



Institutional Review Board For
Human Subjects Research

APPLICATION FORM

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You must have IRB Approval **before** you can start any project using human research subjects. **Please type your responses (Word document) or use ink (PDF)** to complete this form and submit it to the IRB/Research Services Office.

Primary Investigator Name:		Phone No.:
Email Address:	Campus Box No.:	Department:
Title of Project:		
Funding Source/Agency:		Project Start and End Dates:
<p>If this a class or practicum research project, please provide the class name and number (e.g. English 421), and the instructor's name:</p> <p>Class: _____</p> <p>Instructor: _____</p>		

Additional Investigators / Researchers: Who else will be working on this project? This list should be updated annually unless there is a major change in personnel. Major changes in personnel (e.g. change of P.I.) must be reported immediately on a revision form and the change must be noted on the consent form.

Name:	E-Mail and Campus Box No.:	Phone:	Role in Project:
	CS Box:		
	CS Box:		
	CS Box:		
	CS Box:		
	CS Box:		

NOTE: If your project has more than five investigators, please list the remaining personnel on an additional sheet and attach it to this form.



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SECTION I — HUMAN SUBJECTS PARTICIPATION

How will you interact with your project’s participants?

1. Are you collecting any Personally Identifiable Information from your participants?

Please check all applicable boxes:

<input type="checkbox"/> Name	<input type="checkbox"/> Physical address/ Phone number
<input type="checkbox"/> Identification Number (Social Security Number or Tech Student ID Number)	<input type="checkbox"/> Email Address and/or IP Address (for web-based survey research and/or user testing purposes)
<input type="checkbox"/> Sensitive health or medical information (i.e., HIV status, drug/alcohol use, mental / emotional issues, etc.)	<input type="checkbox"/> Audiotape recordings, videotape recordings, or photographic images of participants
<input type="checkbox"/> Other sensitive information that could harm participants if it became known (i.e., criminal acts, risky behaviors, etc.)	<input type="checkbox"/> Blood, tissues, fluids, or DNA from participants
<input type="checkbox"/> Check this box if your project will NOT collect any of the data listed above	

2. What type of research are you performing with your participants?

Please check all applicable boxes:

<input type="checkbox"/> Survey / Questionnaire / User Testing -- Participants take a survey or questionnaire to evaluate or describe their use of a program, software, equipment, service, or class; or take a test to determine retention or skill development.
<input type="checkbox"/> Interview -- Interviewing or actively interacting with participants in the following setting: <input type="checkbox"/> An educational setting (i.e., in a classroom, library, school/university meeting room, etc.) <input type="checkbox"/> A NON-educational setting (i.e., conducted at a supermarket/mall, park, church, via telephone, in homes)
<input type="checkbox"/> Observation -- Passive (non-interactive) observation of participants in the following setting: <input type="checkbox"/> An educational setting (i.e., in a classroom, library, school/university meeting room, etc.) <input type="checkbox"/> A NON-educational setting (i.e., conducted at a supermarket/mall, park, church, via telephone, in homes)
<input type="checkbox"/> Social / Behavioral Research —Investigating individual / group characteristics or behaviors (e.g., research on political / religious / cultural beliefs, perception, cognition, motivation, identity, language, social behaviors). <input type="checkbox"/> Data to be collected is benign (participants’ beliefs, opinions, perceptions) <input type="checkbox"/> Data to be collected is sensitive health, medical, or personal information (e.g., HIV status, drug/alcohol use, mental/physical disorders; illicit or criminal behavior; sexual preferences; or other information that could cause harm to the participant if it became known in the community)
<input type="checkbox"/> Biological Research – Please complete the following page to describe your project to the IRB.



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FOR BIOLOGICAL RESEARCH ONLY:

1. What biological research procedures will you perform on your project's human participants?

Please check all applicable boxes:

<input type="checkbox"/> Cheek swab for cells or DNA	<input type="checkbox"/> Urine sample
<input type="checkbox"/> Needle / lancet stick to obtain drops of blood	<input type="checkbox"/> Blood draw of approx. _____ cc.
<input type="checkbox"/> Exercise or physical testing	<input type="checkbox"/> Non-invasive procedures (MRI, EEG, EKG, sensors)
<input type="checkbox"/> NOT APPLICABLE: Project uses only blood / tissues / fluids / DNA provided by a non-NM Tech source Source:	
<input type="checkbox"/> OTHER: Please make sure you attach a thorough written description of the research procedures used by your project	

2. What level of risk will your participants experience during your research?

<input type="checkbox"/> MINIMAL – The potential harm or discomfort experienced are not greater than those ordinarily encountered during routine physical or psychological exams or tests.	<input type="checkbox"/> GREATER THAN MINIMAL RISK – The potential for harm or discomfort might cause a participant to feel unsure about participating, or could cause the participant to become ill or incapacitated.
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3. Will your project's participants be informed of the risks involved with the procedure before they participate?

