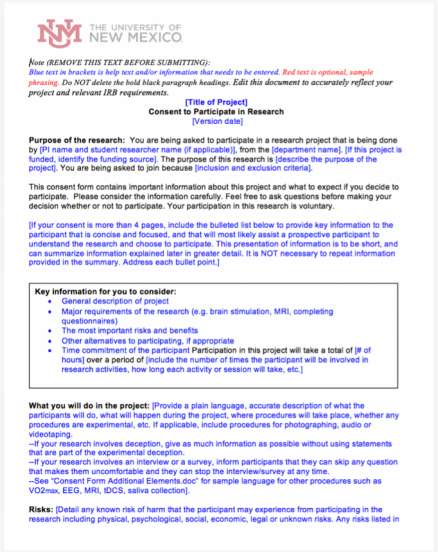
INFORMED CONSENT

Prepared by The University of New Mexico Office of the Institutional Review Board

OFFICE OF
THE INSTITUTIONAL
REVIEW BOARD

Informed Consent

A CONVERSATION PAIRED WITH A FORM THAT PEOPLE SIGN.



THE UNIVERSITY OF NEW MEXICO

Note (REMOVE THIS TEXT BEFORE SUBMITTING):
Blue text in brackets is help text and/or information that needs to be entered. Red text is optional, sample phrasing. Do NOT delete the bold black paragraph headings. Edit this document to accurately reflect your project and relevant IRB requirements.

[Title of Project]
Consent to Participate in Research
[Version date]

Purpose of the research: You are being asked to participate in a research project that is being done by [PI name and student researcher name (if applicable)], from the [department name]. [If this project is funded, identify the funding source]. The purpose of this research is [describe the purpose of the project]. You are being asked to join because [inclusion and exclusion criteria].

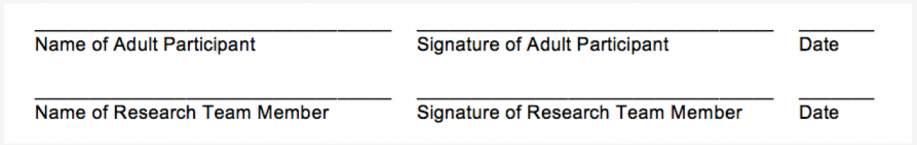
This consent form contains important information about this project and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate. Your participation in this research is voluntary.

[If your consent is more than 4 pages, include the bulleted list below to provide key information to the participant that is concise and focused, and that will most likely assist a prospective participant to understand the research and choose to participate. This presentation of information is to be short, and can summarize information explained later in greater detail. It is NOT necessary to repeat information provided in the summary. Address each bullet point.]

Key information for you to consider:
- General description of project
- Major requirements of the research (e.g. brain stimulation, MRI, completing questionnaires)
- The most important risks and benefits
- Other alternatives to participating, if appropriate
- Time commitment of the participant Participation in this project will take a total of [# of hours] over a period of [include the number of times the participant will be involved in research activities, how long each activity or session will take, etc.]

What you will do in the project: [Provide a plain language, accurate description of what the participants will do, what will happen during the project, where procedures will take place, whether any procedures are experimental, etc. If applicable, include procedures for photographing, audio or videotaping.
--If your research involves deception, give as much information as possible without using statements that are part of the experimental deception.
--If your research involves an interview or a survey, inform participants that they can skip any question that makes them uncomfortable and they can stop the interview/survey at any time.
--See "Consent Form Additional Elements.doc" for sample language for other procedures such as $VO2_{max}$, EEG, MRI, tDCS, saliva collection].

Risks: [Detail any known risk of harm that the participant may experience from participating in the research including physical, psychological, social, economic, legal or unknown risks. Any risks listed in



Name of Adult Participant	Signature of Adult Participant	Date
Name of Research Team Member	Signature of Research Team Member	Date

Informed Consent: A Process

- Informed Consent is a process through which the researcher takes steps to ensure that potential participants are given sufficient information that they are able to make an informed decision about volunteering for a research project.
- The researcher should ensure that participants are free from coercion when making a decision to participant in research.
- The consent process often begins in the recruitment phase of a study and may last through the final contact with a participant.
- Researchers should have a straightforward conversation in plain language with potential participants to help make sure they understand the particulars of a project.

