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Tufts University, Department of Psychology
POLICY ON HUMAN PARTICIPANTS RESEARCH

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I. WHAT RESEARCH NEEDS HUMAN PARTICIPANTS APPROVAL?

A. RESEARCH REQUIRING APPROVAL

All research conducted by faculty, graduate students, or undergraduates in the Psychology Department that involves human participants must be reviewed and approved by the University IRB prior to conducting the research. This requirement is not limited to research using the Psychology Department's participant pool; it encompasses questionnaires and field studies, any research on or off campus that involves children or adults, and studies conducted as part of undergraduate independent research (see Section II, part B for information on course-related research). The only exception is research conducted at another institution that has received written approval from their review committee.

B. DEFINITIONS OF TERMINOLOGY

Principal Investigator (PI) – Individual primarily responsible for research; generally individual who is requesting human participants approval and/or research hours from the participant pool.

Experimenter(s) or Researchers – Any individuals involved with administering and carrying out procedures of an experiment.

Participant(s) – Individuals participating in an experiment from or about whom information or data is collected.

Instructors – Individuals teaching courses from which students will be drawn for the participant pool.

Participant Pool – Students from PSY 1, 9, and 31 who opt to complete the research requirement of their course by participating in departmental research.

Sona Systems – The website portal through which all participant pool research recordkeeping and sign-ups take place. All research using the participant pool must go through the Sona site; no other departmental research may make use of the site.

Human Participants Committee (HPC) – Committee composed of members of the Psychology Department, faculty and graduate students, who oversee research conducted on human participants.

II. PROCEDURE FOR APPROVAL OF RESEARCH INVOLVING HUMAN PARTICIPANTS

A. GENERAL PROCEDURE

Researchers wishing to conduct research involving human participants must submit for approval from the IRB. All forms can be found on the IRB website (<http://www.tufts.edu/central/research/IRB/main.htm>). Information about submission deadlines and IRB committee meeting dates can also be found on their website. Note that most Psychology research can be reviewed as expedited. Expedited reviews take place upon submission by a member of the IRB; they do not wait until the IRB committee meeting. Thus, the deadlines noted apply to protocols needing full review; expedited protocols may be submitted at any time. Approval forms must be filled out in detail, and must include the consent form and complete debriefing statement (see Appendix C for information that should be contained on consent forms). Incomplete forms will be returned to the researcher. All students submitting proposals must obtain their advisor's signature on the forms.

Approval forms should be submitted as far in advance of the planned start date as possible. Submission dates for the University IRB are listed on their web site. Studies cannot be listed as active on the Sona Systems website until an IRB approval number and expiration date have been obtained.

B. PROCEDURE FOR RESEARCH CONDUCTED BY UNDERGRADUATES STUDENTS AS PART OF A COURSE REQUIREMENT

Studies using human participants that are conducted as part of a course requirement typically are not intended to contribute to the generalizable knowledge of the field. Such investigations are therefore not technically “research” and need not be submitted for review by the IRB. Instead, the professor may register the course as a research practicum following the procedures established by the University IRB. In doing so, the course instructor(s) must agree to ensure that these research exercises are conducted in line with APA ethical standards. This may include the use of written consent forms, practices intended to maintain confidentiality, efforts to minimize risks posed to participants, full debriefing, and completion of an IRB-style proposal to be reviewed by the course instructor. In reviewing such proposals, the instructor’s approval process should be no less stringent than would be for research conducted by members of the Psychology Department. The instructor must have completed IRB training him or herself and must discuss research ethics and the protection of human participants as part of the research practicum. Such investigations should be described to potential participants as “class research projects” and not labeled as “research.” Under no circumstances may data collected in such in-class practica be publicly disseminated for the purpose of furthering generalizable knowledge in the field.

C. PROCEDURES FOR MINOR MODIFICATIONS OF APPROVED RESEARCH

In some cases a researcher may want to run a modified version of research previously approved. The modification request form asks for information about the previously approved research and about proposed modifications.