<input type="checkbox"/> YES – A complete description will be provided to each participant	<input type="checkbox"/> NO – Please see the IRB administrator for more information
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4. Do you have procedures in place for emergency care if a participant requires it?

<input type="checkbox"/> YES – A procedure or provision for emergency care is included in this research project	<input type="checkbox"/> NO – Please see the IRB administrator for more information
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5. Has a qualified M.D. participated in planning this research project?

<input type="checkbox"/> YES – The research project was planned with guidance from the following physician: 	<input type="checkbox"/> NO – Please see the IRB administrator for more information
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SECTION II — TYPES OF DATA COLLECTED BY PROJECT

What type(s) of data will be collected by your project?

Please check all applicable boxes:

<p><input type="checkbox"/> New or novel data produced during the course of the project:</p> <p><input type="checkbox"/> Anonymous data gathered by survey, questionnaire, or test</p> <p><input type="checkbox"/> Personally Identifiable Information and additional data gathered by survey/questionnaire/test/interview:</p> <p><input type="checkbox"/> Data to be collected is benign (beliefs, opinions, perceptions)</p> <p><input type="checkbox"/> Data to be collected is sensitive health, medical, or personal information (e.g., HIV status, drug/alcohol use, mental/physical disorders; illicit or criminal behavior; sexual preferences; or other information that could cause harm to the participant if it became known in the community)</p> <p><input type="checkbox"/> Biological specimens or physiological data <u>drawn or collected by the NM Tech researcher</u></p> <p><input type="checkbox"/> Photographs, audiotape, videotape/ film of participants</p> <p><input type="checkbox"/> OTHER: please describe:</p>	<p><input type="checkbox"/> Already-existing data from the following source(s):</p> <p><input type="checkbox"/> Public data sources (library, archives, Census information, etc.)</p> <p><input type="checkbox"/> Data from Social Networking sources (Facebook, MySpace, etc.)</p> <p><input type="checkbox"/> Non-public data sources (personnel files, medical files, financial files, etc.)</p> <p><input type="checkbox"/> Biological specimens <u>provided by a non-NM Tech source</u></p> <p><input type="checkbox"/> Other: please describe:</p>
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SECTION III – DATA SECURITY AND CONFIDENTIALITY

1. How will you keep your project's data secure during the duration of the project?

(If your project is collecting Personally Identifiable Information, you MUST ensure that ALL such data is kept secure and fully confidential.)

2. What will you do with your project's data at the conclusion of your project?

(All Personally Identifiable Information MUST be destroyed at the conclusion of your research project.)



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SECTION IV – YOUR RESEARCH POPULATION

What types of subjects are participating in your research project?

Please check all applicable boxes to describe your research subjects:

<input type="checkbox"/> NM Tech Students (age 18 and older)	<input type="checkbox"/> Children / Minors under age 18
<input type="checkbox"/> NM Tech Faculty	<input type="checkbox"/> Women only
<input type="checkbox"/> NM Tech Staff or Employees	<input type="checkbox"/> Minorities only
<input type="checkbox"/> Adults (age 18 and older) not affiliated with NM Tech	<input type="checkbox"/> Prisoners only

SECTION V – TRAINING REQUIREMENTS FOR RESEARCHERS

Have you completed any training programs on Human Subjects Research?

Please check all applicable boxes to describe your training:

<input type="checkbox"/> For Social / Behavioral Research: UCLA CTRL Online Training Course: http://www.training.arc.ucla.edu/ucla/
<input type="checkbox"/> For Biological / Medical Research: The NIH Office of Extramural Research's <i>Protecting Human Subject Research Participants</i>: http://phrp.nihtraining.com/users/login.php
<input type="checkbox"/> I have not taken either training course All NM Tech researchers are strongly urged to take one or both of the online training courses listed above before performing any Human Subjects Research. Federal law requires PIs to be adequately trained before starting Human Subjects Research projects.