INFORMED CONSENT: THE FORM

Informed Consent: The Form

- Typically, the informed consent process includes a consent form that aides the researcher in ensuring that all information is provided to the potential participant.
- Participants should be given a copy of the form. The consent form is also a resource for participants during and after participating in the research so that they can remain aware of risks and benefits as well as have contact information in case of questions or complaints.
- Human research regulations have specific requirements for what should be included in a consent form, known as elements of consent.

Elements of Consent

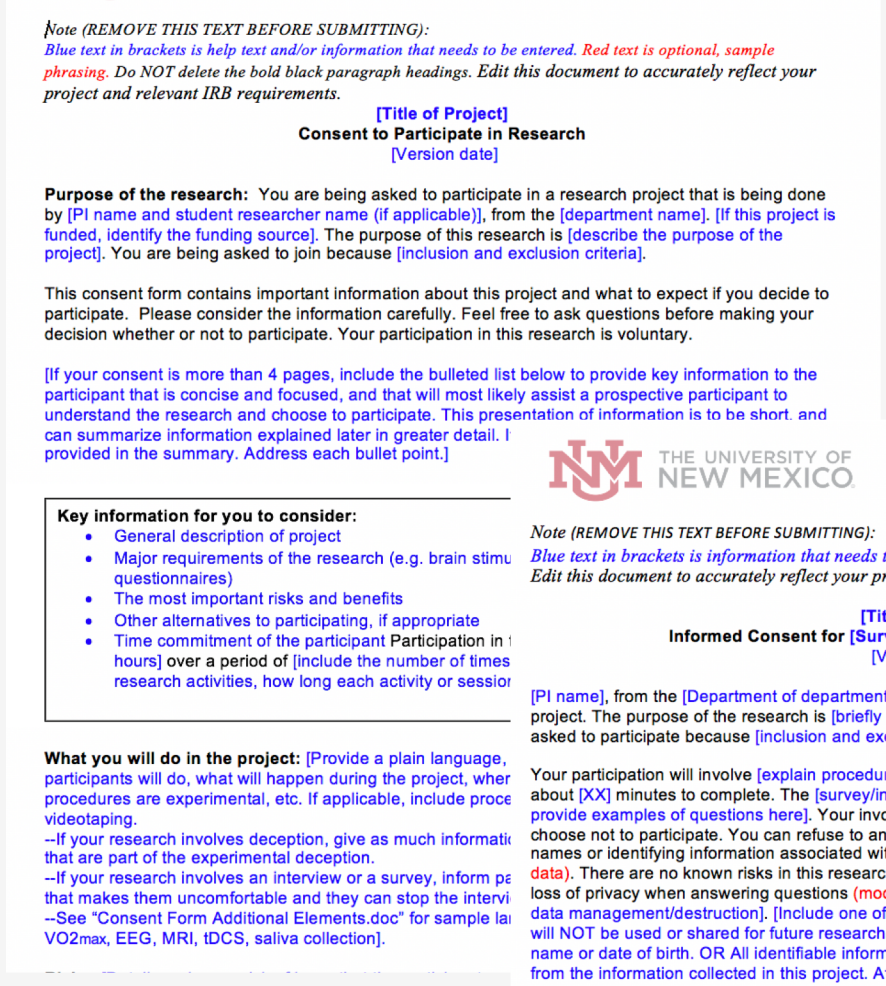
Consent forms for all projects frequently contain the same types of information.

- Statement that it is research
- Explanation the purposes, duration, and procedures of the research
- Description of any reasonably foreseeable risks and benefits
- Description of how confidentiality will be maintained
- As applicable, an explanation as to whether there is compensation
- Information of whom to contact for answers about the research and research participants' rights
- Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled
- Intention for future use of the data
- Key Information

Consent Form Template

Use the Consent Form templates (available on the OIRB website) to ensure that you have included all of the required elements of consent.

