

TROY UNIVERSITY

Institutional Review Board



Policies & Procedures

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INSTITUTIONAL REVIEW BOARD – TROY UNIVERSITY
POLICIES AND PROCEDURES

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Prepared with the assistance of the members of the IRB Policy and Procedure Review Committee

Also available on the web

<http://trojan.troy.edu/institutionalreview/>

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1. Introduction

1.1. Mission Statement

Troy University's Institutional Review Board (IRB) functions as the IRB for TROY. Institutional Review Boards are committees mandated by the National Research Act, Public Law 93-348, to be established within each university or other institution that conducts biomedical or behavioral research involving human subjects. The policies and regulations of the IRB are guided by federal rules and regulations and are based on 45 CFR part 46, Protection of Human Subjects Code of Federal Regulation and the Belmont Report. According to 45 CFR, at institutions receiving federal funds all research involving human participants must be reviewed and approved by an IRB.

In reviewing research proposals, the IRB performs an assessment of risks and anticipated benefits that involves:

1. Identifying the risks associated with the research, as distinguished from the risks the participants would encounter even if not participating in research;
2. Determining that the risks will be minimized to the extent possible;
3. Identifying the probable benefits to be derived from the research;
4. Determining that the risks are reasonable in relation to the benefits to research participants, if any, and the importance of the knowledge to be gained;
5. Assuring that potential participants will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits;
6. Determining intervals of periodic review, and, where appropriate, determining that adequate provisions are in place for monitoring the data collected;
7. Protecting the confidentiality of participants to the greatest extent possible.

In addition, the IRB will determine the adequacy of the provisions to protect the privacy of research participants and to maintain the confidentiality of the data, and where participants are likely to be members of a vulnerable population, determine that appropriate additional safeguards are in place to protect the rights and welfare of these research participants.

1.2. Purpose of the Institutional Review Board

The purpose of the IRB is to review and approve ALL RESEARCH STUDIES INVOLVING HUMAN SUBJECTS across TROY. As defined in Title 45 of the *Code of Federal Regulations*, a human subject “means a living individual 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.”

The major function of the IRB is to ensure protection of the rights of human subjects who participate in research endeavors conducted by TROY faculty, staff, students, or any other individual, such as adjunct faculty, who is directly affiliated with TROY during the period in which research would be conducted. In ensuring such protection, the IRB specifically performs an assessment of risks and

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anticipated benefits, and where the participants are likely to be members of a vulnerable population, determines that appropriate additional safeguards are in place. Researchers not affiliated with Troy University who would like to conduct research on Troy University students, faculty, or staff must request permission from the TROY IRB.

1.3. Policy Violations

If allegations of violation of policies on research with human subjects are made, the IRB and the Human Protections Administrator will investigate the allegations. If the IRB or the Human Protections Administrator determines that violation of the policy have taken place, the board will take one or more of the following actions:

1. The project will be halted and researchers informed of corrections to be made before research can begin again. These corrections must be implemented and presented to the Board for review within 30 days of the notification.
2. Violations of the policy will be reported to the appropriate offices, who will decide on appropriate disciplinary actions and penalties.
 - a. Faculty: Department Chair/Academic Supervisor; Faculty Development Committee (if the research is funded by the Faculty Development Committee)
 - b. Graduate Students: Faculty Advisor; Department Chair/Academic Supervisor; Dean of Student Affairs; College Dean; Dean of the Graduate School
 - c. Undergraduate Students: Faculty Advisor; Department Chair/Academic Supervisor; Dean of Student Affairs; College Dean
3. The offices will report their decisions and penalties to the IRB.

1.4. Process for IRB Review and Update of Policies and Procedures

Federal guidance for Institutional Review Boards is periodically updated and changed. Also, issues may arise at TROY that will necessitate changes in IRB policies and procedures. With these potential changes in mind, the IRB will systematically review its current policies and procedures every three years or as needed. All changes to the policies and procedures must be approved by a majority vote of the IRB.

1.5. Website Update

The IRB website will be reviewed and updated at least every year, at the beginning of the Fall semester.