SECTION VI – SUPPORTING DOCUMENTATION

Please attach the following items to this Application Form:

- A written research plan that describes how your project will use human subjects. If your research proposal does not provide specific information about how human subjects will be used in your research project, please download and fill out **FORM A: RESEARCH DESCRIPTION** and submit it with this Application.
- Samples of all documents to be used in your project (including questionnaires, surveys, tests, advertisements, flyers, permission slips, procedure descriptions given to participants, etc.)
- A sample of the Informed Consent document you will use in your project (please see the Informed Consent Requirements attached to the end of this Application Form)
- A copy of your IRB Training Course completion certificate (if available)

After completing this Application Form, send it and all attachments to the IRB/Research Services Office, Room 111B, Brown Hall



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PRINCIPAL INVESTIGATOR ASSURANCE:

As the PI on this project, I hereby assure that I will follow procedures to ensure that the rights and welfare of the participants will be safeguarded and protected. I will not begin data collection until I receive a written approval from the IRB.

Signature of Principal Investigator/ Researcher:

Date:

Faculty Advisor Assurance for Student Research Projects:

As faculty advisor to this project, I hereby assure that I will be responsible for supervising the project, and that the student(s) working on this project will follow procedures to ensure that the rights and welfare of the participants will be safeguarded and protected.

Signature of Faculty Advisor:

Date:

For IRB Use ONLY:

Date Received by IRB Administrator:

IRB Database No.:

Protocol qualifies for: Exempt (administrative) Review

Expedited Review

Full Board Review

Administrative Review completed on:

Expedited Review completed on:

Full Board Review completed on:

Notification of IRB decision sent to PI on:

MEMO TO: PIs on research projects that use human subjects
 FROM: New Mexico Tech’s IRB

Informed consent MUST always be sought from the participants in your research project.

These four pages describe what you must do to provide and obtain informed consent from your research subjects. Please keep these four pages for your records.

The type of Consent Form that your project should use will depend on the type of information it collects, and whether your participants are adults or minors. See the table below to determine which type of consent your project will need to obtain from participants.

Type of Information Collected / Type of Participant
If your research project <u>DOES NOT COLLECT</u> Personally Identifiable Information, you can obtain informed consent by adding the paragraph listed on page 2 to your documents.
If your research project <u>COLLECTS</u> Personally Identifiable Information, you must obtain a signed Consent Form from each participant. The requirements that your Informed Consent document must meet are described on page 3.
If your research project includes <u>MINORS</u> (persons under age 18), you must receive a signed Assent Form from each minor participant, as well as a signed Consent Form from the minor’s parent. The requirements that your Assent document must meet are described on page 4
Additionally: If you are performing your research project within a school setting, the school administration must also sign a Consent Form allowing your project to use their classrooms and facilities.

[If you have any questions about informed consent, please see the IRB Administrator.](#)



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Informed Consent Requirements for projects using human subjects

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Informed Consent Requirements for projects that DO NOT collect Personally Identifiable Information

If your project uses a survey, questionnaire, or test that **DOES NOT COLLECT** Personally Identifiable Information, you do not need to obtain a signed Consent Form from each participant over age 18. However, you **DO NEED** to include the following paragraph at the top of your survey / questionnaire / test document:

The Institutional Review Board for the Protection of Human Subjects at NM Tech has reviewed and approved this research project. By completing this [survey / questionnaire / test], you agree to participate in this project. Your participation in this research project is strictly voluntary and you may choose not to participate by simply not completing the [survey / questionnaire / test]. You may also refuse to answer specific questions on this [survey / questionnaire / test] if you so desire. If you have any questions or concerns about this survey / questionnaire, please contact the researcher at [provide your contact information] or the New Mexico Tech IRB Administrator at 575-835-5690.

Please note: You **CANNOT** use this type of consent if your project will survey minors (under age 18). Instead, you must get a signed Assent Form from each minor participant as well as a signed Consent Form from the minor's parent.



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Informed Consent Requirements for projects using human subjects

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Informed Consent Requirements for Projects that DO COLLECT Personally Identifiable Information

If your project DOES COLLECTS Personally Identifiable Information, you must obtain a signed Consent Form from each participant over age 18. Use the following instructions to create a valid Informed Consent Form for your project. A sample Consent Form that meets these requirements has been provided at the end of this document.