There are two styles of consent forms, choose the one that fits best with your research population and procedures.



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[Title of Project]
Informed Consent for [Surveys or Interviews or Focus Groups]
[Version Date]

[PI name], from the [Department of department name or organization name] is conducting a research project. The purpose of the research is [briefly describe the purpose of the project]. You are being asked to participate because [inclusion and exclusion criteria].

Your participation will involve [explain procedures here]. The [survey/interview/focus group] should take about [XX] minutes to complete. The [survey/interview/focus group] includes questions such as [briefly provide examples of questions here]. Your involvement in the research is voluntary, and you may choose not to participate. You can refuse to answer any of the questions at any time. There are no names or identifying information associated with your responses (modify if identifiers will be linked to data). There are no known risks in this research, but some individuals may experience discomfort or loss of privacy when answering questions (modify to reflect risks of the research). Data will [describe data management/destruction]. [Include one of the following: Your information collected for this project will NOT be used or shared for future research, even if we remove the identifiable information like your name or date of birth. OR All identifiable information (e.g., your name, date of birth) will be removed from the information collected in this project. After we remove all identifiers, the information may be used for future research or shared with other researchers without your additional informed consent.]

The findings from this project will provide information on [explain expected generalized benefit]. If published, results will be presented in summary form only [include if quotes with names will be used].

If you have any questions, concerns, or complaints about the research, please feel free to call [PI name] at [number]. If you have questions regarding your rights as a research participant, or about what you should do in case of any harm to you, or if you want to obtain information or offer input, please contact the UNM Office of the IRB (OIRB) at (505) 277-2644 or irb.unm.edu.

By [provide method of enrollment] (ie signing below, clicking "OK", returning this survey in the envelope provided, participating in the focus group/interview) you will be agreeing to participate in the above described research.

If you are requesting waiver of documentation of consent (no signature), delete the lines below.

Name of Adult Participant	Signature of Adult Participant	Date
Name of Research Team Member	Signature of Research Team Member	Date