1.6. Meetings/IRB Minutes

The IRB is scheduled to meet on a monthly basis. Each meeting is scheduled for two hours. The meeting schedule for each new academic year will be posted on the IRB website in August for each new academic year.

All proposals that require Full Review must be submitted with all required attachments in a single document at least two weeks prior to the scheduled meeting date.

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Minutes for the meetings are posted on the TROY Standing Committee website once they are approved by the Board.

1.7. Approval Timeframes

The following is a general guide for the minimum amount of time that a proposal will take to review. Many factors can increase the review time, including semester breaks and unusual numbers of proposals being submitted in a short time frame. Proposals that are missing necessary elements will not be reviewed until the application together with every required attachment is received by the IRB.

Proposals will be reviewed and approval made according to the following schedule:

1. Proposals that qualify for "Exemption" status: three - five days
2. Proposals that qualify for "Expedited" review: one - two weeks
3. Proposals that necessitate "Full" review: will be reviewed at a scheduled IRB meeting. The Board's decision will be sent to the Principal Investigator(s) within three working days after the meeting.

See "Types of Reviews" on the IRB webpage to estimate the probable review status of your research http://trojan.troy.edu/institutionalreview/types_of_review.html. The IRB Chair decides what type of review is required.

1.8. IRB Members

Faculty representatives to the IRB are appointed by the deans from the faculty who are knowledgeable of (but not necessarily actively engaged in) research or who teach the research courses in each College. The Vice Chancellor for Global Campus will appoint three faculty members from separate Global Campus Regions. The Senior Vice Chancellor for Academic Affairs and Campus Vice Chancellors will appoint knowledgeable community professional representatives from the Dothan, Montgomery, Phenix City, or Troy communities upon the recommendation of the IRB Chair. Each faculty representative is appointed for a three-year term and may only be appointed for two consecutive terms. Members of the IRB consist of the following representatives: Faculty Members:

College of Arts and Sciences (1)

College of Business Faculty (1)

College of Education Faculty (1)

College of Communications & Fine Arts Faculty (1)

College of Health and Human Services Faculty (1)

Troy Dothan Campus (1)

Troy Montgomery Campus (1)

Troy Phenix City Campus (1)

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Troy Campus (1)

Global Campus (3 separate Divisional representatives)

Appointed Community Professional Representatives: (2)

Member(s) by Position:

Human Protections Administrator

Director of Sponsored Programs

Ex officio Member(s):

Dean of the Graduate School

1.9. Chair election

The IRB will elect a member to serve as Chair-Elect for a one year training period, after which the member will serve a one-year term as Chair. During the training year, the Chair-elect will attend IRB training workshops and conferences as they become available and needed. To help the Chair-elect better understand the day-to-day operations of the IRB, the Chair will send the Chair-elect copies of all IRB email correspondence. At the beginning of a Chair's year of serving as Chair, the Board will elect another member to serve as Chair-elect. After a year of service, the Chair will serve as Past Chair for a year. The Past Chair will help the new Chair in an advisory capacity.

1.10. Records Retention Requirements

The IRB keeps both electronic and paper copies of all records. Paper copies of records will be readily accessible to IRB members and staff for three years. After this period, paper records are moved to long-term storage. Electronic copies of records will be retained permanently on a storage device that is readily accessible to IRB members. Records will include the following:

1. Proposal files that include the applications and all correspondence and decisions pertaining to a particular study
2. Approved minutes of IRB meetings
3. IRB member and Principal Investigator training certificates and lists of training workshop attendees
4. Membership Files and IRB Roster
5. Documentation and notes on training conferences and workshops attended by the IRB Chair, the Chair-elect, or other IRB members
6. Copies of slides and attendance lists of IRB Training Workshops

2. Training in the Protection of Human Participants

2.1. Training for Principal Investigators

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All researchers will read the FAQ page and the Definitions page on the IRB website and will complete approved training before they submit applications to the IRB. Proof of training completion should be attached to each application. Once researchers have completed their initial training, they must complete refresher training every three years.