Requirements for the Consent Form:

1. **Letterhead:** The Consent Form should be printed on Department letterhead (every page)
2. **Page Numbering:** Every page of the Consent Form should be numbered using *Page X of Y* format.
3. **Page Dating:** Every page of the Consent Form should have the date that the document was created.
4. **Document Heading:** The words CONSENT TO PARTICIPATE IN RESEARCH should be centered at the top of the first page. The title of the research project should be given on the next line(s).
5. **Body of Consent Form:**
 - Provide the researcher's name, department, and a description of the procedures to be used in the research project.
 - Describe the subject's role in the project, and the expected duration of the subject's participation.
 - List any risks or discomforts that participants could experience as a result of their participation. (In projects involving surveys or questionnaires that collect non-sensitive Personally Identifiable Information, there may be no risks to participants. In projects involving sensitive issues [e.g. gathering data on drug/alcohol abuse, criminal activity, HIV status, etc.] state that there's a risk that data may be released through legal methods.)
 - State that participants can withdraw or refuse to participate in the project at any time without consequence, even if they initially agree to participate.
 - State that All research records will be kept confidential consistent with applicable federal and state regulations. State who will have access to the data, and how it will be kept (e.g., it will be kept in a locked file cabinet in a locked room). State how long the data will be kept and then how will it be destroyed, or if it will be kept indefinitely. If the study involves video or audio recordings, explain if such recordings will be destroyed in a certain period of time or kept indefinitely).
 - Include the following IRB Approval Statement: The Institutional Review Board for the Protection of Human Subjects at NM Tech has reviewed and approved this research project.
 - Provide contact information for both the PI and the IRB Administrator so that subjects can ask any questions or report any research-related problems.
6. **Signature Lines:**
 - Provide the following verification statement and a signature line for adult participants: By signing below, I verify that I have been informed of and understand the nature and purpose of the project, freely consent to participate, and I am at least 18 years of age.
 - Provide the following verification statement and a signature line for the researcher: I certify that I have explained this research project to the participant and have answered any questions raised by the participant. Underneath the researcher's signature line, print the researcher's full name and title.
7. **Two copies of Consent Form:** Provide two copies of the Consent Form to the participant. State on the Consent Form that participants will be given two copies of the Consent and they are to sign both, return one to the researcher, and keep the other for their files.

Informed Assent Requirements for projects with children or minors under the age of 18

If your project will use children or minors under age 18 as participants, you must obtain a signed Assent Form from each minor AND a signed Consent Form from each minor's parent(s). Use the following instructions to create a valid Assent Form for your project. *A sample Assent Form that meets these requirements has been provided at the end of this document.*

Requirements for the Assent Form

Minors between the ages of 7 and 17 are required by law to sign and give **assent** in addition to their parents consent. The language used on the Assent Form should be appropriate to the specific age group participating in your project.

1. **Letterhead:** The Assent Form should be printed on Department letterhead (every page)
2. **Page Numbering:** Every page of the Assent Form should be numbered using *Page X of Y* format.
3. **Page Dating:** Every page of the Assent Form should have the date that the document was created.
4. **Document Heading:** The words ASSENT TO PARTICIPATE IN RESEARCH should be centered at the top of the first page. The title of the research project should be given on the next line(s).
5. **Body of Assent Form:**
 - Use language that is appropriate to the minor's maturity level and age.
 - Provide the researcher's name, department, and a description of the procedures to be used in the research project.
 - Describe the subject's role in the project, and the expected duration of the subject's participation.
 - Include separate lines of Assent, as initialed lines: (1) assent to participate; (2) assent to be videotaped; (3) assent to be audio-taped; (4) assent to be photographed; (5) assent to have their direct quotes used in the results of the study.
 - List any risks or discomforts that participants could experience as a result of their participation.
 - State that participants can withdraw or refuse to participate in the project at any time without consequence, even if they initially agree to participate.
 - Include the following IRB Approval Statement: The Institutional Review Board for the Protection of Human Subjects at NM Tech has reviewed and approved this research project.
 - Provide contact information for both the PI and the IRB Administrator so that subjects can ask any questions or report any research-related problems.
6. **Signature Lines:**
 - Provide an understandable verification statement and a signature line for minor participants.
 - Provide the following verification statement and a signature line for the researcher: I certify that I have explained this research project to the participant and have answered any questions raised by the participant. Provide space for the researcher's signature line as well as the researcher's full name and title.
7. **Two copies of Assent Form:** Provide two copies of the Assent Form to the participant. The participant should sign both, return one to the researcher, and keep the other for their files.



CONSENT TO PARTICIPATE IN RESEARCH

Project Title: [Insert title of project here]

Department: [Insert Dept. Name here]

About the researcher and the project:

My name is [Insert PI name] and I am [a student][a faculty member in the ___ department] at New Mexico Tech. I am conducting a research project entitled [enter title]. I am asking you to take part in this research project because I am trying to learn more about [insert purpose of your project]. Your participation in this project will take [enter length of participation].

About your participation in this project:

If you agree to be in this project, you will be asked to [describe what you want the participant to do in your project].