III. CRITERIA FOR APPROVAL OF RESEARCH INVOLVING HUMAN PARTICIPANTS

Research should be in compliance with the ethical principles set forth by the American Psychological Association. According to the APA, research should maximize benefits and minimize risks and costs to participants. Benefits are typically defined in terms of both generalizable scientific knowledge and benefits (usually educational) to participants. Costs are generally defined in terms of possible harm or discomfort that participants might experience as a consequence of participating in the research.

The purpose of a collegial review is to control for possible investigator bias that might exaggerate the possible benefits, or minimize the potential risks, of a study. The review procedure, in addition to protecting human participants in research, is also intended to protect the experimenters, the Psychology Department, and Tufts University. It is further designed to maintain the trust between research participant and experimenter, and to protect the reputation of the community of research psychologists at large.

Criteria for approval by the IRB are described below. In the event that any of the criteria described below are not met, the proposed research will be judged to have some risks. In this case, the burden of proof rests with the investigator to demonstrate that the possible benefits of the proposed research far outweigh the potential risks.

1. Any equipment used in the research must be reliably safe and present no potential risks to participants.
2. The observations collected must always be treated as confidential material in order to protect participant confidentiality.
3. The study must be conducted without coercion. Participants must be informed that they are free to leave at any time if they so choose, without loss of promised credit or remuneration.
4. The instructions of the study should be sufficiently accurate so as to inform participants about the general nature of their experience in the research prior to their actual participation. Written informed consent must be obtained from participants who are normal adults. For any participants who are not normal adults, written informed consent must be obtained from parents, guardians, or institutional officials in charge of their well being.

5. Participants should not be subjected to humiliating or exploitative deception. Deception should be avoided if it is possible to conduct the research without it, and should be minimized when present. When deception is to be used, the investigator must justify the necessity for the use of deception, and must describe the steps that will be taken to minimize any adverse reactions to the deception that participants might experience.

6. Participants should not experience physical or psychological harm as a result of their research participation. In the event that there is any possibility that participants might experience physical or psychological harm, the investigator must justify the necessity of the proposed (risky) procedures and explain the steps that will be taken to minimize any potential harm that might occur. Under these circumstances, the investigator must also describe what will be done in the event that safeguards fail and a participant does experience physical or psychological harm as a result of his/her participation.

7. Debriefing of participants should occur at the end of the research session. Later, more extensive, debriefings are also desirable, but are not a substitute for immediate debriefing. The debriefing must:

- a. reassure participants, reducing any stress or discomfort that they may be experiencing as a result of their participation, and restoring them to the state in which they entered the study, and
- b. educate participants

8. The research should be soundly designed so that it may yield information that will benefit society, psychology, and/or the participant.

IV. PARTICIPANT POOL

A. BACKGROUND

The Participant Pool has two primary purposes. First and foremost, it offers a way for undergraduates in psychology courses to gain first-hand experience regarding how psychological research is conducted, and to gain such experiences across a wide range of subfields within the discipline of Psychology. These experiences comprise an invaluable component of the learning goals for courses such as PSY 1, PSY 9, and PSY 31. ***This is why all studies involving the participant pool should not only include a thorough debriefing sheet, but also a list of keywords and names of researchers conducting related work so that students may conduct further library research on their own if desired.*** Second, the pool provides faculty, graduate students, and undergraduate honors thesis students with potential participants for their ongoing research. Many undergraduates also serve as research assistants for these projects; as such, this is another way in which the participant pool facilitates the undergraduate teaching priorities of the Department.

The participant pool may not be used for research conducted by undergraduate students for course-related projects, nor by individuals from outside the Tufts University Psychology Department, unless an exception is granted by the HPC.

B. COMPOSITION OF THE PSYCHOLOGY DEPARTMENT PARTICIPANT POOL

The Psychology Department participant pool is comprised of students in Psychology 1, Psychology 9, and Psychology 31. Students in these courses have two options for fulfilling the research requirement in their course: 1) participating in a set number of hours of research studies, 2) completion of a research-based paper of equivalent educational value and time commitment. The exact number of hours of participation required each semester will be determined by the departmental HPC (see section C below). Once again, completion of the research requirement is voluntary for all students, as they may opt instead to further their familiarity with research by completing the alternative paper assignment.

