

Adult Research Participation Consent Form

The IRB requires the researcher to provide an exact copy of the consent form that will be distributed to potential subjects. Both the researcher and subject must have a copy of the consent form signed by the researcher and subject before data can be collected from a subject. In the case of consent for online surveys, the email notifying subjects of the survey and providing the link to it must inform subjects that they should either (a) print a copy of the consent form which accompanies the survey, or (b) write down the contact information provided on the consent form for the researcher and the co-chairs of Institutional Review Board.

Under the Forms Tab on the IRB website there is a separate form for Parental Consent when potential subjects are less than 18 years of age.

Below are the sections and typical content that are required for a consent form that will enable a potential subject to make a fully informed consent decision.

Title of Project:

Researcher(s):

Sponsor: This would be a faculty mentor for student researchers, or a Le Moyne College faculty sponsor for researchers who are not affiliated with Le Moyne College and who intend to recruit Le Moyne College employees or students as research subjects.

Your consent is being sought to participate in this study. Please read the following information carefully before you decide whether or not to consent to participate.¹

Purpose of the research: Provide a brief overview of what research issues or hypotheses will be examined with the data collected from subjects. There should also be a brief statement on what the final product of the research will be, such as a Masters or Honors thesis, conference presentation, or journal article.

Procedure to be followed: This section must include a description of all the ways that the researcher will interact with subjects, including informed consent procedures, specific tasks the researcher will ask subjects to do, and all procedures related to data collection.

Discomforts/risks: The researcher should describe carefully the potential risks (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks. If methods are used which create significant risks, an explanation of why these methods were used and not others is required. What alternative methods are available?

Please note that **all** research that intends to respect the privacy, confidentiality, or anonymity of the research participants runs the risk, however remote, that there may be a breach of confidentiality. This must be identified as a risk in this section. You should also identify the level of confidentiality that will be maintained.

In addition to the general risks described in the previous paragraph, researchers who plan to use online surveys must also include the following disclaimer in this section of their consent form:

¹ These statements must appear in your consent form.

Whenever one works with email or the internet, there is always the risk of compromising privacy, confidentiality, and/or anonymity. Your confidentiality will be maintained to the degree permitted by the technology being used. It is important for you to understand that no guarantees can be made regarding the interception of data sent via the internet by third parties.

Incentives/benefits for participation: This section must include any general benefits, such as helping to make a contribution to the knowledge of the topic under study, helping specific groups of people, or providing information that will enable the researcher to make a contribution to the general well-being of society. Specific benefits, such as receiving payment for participation or extra credit in a course, must also be included in this section.

Time duration of participation: The researcher must provide an estimate of how much time the subject can expect to spend participating in the research project. In addition, if subjects will be completing surveys, they should be told how long they will have to submit their survey responses.

Statement of confidentiality: If relevant, the researcher should describe particular procedures (e.g. proper screening of risk-prone individuals, availability of psychological or medical aid, methods of detecting illness) that will be taken to safeguard the welfare of the subjects. In studies that intend to maintain confidentiality or anonymity, this refers to an assessment of the extent to which the names and other private information and data provided by individuals will be protected by the researcher from release. Describing how the confidentiality of private information and research data will be maintained is an important component of the informed consent process.

If anonymity is being claimed, the researcher should describe the procedures by which they will obtain consent and the data from subjects without having any knowledge of the subjects' identities.

The researcher also has an obligation to inform potential subjects about the following aspects of the data collection process: (1) how their data will be presented and used, (2) who will have access to it, (3) what procedures will be in place to ensure that unauthorized individuals will not have access to this information, including how it will be stored during the study, (4) what will become of the data after the completion of the study, and (5) what, if any, limitations exist to these confidentiality procedures. With regard to how the data will be used, you should mention how the collected data will be presented in your final product to minimize the risk of disclosing identities if that is a potential risk. Subjects should be informed of how any written, spoken, or visual responses will be presented. For example, would you use direct quotes? How would the individual subjects be referred to in the final product? Similarly, what types of statistical measures or analyses will be used with quantitative data and to what extent will quantitative data be disaggregated by subgroup according to type of subject?

In compliance with federal guidelines, all records related to research approved by either Expedited review (Form B) or Full Board review (Form C), including signed consent forms and collected data, must be retained in secure storage at Le Moyne College or on a secure Le Moyne College server for at least three years after the research project has been completed.

