception to this policy would be to eliminate apparent, immediate hazards to the subject,

►Promptly report any unanticipated problems or adverse advents, and

►Assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials, and,

►Where consent form(s) have been approved for the research activity, only IRB-approved, stamped consent forms will be used in the consent process.

Signature, Principal Investigator Date

Signature, Department Chair Date

Signature, Senior Administrator of offsite facility (if applicable) Date

CHECKLIST FOR NEW RESEARCH PROJECT SUBMISSION

- ☐ **A signed electronic copy of the application**
- ☐ **An electronic copy of the consent form**
- ☐ **An electronic copy of the detailed research protocol**
- ☐ **An electronic copy of the Research Registration Form to the IRB and Research Committee**
- ☐ **An electronic copy of the CITI training certification verification sheet for each individual.**
- ☐ **For research involving children and/or minors less than 18 years of age, the Investigator's Checklist for Research Involving Children must be included**
- ☐ **IRB Email Address:** tun.irb@tun.touro.edu **Research Committee Email Address:** tun.researchcommittee@tun.touro.edu

NOTE: FAILURE TO COMPLY WITH THE REQUIRED INFORMATION WILL RESULT IN DELAY OF REVIEW AND APPROVAL FOR RESEARCH PROJECTS

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Institutional Review Board

To assure prompt review of your application, ALL researchers should complete this checklist:

- Have you written an appropriate answer for each question on the application form? (Please do not attach research proposals, grant applications, etc. as the committee cannot read such documents.)

- Have you answered all of the questions on the application form? (Please enter "N/A" if a particular question does not apply to your research.)

- Have you provided an e-mail address and a phone number where you can be reached on the application?

- Have you (and any co-researchers) signed the application form? Did you submit an original copy of your application with those signatures?

- Have you included your consent form with your application? Does that consent form identify you as the researcher and your department?

- Does your consent form clearly describe what participants will be asked to do in your research? Does it clearly describe any direct benefit they will receive as a result of their participation? Does it clearly describe any risks they will be exposed to during their participation, and what you will do to minimize those risks?

- Have you included with your application any screening forms that will be used to determine the eligibility of participants for your research?

- Have you included with your application all tests, questionnaires, surveys, interview questions, focus group questions, etc. that will be used in your research?

- Have you checked the grammar and spelling throughout all of your documents?

- Have you prepared an electronic copy of your complete application packet, including all attachments, for the committee?

- Have you submitted a research registration form to the Research Committee?

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STUDENT researchers must also complete this checklist:

- Have you met with your faculty advisor before preparing your application? Has your faculty advisor thoroughly reviewed all of your materials before you submitted your application?

- Have you provided an e-mail address and a phone number where you can be reached on the application? Did you also include your home address on the application?

- Have you included the name of your faculty advisor and that person's e-mail address on your application?

- Has your application been signed by you, any co-researchers, and your faculty advisor? Did you submit an original copy of your application with all of those signatures?

- Your research must be reviewed and approved by the school or college's committee **first**. Submit copies to the school or college-level review committee with the appropriate face sheet. If your proposal is found to present risk to human subjects it will be reviewed by the University IRB, and an electronic copy of the proposal and associated documents will be required. Has your school of college's committee completed the following form?

SCHOOL OR COLLEGE SUBCOMMITTEE APPROVAL

Project Title: _____

Student Researcher: _____

Faculty Sponsor: _____

The College of Health and Human Service's Subcommittee has reviewed and approved this application. It requires review by the IRB because the research is At Risk.

_____
Name of school or college's Subcommittee Chairperson:

_____
E-mail address of Chairperson:

_____
Signature of school or college Subcommittee's Chairperson

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Supplemental Form 1: Research in Schools

The IRB requires that research conducted in schools with children be approved by schools, or school district authorities (Provide documentation of approval/acknowledgement from school board or principal of school that research is being conducted)

Documented approval is required for both NEW studies and CHANGES in existing studies.

Identify the school district and name of school(s):
Who is the subject of the research?
☐ Teacher (include teacher's consent form)
☐ Student (include parental permission and student assent form)
☐ Administrative Personnel (include consent form and describe personnel:
If student subjects, explain what role the teacher plays in the project:

For each school involved, please attach a copy of an approval letter permitting the research, and signed by an appropriate campus upper administrator. Dates for which the research is approved to occur should also be documented in the letter.