The training will provide researchers with basic information on human subjects' rights, and will also guide them in preparing their applications and their informed consent documents. The training requirement may be satisfied in one of these different ways:

1. Attendance at an IRB Training Workshop. The IRB Chair will organize and conduct training workshops at a regular basis for each campus and site. IRB campus and site representatives will assist in scheduling and organizing the workshops. Each workshop will be open to all TROY faculty, staff, students, or any other individual, such as adjunct faculty, who is directly affiliated with TROY during the period in which research would be conducted. After attending the workshop, researchers must take the Training Quiz located and must obtain a score of 80% or higher to "pass" the training. Researchers will keep a copy of their proof of successful quiz completion and will submit it with each application.
2. Completion of the on-line IRB Training Workshop. After watching the PowerPoint, researchers must take the quiz at the end and must obtain a score of 80% or higher on the quiz to "pass" the training. Researchers will keep a copy of their proof of successful quiz completion and will submit it with each application.

2.2. Training for IRB Members

All IRB members will complete required on-line training before they review any research. The training will provide members with in-depth information on human subjects' rights and appropriate research procedures. Members will complete the Assurance training at the Office for Human Research Protection [OHRP] website at <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>. They will print out the certificate of completion for each of the modules, and will send copies to the Chair of the IRB.

The Chair of the IRB will attend at least one IRB workshop or conference per year. The Chair will give periodic training sessions during IRB meetings on new information learned during these workshops. The Chair will also provide IRB members with updated information obtained from the OHRP website as needed.

2.3. HIPAA

The IRB membership must include at least one member who has completed Health Insurance Portability and Accountability Act (HIPAA) training.

3. General Research Procedures

3.1. Qualifying Research Studies

All research involving human subjects conducted by TROY faculty, staff, students, or any other individual, such as adjunct faculty, who is directly affiliated with TROY during the period in which

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research would be conducted must be submitted to the IRB for review and approval before recruitment or data collection may begin. "Faculty" is defined as any individual, whether full-time or adjunct, who will be teaching at least one class for TROY during the study period. A person is considered a TROY student if they are enrolled in at least one class during the study period.

3.1.1 Conducting Research for Outside Institutions

TROY faculty, staff, and students who wish conduct research that has been approved by the IRB of an outside institution must also apply to the Troy University IRB for approval, regardless of where the research is conducted. In order to ensure compliance with federal research guidelines, the approval letter from the other IRB should be attached to the application.

3.1.2 Animal Research

Animal research studies need to be submitted to and reviewed by the TROY Animal Research Review Board. Further information and instructions can be found at http://trojan.troy.edu/institutionalreview/animal_research.html.

Research that involves the use of the following types of data should NOT be sent to the TROY IRB:

- Secondary data sources:
 - Literature reviews, or propositional studies
 - Publicly available documents, such as newspapers, magazines, books and websites
 - Private documents of deceased individuals, such as journals, diaries, letters, emails, with appropriate legal approvals
 - Publicly available audiovisuals, such as video and audio tapes and disks, software, and film
 - External databases that do not contain any information that can be used to identify individuals:
 - Government, such as Census, Bureau of Labor Statistics (BLS)
 - Stock market (Compustat)
 - Trade association data
 - Other existing quantitative databases
- Case studies of organizations that do not involve human subjects
- Research that will not be published in any manner accessible by the public (e.g. manuscript, paper or poster presentations, website, etc.).
- Internal data:
 - Corporate, such as customer or accounting data
 - Workplace research conducted solely for institutional use and not accessible to the public.
 - Student conducted research that will not be published, other than theses and self-research.