C. DETERMINATION OF REQUIRED HOURS OF PARTICIPATION

Early each semester, the HPC will solicit estimates of participant hours needed for research from each faculty member and graduate student in the Psychology Department. Those planning to conduct research using the Psychology Department participant pool must submit realistic estimates of the number of participant hours required for their research by the specified deadline. Late requests will typically not be honored, as the demand for hours typically exceeds the supply, though such requests will be evaluated on a case-by-case basis by the HPC.

Based on researchers' requests for hours and on course enrollments, the HPC will make a determination of the number of hours of research experience that will be required of students in those courses. Most commonly, Psychology 1 and 9 students have been required to complete 5 or 6 hours of participation, while Psychology 31 students have been required to complete 3 or 4 hours. This varies, however, depending upon the level of demand for participants during any given semester and the number of students enrolled in these courses.

D. NEEDS FOR ADDITIONAL PARTICIPANT HOURS

If, as is typically the case, there is an insufficient number of participant hours available to meet all requests, investigators will not receive all the hours that they requested. In the event that demand exceeds supply, investigators will be awarded a percentage of their requested number of research hours. Cuts are often made in a graduated manner, so that those requesting the most research hours receive proportionately greater cuts. Additionally, research of higher priority (e.g. grant-related) will frequently be awarded a higher percentage of requested hours.

If experimenters find that they require additional hours as the term progresses, they can attempt to acquire those hours from other researchers who may not be able to use all of their own allotted participant hours. However, researchers using this option should be sure that credits are recorded under the name of the researcher who originally received the hours. That is, if researcher A convinces researcher B to give her 30 participant hours, those hours should be recorded under researcher B, even though the participants were run by researcher A. Researchers may also ask the HPC for additional hours during the course of the semester, requests which will be evaluated on a case-by-case basis.

E. PROCEDURES FOR RECRUITING RESEARCH PARTICIPANTS

Participants may not be recruited until IRB approval of the research has been obtained. All recruitment of participants must take place via Sona Systems (for more details regarding these procedures, see "Sona Systems Guidelines" at <http://ase.tufts.edu/psychology/forms.htm>). Note that researchers are required to allocate credit (or assign no-show penalty) within 24 hours of the completion of an experimental session. This is the only way to ensure that students have access to an up-to-date accounting of their accumulated credits.

F. AWARDING EXPERIMENTAL CREDIT

Participants are awarded .5 research credit hours for every half-hour of research participation. There is a 5-minute grace period. Thus, for example, 35 minutes of participation earns .5 research credit, while 36 minutes of participation earns 1 research credit.

Credit is awarded via the Sona Systems website. All credits should be posted within 24 hours of completing an experiment. Students should check the website after this time period and contact the researcher directly if credit has not been assessed.

G. PAYING PARTICIPANTS

No participant is to be both paid and given course credit for participation in the same experiment unless special approval is obtained from the HPC. Additionally, sign-ups offering pay for participation should not be posted on the Sona Systems website. Such studies must be advertised through other means.

H. FAILURE TO APPEAR AT SCHEDULED RESEARCH TIME

Should a researcher fail to appear at the appointed time without notifying participants 24 hours in advance, participants shall be given twice as much credit as normally awarded for the study. Participants must allow 10 minutes past the start of the experimental session to ensure that the experimenter is not there, and at that point they should secure verification of their presence at the study from a member of the Psychology Department (faculty, staff assistant, or graduate student). In the event of equipment failure, etc., or if participants elect to discontinue their participation, they shall be awarded full credit for participating in the study. These regulations are in place to ensure that participants who have taken the time to sign up and arrive on time for a study are given the credit that they have been promised for doing so.