PI Name: _____ Date: _____

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Supplemental Form 2: Research Involving Deception: Debriefing

Subjects must be told the purpose of the study, the reason for the deception, and given an opportunity to withdraw their data from the project.
For guidance: see American Psychological Association ETHICAL PRINCIPLES OF PSYCHOLOGISTS AND CODE OF CONDUCT- Section 8.07

Explain the scientific rationale for deceiving study participants. Which aspects of the study will be withheld from subjects. Explain:_____ _____ _____
Describe when the subjects will be informed the "true" purpose of the study, the reason for the deception and explain how they will be informed and by whom *(attach a copy of the material or script to be used in this process)* _____ _____ _____
Describe how/when subjects will be given an opportunity to withhold use of data: _____ _____ _____

PI Name: _____ Date: _____

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Supplemental Information: Constructing a Consent Form

Federal regulations require that the following information be provided to prospective participants when obtaining consent [Federal Policy §46.116(a)]:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and whether any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and about the rights of research subjects, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, the following additional information must also be provided to subjects [Federal Policy §46.116(b)]:

(1) A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be discontinued by the investigator without the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which might affect the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

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Supplemental Information: Constructing a Consent Form

Several examples of consent forms, for studies with different levels of risk, are shown on the following pages. These are adapted from protocols which have been reviewed by the committee, and they are meant to provide specific information about the kind of content and language that should appear in a consent form. Thus, they are not templates, and researchers will need to look at all examples and adapt the guidelines reflected in these examples to the investigator's particular research situation. Italicized headings at the beginning of a paragraph are merely reminders of the major topic in that paragraph; such headings do not necessarily need to be included in the consent form. Please keep in mind that the consent form must provide the information a subject would need to weigh the risks and benefits of participating in the research, and that the benefits to the individual participant may be different from the overall benefits of conducting the research study.

Sample 1 shows a consent form for a study which is considered "no risk," because the risks inherent in the research are effectively eliminated by the confidentiality protections built into the research procedures.

Sample 2 shows a consent form for research which is considered "minimal risk" because the confidentiality provisions, while appropriate and good, cannot completely eliminate all of the risks in the research.

Sample 3 shows a consent form for research in which the magnitude of risk is substantially higher, although the probability of risk is still quite small and made even smaller by health screening procedures that would disqualify some potential participants.

Sample 4 shows a consent form for research in which the probability as well as the magnitude of risk is higher than usual. Although the study uses the best protections available for its psychological risks, it is considered an "at risk" project. See the earlier sections of this manual on *Level of Risk* and *Informed Consent*.

If a waiver of written consent or an alternate method of documenting consent is requested in a protocol, the investigator must still clearly indicate how the research will be explained to each subject, how the consent of the participants will be obtained, and who will validate the act of consent. In some instances the committee can waive the requirement of a signed written consent form, but only rarely can it waive the process of obtaining informed consent, and only if the participants are not placed at any risk by doing so.

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Sample 1: Example of a "No Risk" Consent Form

Consent to Participate in Research

(purpose of the research) You are being asked to participate in research which will be conducted by Dr. _____ in the Department of Basic Sciences at Touro University Nevada . The purpose of the study is to investigate the naturally-occurring frequencies of certain human DNA identity markers. This information is important because of its implications for the accuracy of human identity testing.

(research procedures) You will be given a sterile Q-tip and asked to gently swab the inside of your cheek to collect a small sample of cheek cells. Your Q-tip will then be placed in a plastic bag for safe and sterile transport to a laboratory where the DNA will be extracted and analyzed.

(risks) This procedure is completely safe and is not associated with any known health risks.

(Benefits) You may not personally benefit from participating in this research. However, DNA studies like this have led to clearer evidence of guilt or innocence in criminal cases, more accurate resolution of paternity conflicts, and increased ability to identify victims of war and natural or man-made disasters.

(confidentiality) Your cheek sample will be labeled in a way that it cannot be traced back to you by the technicians handling your sample. Your participation in this study will also be kept confidential. However, the results of the study as a whole may be shared with the scientific community and become a matter of public record. Once your profile for the DNA markers we are studying has been obtained, your cheek sample will be destroyed. Furthermore, no other genetic testing will be done on your sample. Any sample remaining in the laboratory two years after you provided it will also be destroyed, regardless of whether the sample has been successfully tested.