3.1.3 Outside Researchers

Researchers not affiliated with Troy University as a current employee or student (hereafter referred to as outside researchers) but who wish to recruit TROY students, staff, or faculty for participation in research projects must do the following:

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1. Contact the Troy University IRB to request permission. The outside researcher shall include his/her IRB application from his/her home institution; that institution's official IRB letter of approval; all related materials (e.g., surveys, questionnaires, informed consent documents); and a brief letter addressed to the TROY IRB explaining in what way he/she would like Troy University to cooperate with his/her research project. The outside researcher shall also submit the Outside Research IRB Form.
2. After the TROY IRB receives the signed Outside Research IRB form, the IRB chair will review the application, possibly requiring a second review from another board member, sub-committee, or convening the full IRB at his/her discretion.
3. The IRB chair will forward his or her recommendation to the Human Protections Administrator (HPA) for final approval. A letter will be sent to the outside researcher once the HPA has made his/her decision.
4. The outside researcher is responsible for obtaining any necessary approvals from his/her home institution's IRB. He/she must promptly report any proposed changes in approved research or any unanticipated problems involving risk to subjects or others to the TROY IRB. Permission for multi-year projects must be renewed each year.

Note: TROY IRB consideration of outside research projects is an administrative review, not an IRB review.

3.2. Research Conducted at Non-TROY Locations

All research applications for research conducted outside TROY must include permission to conduct research from the off-campus locations. These locations may include such facilities and institutions as school districts, day care centers, nursing homes, prisons, private clinics, shelters, treatment facilities, churches, or businesses.

The Principal Investigator should request written approval from the institutional entity or official with the necessary authority to approve research. Researchers should determine and follow all policy and procedures required by the host site for research involving human subjects. Research conducted in only one school needs to be approved by the school's principal. Research conducted in multiple schools needs to be approved by the school district superintendent.

If the research is federally supported, then the Principal Investigator must obtain assurances for performance sites engaged in the research if these sites do not have an appropriate OHRP or federally-approved assurance.

3.3. Student Research

All TROY students taking at least one class during the study period must submit their proposals to the IRB for review and approval if they are conducting an actual "research" study. In this instance, a study is not considered "research" unless it is designed for public display of the data or the results, including, but not limited to, poster or paper presentations, journal articles, or Internet postings.

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Students conducting research solely for class purposes, and who do not plan on placing the results in any source in which it can be publicly viewed, do not have to submit their proposals to the IRB for review, with the exception of theses and self-research. In these cases their class instructors have the responsibility of ensuring that the students' research protects the rights of human subjects. Whenever possible, instructors should guide their students into developing and conducting studies that would be considered "Exempt" from IRB review. It is recommended that instructors who supervise student research hold current IRB training certification. Under no circumstances may students conduct any research without faculty approval and oversight. It is the responsibility of the faculty adviser to verify the complete and proper completion of the student researcher's IRB application.

Each student must have a faculty member sign off on each proposal certifying that the faculty member will do the following:

1. Oversee the work described
2. Ensure that all of the PI responsibilities are fulfilled
3. Check application for content, clarity, and methodology to ensure that it is in compliance with the Troy University IRB Policies and Procedures. If the faculty member is a co-Principal Investigator of the study, or if he/she plans on being a co-author on the published results, he/she must also obtain the signature of his/her academic supervisor on the application.

If students are conducting thesis or dissertation research, they must submit copies of their completed "Human or Animal Subjects Review" form to the IRB after their proposal is approved. These forms must be signed by their Thesis or Dissertation Committee Chair prior to submission to the IRB. Students must submit enough forms so that there is one for each bound copy of their thesis or dissertation. All of the copies must be on the same bond paper that they are using for their theses or dissertations.

3.4. Scientific Merit

In evaluating the benefit-to-risk ratio of research studies, the IRB must look at the scientific or scholarly validity of the research. The IRB will limit this evaluation to determining whether the research will result in benefits, either to the participants or to the advancement of knowledge in the subject area, that outweigh the risks of the research. Poorly designed studies that will not yield valid results or other benefits will not be approved. The IRB may seek advice from external consultants if the research design is outside the members' areas of expertise.