Participants who fail to appear at the appointed time without notifying the researcher at least 24 hours in advance are considered “no-shows,” and will be assessed a penalty on the Sona Systems website within 24 hours of the no-show. No-show students will be penalized the number of credits associated with the study in question. For example, a student who missed a 1-credit study not only fails to receive credit for that study, but is also docked 1 credit as a no-show penalty. Setting up for an experimental session often takes a great deal of time and effort (and potentially money) on the part of the researcher, and this penalty is in place to help ensure that this time and effort are not wasted.

V. RESPONSIBILITIES OF THOSE INVOLVED WITH THE PARTICIPANT POOL

A. RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS

1. PIs are responsible for ensuring that no research is conducted until it has been approved by the IRB and assigned a departmental study number by the HPC, and that approved research is conducted in the manner in which it was approved.
2. All PIs, graduate student researchers, undergraduates doing honors theses must have taken an approved course in ethics and experimentation with human participants. Certification that such a course has been completed must be in file with the HPC. Such certification can be obtained on-line at <http://cme.nci.nih.gov>.
3. PIs are responsible for the proper supervision of any personnel associated with their research. Assistants and technical personnel often conduct research. Such arrangements impose on the investigator the additional ethical responsibility of ensuring that these assistants conduct the research as it was approved. This responsibility requires instructing all personnel involved in the research about departmental procedures as well as ethical issues, and ensuring that they are sensitive to these issues. The PI should also provide all involved personnel with adequate supervision and monitor their performance appropriately.
4. PIs must ensure that they do not exceed their allotted credit hours, as specified by the HPC. PIs exceeding their allocated hours will be excluded from research hour allocations during the subsequent semester.
5. PIs are responsible for ensuring that accurate records of participation are kept on the Sona Systems website. PIs failing to do so in a regular and timely manner will be excluded from research hour allocations during the subsequent semester.

B. RESPONSIBILITIES OF RESEARCHERS

1. Researchers are responsible for conducting the research as the IRB approved it. They should be aware of any ethical issues involved in the research and should be sensitive to participants' reactions to the research. They should be willing and able to answer participants' questions, and should be well versed in the procedures to be followed if any participants evince distress as a result of their participation (see Appendix A).
2. Researchers should be aware of departmental procedures regarding participant recruitment, as well as those dealing with the awarding of research credit, and should follow those procedures.
3. Researchers should inform the principal investigator of any problems arising with the research. The principal investigator is ultimately responsible for the conduct of the researchers.

C. RESPONSIBILITIES OF INSTRUCTORS

1. At the beginning of each semester, instructors in Psychology 1, Psychology 9, and Psychology 31 will inform students of the rights and responsibilities of research participants (both students and experimenters). In particular, instructors will provide all students with a copy of the guidelines for research participation (see Appendix B), and will discuss these guidelines with students.
2. Early in the term, after the number of research participation hours required of each student has been determined by the HPC, instructors will announce this required number of research participation hours to their classes. Instructors will also remind students that they may elect to complete a work project of equivalent educational value in lieu of participating in research if they so desire. Instructors should also inform students that failure to complete this assignment will result in a grade of incomplete.
3. Instructors will supervise Teaching Assistants and ensure that they understand how to access students' participation records from the Sona Systems website.

D. RESPONSIBILITIES OF TEACHING ASSISTANTS

1. Teaching Assistants are responsible for accessing student participation records at the end of the semester using the Sona Systems website to determine if the participation requirement has been fulfilled. Instructors may also request that TAs periodically download the participation summary form from the website throughout the semester for the purposes of maintaining a backup file or checking on student progress.

E. RESPONSIBILITIES OF HUMAN PARTICIPANTS COMMITTEE

1. The HPC will solicit, at the beginning of each semester, estimates of the number of research hours required by faculty and graduate students and senior honors thesis students in the psychology department. Based on these estimates, and on course enrollments, the committee will determine the number of research hours in which students will be required to participate. Additionally the HPC will allocate research hours to each investigator.
2. The HPC will notify course instructors of the number of research hours required of students.
3. The HPC will set and publicize deadlines for the use of the participant pool.
4. The HPC will be available to answer any questions about departmental procedures, and to assist with any problems involving human participants that may arise.
5. The HPC will monitor use of the participant pool in order to (a) determine the optimal means of allocating research hours in the future, (b) ensure that investigators do not overrun their allotted hours, (c) identify other abuses and problems and take measures to amend procedures accordingly.