As a participant in this project, you may be exposed to the following risks: [List potential risks to your participants here. In projects involving surveys or questionnaires that collect non-sensitive Personally Identifiable Information, there may be no risks to participants. In projects involving sensitive issues (e.g. gathering data on alcohol/drug abuse, criminal activity, HIV status, etc.) state that there's a risk that data may be released through legal methods.]

Security and confidentiality of research records:

All research records for this project will be kept confidential in accordance with federal regulations. The records for this project will be kept as follows: [State who will have access to the data, and how it will be kept (e.g., it will be kept in a locked file cabinet in a locked room). State how long the data will be kept and then how will it be destroyed, or if it will be kept indefinitely. If the study involves video or audio recordings, explain if such recordings will be destroyed in a certain period of time or kept indefinitely.)]

What if I do not want to participate?

Please understand that your participation is voluntary. Your refusal to participate will involve no penalty and you may discontinue your participation at any time without penalty.

If you have any questions or concerns about this project or your participation in it:

The Institutional Review Board for the Protection of Human Subjects at NM Tech has reviewed and approved this research project. But if you have any questions or concerns about this project or your participation in it, please contact me directly at [provide your contact information]. For additional information regarding your rights as a research subject, please feel free to contact the IRB Administrator for New Mexico Tech at 575-835-5690 or via email at smoores@admin.nmt.edu.



CONSENT TO PARTICIPATE IN RESEARCH

Project Title: **[Insert title of project here]**

Department: **[Insert Dept. Name here]**

Signature of Participant:

By signing below, I verify that I have been informed of and understand the nature and purpose of this project; that I freely consent to participate in this project; and that I am over age 18.

Participant's Signature

Your Printed Name

Date

**To the Participant: You should sign two copies of this form.
You will keep one and return the other to the researcher**

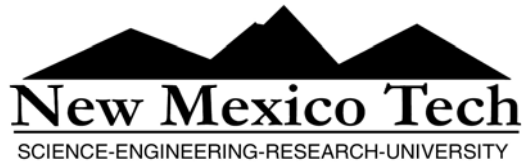
Signature of Researcher:

By signing below, I certify that I have explained this research project to the participant and have answered any questions raised by him or her.

Researcher's Signature

Your Printed Name

Date



ASSENT TO PARTICIPATE IN RESEARCH

Project Title: [Insert title of project here]

Department: [Insert Dept. Name here]

My name is [Insert PI name] and I am [a student][a faculty member in the ___ department] at New Mexico Tech. I am conducting a research study entitled [enter title]. I am asking you to take part in this research study because I am trying to learn more about [insert purpose]. This will take [enter length of participation].

If you agree to be in this project, you will be asked to [describe what you want the participant to do in your project].

If you agree to be in this project, you may be exposed to the following risks: [List potential risks to your participants here].

An important part of research is keeping a record of all the questions I ask you and what your answers were. For this project, I will keep your answers in a safe place like this: [State how your data will be kept (e.g., it will be kept in a locked file cabinet in a locked room, or on a secure computer, etc.)].

The only people who will have access to these records will be: [State who will have access to the data]

I will keep the records for [State how long the data will be kept, or if it will be kept indefinitely] and then I will destroy the records by [State how the data will be destroyed].

Please talk about this project with your parents before you decide whether or not to participate. I will also ask your parents to give their permission for you to participate. Even if your parents say "yes" you can still decide not to participate. You may also change your mind before or during the survey. No one will be upset with you if you don't want to participate or if you change your mind later and want to stop.

You may ask me any questions about this research project. You can call me at any time [provide your contact information] or talk to me the next time you see me. The Institutional Review Board (IRB) for the Protection of Human Subjects at NM Tech has reviewed and approved this research project, so if you want to talk to someone else about this project instead of me, you can call the IRB Administrator at 575-835-5690.

Please write your initials on the line in front of the way that you've agreed to participate in this project:

_____ I agree to participate in the project.

_____ I agree to be videotaped as part of this project.

_____ I agree to be audio-taped as part of this project.

_____ I agree to be photographed as part of this project.

_____ I agree to have the things that I say (my direct quotes) used in the results of this project.



ASSENT TO PARTICIPATE IN RESEARCH

Project Title: **[Insert title of project here]**

Department: **[Insert Dept. Name here]**

Sign this form only if you:

- understand what the research is about and why it's being done
- have had all your questions answered
- have gotten your parent(s)/legal guardian's permission to participate in this project, and
- agree to take part in this research project.

Your Signature

Your Printed Name

Date

**You should sign two copies of this form.
You will keep one and return the other to the researcher**

Signature of Researcher:

By signing below, I certify that I have explained this research project to the minor participant and have answered any questions raised by him or her.

Researcher's Signature

Your Printed Name

Date