3.5. Confidentiality

To limit the risks of research study participation, confidentiality must be maximized in all studies. Confidentiality procedures must be described in detail on the IRB Application (in the "Risks of Participation" section). To maximize confidentiality researchers should not collect any data, especially demographic, unless doing so is necessary and they have specific plans to analyze or otherwise make use of the data. Projects that will address sensitive, stigmatizing, or illegal subjects must explicitly outline the steps that will be taken to assure that individual participant responses will not be seen or known by anyone outside the research team. Sensitive subjects are those which could affect a person's reputation or employability, including, but not limited to, the following: any addictive behaviors, any illegal behaviors, antisocial tendencies, sexual preferences or behaviors,

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religious preferences or beliefs, political beliefs, or attitudes towards work or supervisors. In some cases, information may be sensitive only in certain situations or contexts, and this will be taken into consideration by the IRB.

The requirement of signed consent forms is often waived in sensitive studies, if the consent document is the only written record linking participants to the project and a breach of confidentiality presents the principal risk of harm anticipated in that research. If there is any chance that data or participants' identities might be sought by law enforcement agencies or subpoenaed by a court, the IRB may require that researchers request a certificate of confidentiality. This is a federal document that grants legal immunity from forced data and participant identity disclosures. See "Certificates of Confidentiality" for contact and application information.

3.6. Certificates of Confidentiality

When data are being collected about sensitive issues (such as any addictive behaviors, any illegal behaviors, antisocial tendencies, sexual preferences or behaviors, religious preferences or beliefs, political beliefs, or attitudes towards work or supervisors), Principal Investigators may consider applying for a certificate of confidentiality. Under federal law, researchers can obtain an advance grant of confidentiality that will provide protections against a subpoena for research data [Public Health Service Act 301 (d)]. Protection will be granted sparingly and only when the research is of a sensitive nature and where the protection is judged necessary to achieve the research objectives. See the Certificates of Confidentiality page for more information. In some cases the IRB may require Principal Investigators to obtain certificates of confidentiality prior to beginning their research.

3.7. Conflict of Interest

IRB members who have a conflict of interest with a specific study may not participate in the review of a proposal, except to present the study and/or answer questions. If a member has a conflict of interest with a particular study they must leave the meeting room during the final discussion and vote. Conflicts of interest will be considered present if any of the following apply:

1. The IRB member and/or family member and/or business interests will benefit financially from the research
2. The IRB member is a principal investigator of the project or is otherwise on the research team
3. The IRB member is the supervising faculty member for a student project

In the case of the IRB Chair having a conflict of interest, the Chair-elect or designee will preside over the discussion and vote of the proposal.

Consultants found to have a conflict of interest will not serve as consultants for the study under review.

3.8. Minimizing Coercion

When recruiting participants, coercion, or even the appearance of coercion, should be avoided whenever possible. There are several institutional settings where the potential for coercion is particularly high because of the researcher/participant relationship. If at all possible, Principal

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Investigators should avoid these situations. However, if the success of the research project depends upon research being conducted in these settings, PIs should take additional precautions when obtaining informed consent. These precautions should be explained in the "Description of Participants and Recruitment" section of the application. The following relationships are inherently potentially problematic:

1. The instructor/student relationship. Students at all levels, from pre-K through college, may feel pressured to agree to participate in research studies conducted by their teachers. If at all practicable, teachers should have another member of the research team recruit the participants and collect the data. It should be made very clear to the students that participation or non-participation will not affect their grades. If extra credit is offered to students for participation, then an alternative extra credit activity must be offered to those who do not wish to participate. The alternative extra credit activity must not require more time and effort than study participation.
2. The employer/employee relationship. Employees may feel pressured to agree to participate in research studies conducted by, or presented to them, by their employers. Employers should refrain from asking their employees to participate in any research studies where the employee's identity is linked to, or can otherwise be traced to, the data. It should be made very clear to the employees that participation or non-participation will not affect their employment in any way. If at all practicable, employers should have another member of the research team recruit the participants and collect the data.
3. Institutional representatives/institutionalized individuals. Individuals who reside in institutions may feel pressured to agree to participate in research studies conducted by, or presented to them, by representatives of the institution. If at all practicable, someone who is not part of the institution should recruit the participants and collect the data. It should be made very clear to the participants that participation or non-participation will not affect their relationships with the institutions.