Appendix A: Contingency Plan for Emergencies

TUFTS UNIVERSITY, DEPARTMENT OF PSYCHOLOGY

Protection of Human Participants:
Contingency Plan for Emergency Action

When one conducts research in which humans participate, the experimenter must accept a greater level of responsibility for the well being and safety of the participant than is the case for ordinary interpersonal relationships. Remember, people who volunteer to participate in an experiment are doing you a favor - not the other way around - and they deserve to be treated with courtesy and respect. They should not be misled, humiliated, coerced, or placed in jeopardy.

If, in spite of your best efforts, a participant should show signs of physical or psychological injury as a consequence of participating in your research, it is your responsibility to stay with and aid that person until such time as other responsible professionals or agencies relieve you of that responsibility. At Tufts, there are three main sources of help in such situations: the Tufts Police, Health Services, and the Counseling Center. Information about each of these resources is provided on the back of this sheet.

REMEMBER:

1. Stay calm and think clearly.
2. Don't leave the participant in an emergency until it is clear that someone else is on the scene and is capable of assuming your responsibility.
3. If the research participant involved is a Tufts student, notify the Dean of the school in which the student is enrolled, and describe the events that took place.

Tufts University Police (Dowling Hall)

AVAILABLE: 24 hours/day, every day

CALL: From outside lines: Police 627-3030. From inside lines: ext. 7-3030 or ext. 66911 for emergencies.

SERVICE: Officers treat problems themselves, or make referrals (to Health Service, Counseling Center, and Lawrence Memorial Hospital). They are trained in first aid, and some also know CPR; a few are Emergency Medical Technicians.

Hooper Health Services (124 Professors Row)

AVAILABLE: At all times (although staffed at lower levels on weekends, evenings, and school breaks).

CALL: From outside lines: 627-3350. From inside lines: ext. 73350

SERVICE: All types of medical services. Specialists are on call. Patients must be able to get to the infirmary themselves; otherwise, call Campus Police for transportation.

Counseling Center (120 Curtis Avenue)

AVAILABLE: During business hours; at other times, call Health Services.

CALL: Routine calls during business hours

From outside lines: 627-3360 From inside lines: ext. 73360 (For emergencies or crises, or during evenings, weekends, or breaks, call the Campus Police or Health Services]

SERVICE: Counselors are available to discuss all personal and academic concerns. Crises and emergencies can be handled by Psychiatrists and Psychological Counselors who are on call.

Appendix B: Guidelines for Research Participants**RESEARCH PARTICIPANT GUIDELINES**

1. What is the research experience requirement, and how can it be fulfilled?

In order to undergraduates in psychology courses first-hand experience with how psychological research is conducted, students in PSY 1, PSY 9, and PSY 31 have a research experience requirement. The vast majority of students choose to complete this requirement by participating in a fixed number of research studies conducted in the Department (the precise number of hours will be specified by your instructor at the start of the semester). Participation in these studies comprises an invaluable component of the learning goals for courses such as PSY 1, PSY 9, and PSY 31. This “participant pool” also provides faculty, graduate students, and undergraduate students with potential participants for their ongoing research. Participation in such studies is entirely voluntary; students may also fulfill the research experience requirement by completing a written, research-based assignment of equivalent educational value and time commitment, to be provided by the course instructor upon request.

2. How can I find studies in which to participate?

All studies to fulfill this requirement have been approved with respect to the treatment of human participants by the Tufts University IRB and Psychology Department’s Research Committee. Sign-up for experiments take place on-line using the Sona Systems website (<http://tufts.sona-systems.com>). For detailed instructions on using this site, see the documentation provided by your course instructor.