(compensation) You will receive $2 for providing your DNA sample.

(contact information) If you have any questions about this research, you may contact Dr. _____ at (702) 777-xxxx or by e-mail at xxxxxxxx@touro.edu

You may decline to be a participant in this study without any consequences. Your signature below indicates that you have read this page and agree to participate in the research.

Signature of Participant_____ Date_____

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Sample 2: Example of a "Minimal Risk" Consent Form
Consent to Participate in Research

Initials:_____

(purpose of the research) You are being asked to participate in research which will be conducted by _____, a graduate student in Education at Touro University Nevada. The study will investigate factors related to academic success among college students.

(research procedures) You will be asked to complete several questionnaires about your academic abilities, your personal traits and values, and your relationships with other students, family, and friends. The questionnaires may require up to an hour of your time. If you agree to be contacted, you may also be asked later to participate in a focus group discussion with about five other students on these topics. The focus group discussion could also last up to one hour.

(risks) Some of the items in the questionnaires may seem personal, but you don't have to answer any question if you don't want to. Some of the topics in the focus group discussion may also seem personal, but you may participate as much or as little in the discussion as you wish.

(benefits) You may gain additional insight into factors that affect success in college, or you may not personally benefit from participating in this research. It is hoped that the results of the study will be beneficial for programs designed to encourage students to remain in college.

(confidentiality) You were asked to print a copy of your academic record and bring it with you today. To preserve the confidentiality of that information, you will be asked to use a black marker to remove any information that would personally identify you, such as your name, address, and social security number. Your responses on the questionnaires will be anonymous. Only first names will be used in the focus groups, and you may use something other than your real name if you wish. With the permission of everyone in the group, the focus group discussion will be audio taped. Those tapes will be destroyed as soon as the discussions have been transcribed, and in any event no later than one year after they were made. Until that time, they will be stored in a secure location. Only group results for the project will be reported.

(compensation) You will not receive any compensation for participating in this study.

(contact information) If you have any questions about this research, you may contact _____ at (702) xxx-xxxx or by e-mail at xxxxxxxx@touro.edu

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Sample 2: Example of a "Minimal Risk" Consent Form
Consent to Participate in Research

Your participation in this research is entirely voluntary. Your signature below indicates that you have read this page and agree to participate in the research.

Signature of Participant_____ Date_____

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Initials:_____

Sample 3: Example of a "Minimal Risk" Consent Form

Consent to Participate in Research

(purpose of the research) You are being asked to participate in research which will be conducted by _____ and _____, who are graduate students in Occupational Therapy at Touro University Nevada. The purpose of the study is to investigate the effects of three strategies for pacing yourself (perceived exertion, heart rate, or power output) on performance in exercise tests.

(research procedures) After completing a health history questionnaire to assess your risk factors for cardiovascular disease, you will be asked to perform exercise tests on an electronically braked bicycle and muscular strength tests using a weight machine. For some of these tests, you will wear a heart rate monitor and/or a nose clip and headgear to measure your oxygen consumption. The tests will be conducted on five separate days in the human performance laboratory at Touro University Nevada and will require up to 30 minutes each day.

(risks) Exercise stress testing involves a risk of possible injury or even heart attack, but these risks are considered very small. The risk for heart attack is estimated to be less than 0.04% for people who are suspected to have cardiovascular disease, and substantially less than that for people who are in good health, have few or no risk factors for cardiovascular disease, and have no symptoms of cardiovascular disease. It is essential for you to provide accurate information on the health history questionnaire to be sure that you fall in this low risk category. Muscular strength testing involves a risk of muscle strain. You will experience increased blood pressure, rapid breathing, increased heart rate, sweating, muscular discomfort, and fatigue during the testing procedures for this study. It is also possible that you will experience an alteration in heart rhythm. There is no risk associated with wearing a nose clip and headgear to measure your oxygen consumption, and no risk is anticipated for wearing a heart monitor. All equipment is tested regularly for safety. If you experience any chest pain, tightness, or other abnormal discomfort during the testing procedures, you should notify the researcher immediately. All of the researchers are trained in emergency procedures if the need should arise.