3.9. Changes in Research Proposal

Principal Investigators are responsible for promptly reporting to the IRB any proposed changes in approved research. These changes may not be initiated without IRB review and approval, except when necessary to eliminate immediate hazards to the subject. PIs may notify the IRB of the proposed changes by sending a detailed email to the IRB Office. If changes will be made to any research instrument, including the addition of questions to an approved survey, the modified instrument must be sent as an attachment. The IRB Chair will inform the PI if additional information or review is required.

3.10. Continuing Review of Approved Studies

All research studies approved by the IRB need to be reviewed at least once a year. Studies involving high levels of risk or studies where the level of risk is unknown will need to be reviewed more frequently. The review date for each study will be specified in the approval letter. The IRB will send written notification to the PIs at least 45 days before the approval expires. PIs who wish to continue recruiting participants or collecting data after the approval expires need to submit a Continuing Review application form.

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3.11. Unanticipated Problems

Principal Investigators are responsible for promptly reporting to the IRB any unanticipated problems involving risks to subjects or others. PIs may notify the IRB of the unanticipated problems by sending a detailed email to the IRB Office. The IRB will review the study and will inform the PI of needed proposal changes. If the unanticipated problems are severe, the IRB may suspend or terminate its approval and the study must immediately be halted.

4. Application Package Preparation and Submission

4.1. General Procedures

Principal Investigators must create and include electronic versions of the application form and all required additional documents. Applications cannot be reviewed until all required elements are received by the IRB office as a single electronic document.

Before any application and accompanying documents are submitted to the IRB for review, all Principal Investigators for the project must complete PI training. See the Training link for details. PIs should also read the "Frequently Asked Questions (FAQ)" page on the website.

The PI should print out the signature page and obtain the appropriate signatures. Each PI as well as the immediate supervisor of each faculty or staff PI must sign the signature page. If the proposal is for a student project, the faculty member overseeing the project should sign the signature page. This page should then be scanned into the complete electronic document.

Principal Investigators must convert the application with ALL attachments into one electronic document in MS Word or .pdf format). The submitted application should be less than one MB in size. Informed consents documents shall be sent separately as MS Word documents. Complete applications shall be submitted to the IRB office at irb@troy.edu.

4.2. The Application Document

Principal Investigators should complete all parts of the "Application for Institutional Review Board Review" form. They also need to create and include in the form or append all of the following additional documents.

4.2.1 Grant Proposals

In studies where funding is being sought from any source, whether on or off campus, one copy of the grant proposal must be attached to the study proposal application package.

4.2.2 Thesis and Dissertation Research

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When research is being conducted for a student's thesis or dissertation, one copy of the complete Methods Section shall be attached.

4.2.3 Research Instruments

Research instruments consist of copies of any survey, questionnaire, and/or interview questions. Graphical and verbal stimuli, if not completely described on the IRB application form, should be attached or a complete citation provided. Researchers are advised to obtain permission for all copyrighted material.

4.2.4 Debriefing

Whenever deception is involved as part of the research or information is withheld from a participant prior to or during the research, this information must be disclosed to the participant at the close of the research either verbally or in writing, unless doing so increases the risks associated with participation. A copy of this statement must be attached.

4.2.5 Recruitment Material

If participants will be obtained through advertisements, flyers, emails or other solicitations, include copies of your recruitment materials as part of your IRB submission.

4.2.6 Certificates of Confidentiality

When data are being collected about sensitive issues (any addictive behaviors, any illegal behaviors, antisocial tendencies, sexual preferences or behaviors, religious preferences or beliefs, political beliefs, or attitudes towards work or supervisors), Principal Investigators may consider applying for a certificate of confidentiality. Under federal law, researchers can obtain an advance grant of confidentiality that will provide protections against a subpoena for research data [Public Health Service Act 301 (d)]. Protection will be granted sparingly and only when the research is of a sensitive nature and where the protection is judged necessary to achieve the research objectives. See Information about Certificates of Confidentiality for more information. For information on how to obtain a Certificate, see Certificates of Confidentiality Contacts.