3. What happens when I participate in a study?

When you appear for an experiment, you will be given an explanation of what the study involves and the procedures that will be followed. You will receive full information about what will happen during the study, although you may not always be told all relevant details about the purpose of the research. At this point you will be given a consent form to read carefully and sign before the study begins. Even after signing this form, however, you may ask for clarifications and further information about the study at any time. If after learning about the procedure or at any time during the procedure you wish to discontinue your participation you may do so without any negative repercussion and you will nevertheless receive credit for the research participation you completed. It is important to remember your participation in any study is entirely voluntary and discontinuing your participation will not lead affect your present or future interactions with the Psychology Department. After each study, the researcher will explain more about the purpose of the research, and will answer any additional questions that you have. The researcher will also provide you with a written summary of the study and references you can look up for additional information. The confidentiality of your responses and performance during the studies you are in will protected in accordance with the ethical principles of the American Psychological Association (www.apa.org/ethics).

4. How will I get credit for my participation?

The Psychology Department uses a two-part system to ensure you receive proper credit for research participation. First, credit will be assigned to you via the Sona Systems website within 24 hours of your participation. Second, you will be given a research participation card by your instructor. For each experiment you participate in, you should have the experimenter sign your card. Your card should include information about the Study Number, Study Name, Researcher’s name, the date and time you participated for each study. This card serves as your receipt for participation. If you do not receive credit via the website within 24 hours, you should contact the researcher for the study—as long as you have your participation card signed, you will be able to prove that you did indeed participate and should therefore be given credit.

5. What happens if I miss a study I signed up for?

If you sign up to participate in an experiment, but do not appear at the appointed time and place without having given notice 24 hours in advance, you will not receive credit and you will be penalized for not showing up. If you miss a 1 credit study, not only will you not receive that 1 credit, but you will also be penalized 1 credit from your existing total. Exceptions are only granted in the case of serious illness or emergencies corroborated by a note from a medical professional or Dean. Keep in mind that you may cancel your appointment for a study without repercussion if you do so more than 24 hours before it is scheduled to begin.

6. What happens if I show up for a study but the researcher doesn't?

If you sign up and appear at the appointed time and place for an experiment, and the experimenter is not present 10 minutes after the designated start time (and has not given you notice 24 hours in advance that he or she cannot attend) you will receive credit for this experiment plus an additional hour of credit as compensation. Once you have allowed 10 minutes past the start of the experimental session to ensure that the experimenter is not there, you should secure verification of your presence from a member of the Psychology Department (faculty, staff assistant, or graduate student) and then contact the experimenter to ensure that you receive the proper credit.

7. What happens if I am late for a study?

If you are late for a study, it is up to the researcher to decide whether to allow you to participate in the study and whether you will be considered to have missed your research appointment.

Appendix C: Standardized Language for Consent Forms

The following issues should be included in any experiment consent form:

- Purpose
- Study contacts
- Procedures
- Costs
- Risks & Discomforts
- Benefits
- Assurance of confidentiality
- Assurance that data is for research purposes only
- Information about ability to withdraw from experiment without penalty

The following is some standardized language that can be used on consent forms (not mandatory, but suggested):

Confidentiality

The results of this study may be published in a scholarly book or journal or used for teaching purposes. However, your name and other identifiers will not be used in any publication or teaching materials without your specific permission. In addition, if photographs, audiotapes, or videotapes were taken during the study that could identify you, then you must give special written permission for their use. In that case, you will be given the opportunity to view or listen, as applicable, to the photographs, audiotapes, or videotapes before you give your permission for their use if you so request.

Request for More Information

You may ask more questions about the study at any time. The investigators will provide their telephone number so that they are available to answer your questions or concerns about the study.

Refusal or Withdrawal of Participation

You do not have to participate in this study. Your present or future interactions with the psychology department will not be affected should you choose not to participate. If you decide to participate, you can change your mind and drop out of the study at any time without affecting your present or future interactions with members of the Psychology Department and with no loss of credit for participation.

Signature

I confirm that the purpose of the research, the study procedures, and the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. All my questions have been answered. I have read this consent form. My signature below indicates my willingness to participate in this study.

_____ (Signature) _____ (date)

_____ (Print Name)