(benefits) The exercise tests may provide you with information about your current state of health and physical fitness. The information may also be helpful in developing or altering an exercise program to enhance your physical fitness.

(confidentiality) All results obtained in this study will be confidential. Your individual performance will not be reported, only the results of all participants as a group. Information you provide on the consent form and the health history questionnaire will be

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Sample 3: Example of a "Minimal Risk" Consent Form

Consent to Participate in Research

stored separately from data for the exercise tests; the exercise test data will contain no personal information about you.

(compensation) You will not receive any compensation for participating in this research. In the event of an emergency, initial medical treatment would be available at the Student Health Center. However, if you were to require any other medical care as a result of participating in this research, you would need to contact your personal physician at your own expense.

(contact information) If you have any questions about this research, you may contact _____ at (702) xxx-xxxx or send e-mail xxxxxxxx@touro.edu, or call _____ at (702) xxx-xxxx or send e-mail to xxxxxxxx@touro.edu

Your participation in this research is entirely voluntary. You are free to decide not to participate, or to decide at a later time to stop participating. The researcher may also end your participation at any time. By signing below, you are saying that you understand the risks involved in this research and agree to participate in it.

Signature of Participant Date

Signature of Witness Date

Touro University Nevada

Initials:_____

Sample 4: Example of an "At Risk" Consent Form

Consent to Participate in Research

(purpose of the research) You are being asked to participate in research which will be conducted by Dr. _____ in the Department of Basic Sciences at Touro University Nevada and Dr. _____ in the Department of Physiology at the University of Las Vegas. The study is about ecstasy and its relationship with behaviors that transmit HIV, the virus that causes AIDS, and psychological outcomes. The study will involve approximately 300 participants.

(research procedures) You will be interviewed and asked written questions about your mental health, sexual behaviors, and drug and alcohol use. The interview may last up to 4 hours but will usually last from 2 ½ to 3 hours. You will be asked to provide three hairs from your scalp; these will be tested for drugs and will be destroyed during the testing. You will be asked to take two computer-based and two paper-and-pencil cognitive tests.

(risks) Some of the questions could make you feel uncomfortable or upset because you may become more aware of your risks from the use of drugs, including your risk of infection with HIV, or because of the highly personal nature of other questions you may be asked. You are free, however, to decline to answer any questions you do not wish to answer or to stop the discussion at any time. If you experience any psychological discomfort during the study, and want help at that time or any time after completing the research, you may call the Psychological Services for Touro University Nevada at (702) 454-xxxx. There could also be momentary discomfort when three hairs are removed for the hair sample.

(benefits) The interview could increase your awareness of HIV risk behaviors and other risks of drug use. However, you may not benefit personally from this research. The information you provide may help health professionals to better understand how the use of ecstasy and other drugs affects people's other behaviors and psychological states.

(confidentiality) A federal certificate of confidentiality has been obtained to protect against research records being subpoenaed by courts of law. Additionally, participants will be identified only by a randomly assigned ID number in any data collected for this research. All research records, including these consent forms, will be stored in a locked file cabinet in a locked office. No individuals will be identified in any reports or publications that may result from this study, and no academic institutions will be identified in any such reports or publications.

(compensation) To compensate you for your time in the interview, you will be paid at the rate of $10 per hour immediately following the interview. If you are physically or psychologically injured as a direct result of the research procedures, you will receive medical

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Sample 4: Example of an "At Risk" Consent Form

Consent to Participate in Research

treatment at no cost. The University of Nevada Las Vegas does not provide any other form of compensation for injury. Psychological treatment will be available through Psychological Services at _____ (702-454-xxxx).

(contact information) If you have any questions about this research, please ask now. If you have questions at a later time, you may contact Dr. _____ at (702) xxx-xxxx or by e-mail at xxxxxxxx@touro.edu.

Your participation in this research is entirely voluntary. You may decide not to participate in this study without any consequences. You may also change your mind and stop participating in the research at any later time without any consequences, or the investigator may decide to discontinue your participation in the study at any time. Your signature below indicates that you have read and understood this consent form and agree to participate in the research.

Signature of Participant Date

Signature of Investigator Date