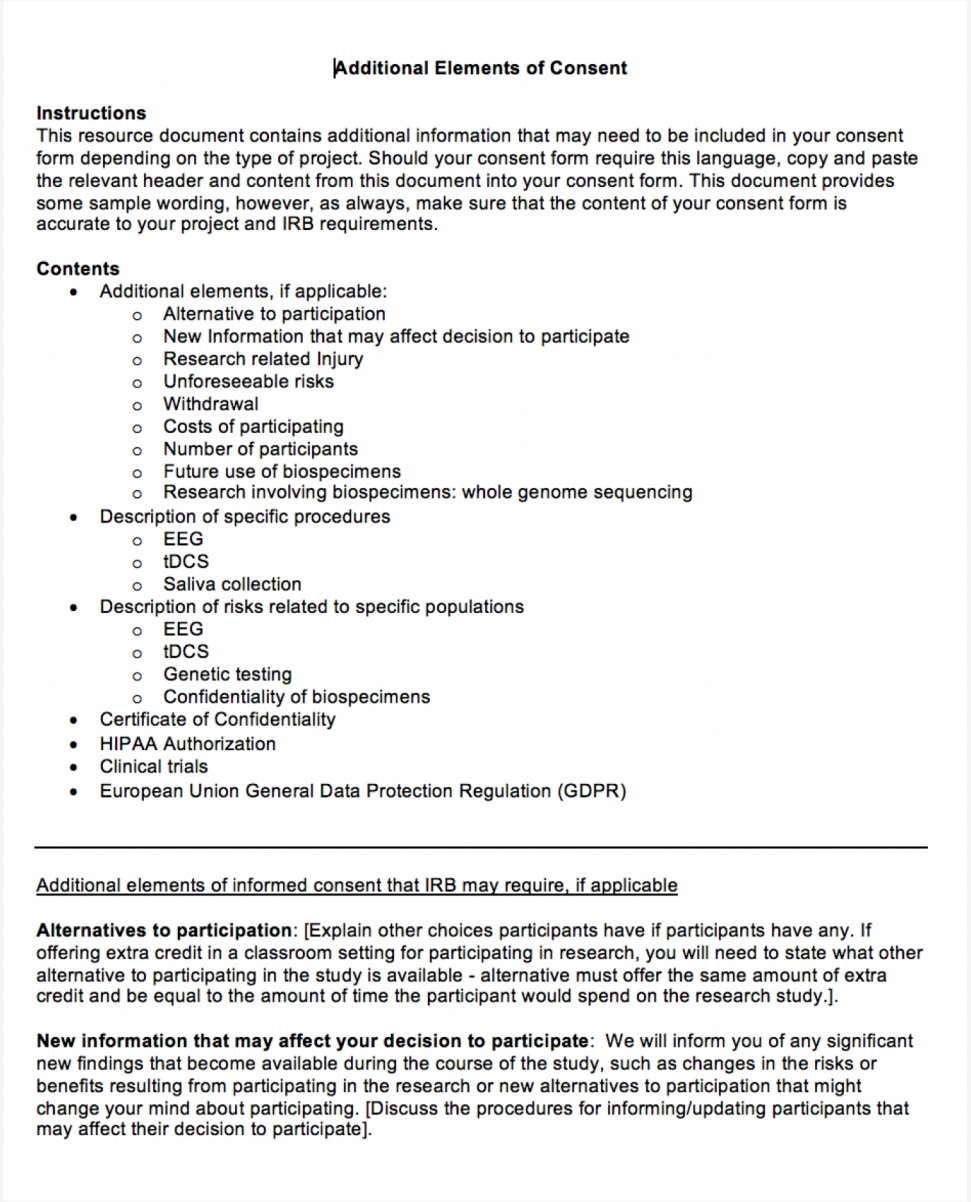
Additional Elements of Consent

Based on the particulars of the project, consent forms may need additional information.

- Statement that there are unforeseen risks
- Description of circumstances where participation may be ended by the researcher
- Any additional costs that may result from participation
- The consequences of and procedures for a participant's decision to withdraw
- Statement that new findings, which may relate to willingness to participate, will be provided
- Approximate number of participants
- Commercial profit
- Return of clinically relevant results to participants
- Whether genome sequencing will be conducted

Additional Elements Template

Should your consent need additional elements, use the Additional Elements of Consent template for language to include in your consent form.



Additional Elements of Consent

Instructions
This resource document contains additional information that may need to be included in your consent form depending on the type of project. Should your consent form require this language, copy and paste the relevant header and content from this document into your consent form. This document provides some sample wording, however, as always, make sure that the content of your consent form is accurate to your project and IRB requirements.

Contents

- Additional elements, if applicable:
  - Alternative to participation
  - New Information that may affect decision to participate
  - Research related Injury
  - Unforeseeable risks
  - Withdrawal
  - Costs of participating
  - Number of participants
  - Future use of biospecimens
  - Research involving biospecimens: whole genome sequencing
- Description of specific procedures
  - EEG
  - tDCS
  - Saliva collection
- Description of risks related to specific populations
  - EEG
  - tDCS
  - Genetic testing
  - Confidentiality of biospecimens
- Certificate of Confidentiality
- HIPAA Authorization
- Clinical trials
- European Union General Data Protection Regulation (GDPR)

Additional elements of informed consent that IRB may require, if applicable

Alternatives to participation: [Explain other choices participants have if participants have any. If offering extra credit in a classroom setting for participating in research, you will need to state what other alternative to participating in the study is available - alternative must offer the same amount of extra credit and be equal to the amount of time the participant would spend on the research study.].