Even when names are not linked to specific data, there is always a possibility, however remote, that a subject's identity could become known based upon the specific content of their responses and/or the number and type of subjects who participate. Subjects should therefore be informed of the number of individuals who will be included in the research project and the size of any subgroups of individuals who might be identified by their responses. Examples would include information about age, sex, race, occupation or any other personal characteristics that could possibly be used to associate an individual or small group of individuals with specific results in the final product. This is especially important when subgroups defined by potentially identifying information are used and there are only a small number of potential subjects who could be classified as members of any subgroup.

The following information must be included (as relevant): (1) whether the subject's biospecimens (even if identifiers are removed) might be used for commercial profit and whether the subject will or will not share in this commercial profit; (2) whether clinically relevant research results, including individual research results, will be disclosed to subjects; if so, state how they will be disclosed; and (3) whether research involving biospecimens will (if known) or might include whole genome sequencing

If the researcher does not apply for broad consent, when the researcher collects private information or identifiable biospecimens that could be used in future studies, one of the following two statements must be included:

Identifiers might be removed and the de-identified information or biospecimens may be used for future research without additional informed consent from the participants.

OR

The participant's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed.

Please note: If you include the first statement above, it means that you (or other investigators) may decide to use the de-identified information or biospecimens in future secondary research studies approved by the IRB. This is consistent with IRB policies and practices that were already in place prior to the recent revisions to federal guidelines; the statement that is now required simply makes this practice explicit for potential research participants. If you include the second statement, identifiable information or biospecimens collected for your study cannot be used in any future secondary research studies, without exception. Researchers applying for approval of secondary research studies will now need to provide confirmation for the IRB that the first statement above was included on the consent form at the time the data was initially collected (this applies only to data collected for primary research studies on or after January 21, 2019).

Finally, subjects have the right to know who will have access to your results and/or see your final product. This would normally include readers of a thesis, as well as any subjects or their supervisors/administrators who may receive the study's results.

Voluntary participation: You must inform your subjects that their participation is voluntary. In addition, you must include a statement that asks them to contact the researcher if they felt coerced to participate in any way. Finally, if you will interview subjects, administer a survey, or ask them to answer questions, you must tell them that they are free to skip any question that they do not want to answer or that makes them uncomfortable. If the nature of the research design necessitates that participants answer some or all survey questions, a justified rationale for requiring responses must be provided in the *Methods and Procedures* section of the Research

Outline (and you would, therefore, not be able to state on the consent form that they can skip any question that they do not want to answer). In all cases, however, respondents must be allowed to skip any and all questions that are not absolutely required for the purposes of the research.

Termination of participation: You must tell your subjects that they may choose to withdraw from the study at any time.

Broad Consent: A researcher may apply for approval of broad consent regarding future use of collected data that contain identifiable private information and/or identifiable biospecimens. **If applicable, the application for broad consent should be included at this point in the standard adult research participation consent form.** Researchers can use de-identified information and de-identified biospecimens for secondary research without getting a subject's broad consent as long as the secondary research project has been approved by the IRB. However, if a subject is asked to provide broad consent and refuses, that subject's data may not be used for any future secondary research project that relies on broad consent, nor can the researcher apply for a waiver of informed consent for said project. Please see Attachment 9 of these Policies and Procedures for additional material on the use of broad consent and the information that must be provided to research participants on the broad consent form.

Questions regarding the research: Questions regarding the research itself should be directed to the researcher and to the college sponsor (in the case of student researchers or researchers not employed by Le Moyne College). Information such as phone numbers and/or email addresses of the researcher and sponsor should be provided.

Questions or concerns regarding a subject's rights as a research participant: Questions or concerns regarding a subject's rights as a research participant should be directed to the co-chairs of the Institutional Review Board. They can be reached at irb@lemoyne.edu.

This research has been reviewed and approved by Le Moyne College's Institutional Review Board.²

Consent Space: For consent that is obtained on a hardcopy form, the consent form must provide a space that includes the following:

- A statement for subjects to read such as: *I have read all the information provided on this form, am at least 18 years of age, and consent to participate in this study.*
- This statement should be followed by a line on which subjects will sign their name if they consent to participate and a line for the date. Below the signature line there should be a line on which subjects can print their name.
- You should include content such as: *If you do not consent to participate, you do not need to sign this form. Simply return it to the researcher.*
- You should also provide a line on which you as the investigator will sign your name and a line on which you write the date for when you sign.

An example of this appears below:

² This statement must appear on your consent form.

I have read all the information provided on this form, am at least 18 years of age, and consent to participate in this study.

Signature

Date

Please print your name here.

If you do not consent to participate, you do not need to sign this form. Simply return it to the researcher

Signature of investigator _____

Date _____