4.2.7 Permission from Institution

If conducting research in a location outside TROY, the Principal Investigator must provide written approval from the institutional entity or official with the necessary authority to approve research. This may take the form of a letter or an email.

4.3. Informed Consent

Informed consent documents are required for every proposal involving human subjects.

4.3.1 Requirements for Informed Consent

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Principal Investigators are responsible for ensuring that all potential research participants are given enough information to make an informed decision on whether or not to participate in a study. PIs must also guard against coercing participation, or even the appearance of coercion. The informed consent process helps address these issues. This should be considered as an on-going process, and questions from research participants must be answered at any time during the research study. Also, PIs must immediately inform participants of any new information that may affect the research risks or requirements. A main component of the informed consent process is the informed consent document. This document is required for all research studies involving human subjects.

In any research where a participant's identity or identifying information will be recorded (including on "coded" lists accessible only to the PI), the signature of the participants verifying that they have read the informed consent document and agree to participate in the study must be obtained by the Principal Investigator. In addition, participants must be given copies of the informed consent documents to keep.

In research where the PI assures participants' anonymity, in which a signed informed consent document would be the only object linking a participant to the research study, written informed consent should not be collected. Instead, the document should be either read (in the case of telephone interviews) or provided to the participant to read before data are collected. In the case of web-based studies, the informed consent document should be on the initial screen that the participant sees. The participant should be able to indicate by clicking one of two buttons: (1) they have read the document and agree to participate in the study. In this case clicking the button will bring them to the research instrument; or (2) they do not wish to participate in the study. In this case clicking the button will bring them to an exit page.

Principal Investigators of research studies involving children or individuals with impaired decision-making capabilities must receive written informed consent from parents or legally authorized representatives.

PIs may only use IRB-approved and stamped informed consent documents in their research.

4.3.2 Elements of Informed Consent

Every informed consent document must contain the following, written at the participants' level of understanding:

1. A statement of who the researchers are and their affiliation with TROY.
2. A statement of the purpose of the study. If the research design makes it essential that the participants do not know the purpose of the study before their participation, then this statement may be omitted.
3. A detailed description of the procedures, including a listing of how many sessions will be required, and how long each session will last.
4. An explanation of the potential risks of study involvement, and an explanation of what the researchers will do to minimize these risks.
5. A detailed explanation concerning how confidentiality will be handled. This section should include an explanation of how the data collection procedure will help ensure confidentiality;

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a listing of the people who will have access to the raw data or the coded lists; and a description of where the data will be kept and for how long it will be kept. If this is a web-based study, participants should be told whether the IP address of their computer will be recorded and/or linked to particular responses.

6. A listing of the benefits of participation. This should include direct benefits to the individual, if any, and/or benefits to society
7. An explanation of alternatives to participation.
8. A statement that the participation is voluntary and participants may decide to leave the study at any time, without repercussions. If identifying information is on the data, then a statement that their data may be withdrawn from the study at any time must be included as well.
9. Contact information for the researcher and the TROY Institutional Review Board.

The informed consent document should not include exculpatory language through which subjects waive any of their legal rights or releases or that appear to release the investigator, sponsor, or institution or its agents from liability for negligence.

For additional information, see sample consent forms.

4.3.3 Verbal Assent Forms

In addition to receiving written informed consent from the legal representatives of children or individuals with impaired decision-making capabilities, Principal Investigators must also obtain verbal assent from the participants before research can be conducted. PIs must submit a "Verbal Assent" script for any research that includes children or impaired individuals. This script should contain all the information contained in the written consent document, but the language should be simplified to be easily understood by the participants. This script should be read to each participant verbatim. After it is read, the researcher should ask the participants if they have any questions and if they are willing to participate.

For additional information, see sample verbal assent forms.

4.3.4 Research on Non-Native English Speakers

If the research participants do not speak English fluently then the informed consent document must be translated into their native language, and a cross-translation of this document must be submitted to the IRB.

Undergraduate or graduate university students who qualify to be admitted to regular college classes are considered to be fluent in English and may be given an English version of the consent document. Written documents should be used whenever possible.