New information that may affect your decision to participate: We will inform you of any significant new findings that become available during the course of the study, such as changes in the risks or benefits resulting from participating in the research or new alternatives to participation that might change your mind about participating. [Discuss the procedures for informing/updating participants that may affect their decision to participate].

Tips for writing a good consent form

- Keep it simple and straightforward.
- Write for clarity.
- The audience for the form is the participants, not the IRB or other researchers.
- The form is a tool to help convince someone to join your research, if it is unnecessarily complex, jargon-y, or lengthy, then it can deter someone from joining the research.
- Have someone from the target population (or similar to the target population) read the consent form to ensure that the form is clear, appropriate, and useable.

Translated Consent Forms

- The consent form should be written in a language that participants can understand. If participants speak/read a language other than English, then consent forms should be translated.
- Translations must be completed by someone with sufficient knowledge to accurately convey the information. The translator will complete the Translation Certification Form to state with documents they translated and their qualifications.
- Translation software is not considered appropriate for translating consent forms.
- The recommended process for submitting translated documents to the IRB is to submit everything in English, then once those documents are approved, translate the final documents and submit those as an amendment (including the translation certification form).

INFORMED CONSENT: WAIVERS

Waivers and Alterations to Consent and Documentation

Waiver of Consent

A waiver of consent means that the researcher is not going to give any information about a project to participants. If there are interactions between the researcher and potential participants (e.g. recruitment), then a waiver in not typically applicable.

In order to be granted a waiver of consent, there are specific criteria that must be met:

- ✓ The research involves no more than minimal risk to the participants;
- ✓ The research could not practicably be carried out without the waiver or alteration;
- ✓ If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- ✓ The waiver or alteration will not adversely affect the rights and welfare of the participants; and
- ✓ Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.

Waivers and Alterations to Consent and Documentation

Alteration of Consent

An alteration of consent is used when the researcher is removing one of the required elements from a consent form. An example of needing to remove one of the elements would be deception research. For example, if detailing the purpose of the research would prevent the project from being successful, then researchers can remove that element and conduct a debriefing after participation to ensure that participants are informed.

In order to be granted an alteration of consent, there are specific criteria that must be met:

- ✓ The research involves no more than minimal risk to the participants;
- ✓ The research could not practicably be carried out without the waiver or alteration;
- ✓ If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- ✓ The waiver or alteration will not adversely affect the rights and welfare of the participants; and
- ✓ Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.

Waivers and Alterations to Consent and Documentation

Waiver of Consent Documentation

The regulations require that consent to participate is documented specifically with a signature on a consent form. There are many cases where this is not possible or necessary. Researchers are still engaging in a consent process, however, they are not collecting signatures on document consent.

In order to be granted a waiver of consent, there are specific criteria that must be met:

- ✓ That the only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.

OR

- ✓ That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

OR

- ✓ If the participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Requesting a Waiver

- Research make requests waivers in the Protocol under Consent Procedures.
- Clearly state that you are requesting a waiver and make sure to follow the criteria and include a justification. E.g. I am requesting a waiver of documentation. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context because (include project specific justification).
- Make sure that you are requesting the appropriate waiver as requesting the incorrect waiver will delay the review process.
- Submit project documents that match the waiver requests. If you request a waiver of documentation, submit consent forms without signature lines.

Researcher Assistance

UNM OIRB

Email: irbmaincampus@unm.edu

Website: irb.unm.edu

Phone: (505) 277-2644

OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Outreach

- OIRB is available to come to your next meeting or class
- Presentations can cover all IRB information and can be tailored to meet your needs

Training

- OIRB provides workshops to explain IRB expectations, policies, and procedures
- See the OIRB website for workshop dates

GPSA Walk-in Hours

- Third Thursday of every month from 10:00 am – 12:00 pm in the GPSA office in the SUB

Consults

- Get answers to your IRB questions
- Complete the Consult Request Form on the OIRB website

COMMUNICATION!!!!!!!

- Nothing will allow us to serve you better than for you to communicate with us early and regularly! Special issues (short funding deadline, international travel)? Let us know; we will do our best to assist.