# ST. MARY'S COLLEGE OF MARYLAND

# Institutional Review Board

**FAQ AND INSTRUCTIONS FOR PROJECT DESCRIPTION FORM**

**0. PROJECT DESCRIPTION FORM FAQ:**

**What does the IRB do?**

Under guidelines established by the U.S. Department of Health and Human Services, and in order to protect our privilege to do research, approval of an Institutional Review Board (IRB) is required for research projects in which human beings are the participants, regardless of the source of funding.

**Where are the appropriate forms?**

IRB proposal submission forms, consent form templates, and instructions are available at <http://www.smcm.edu/irb/forms/>. Instructions and forms also may be obtained through an e-mail request addressed to the IRB (irb@smcm.edu).

**How do I submit my proposal?**

You may submit a proposal to the IRB using the eIRB form. **This is the preferred method of submitting proposals to the IRB**. Send the completed form and any related documents as a **single e-mailed attachment** (please put page breaks between different documents) to irb@smcm.edu. Do **not** paste the text of the form into the body of the e-mail. If you are unable to submit the form electronically, please contact irb@smcm.edu for further instructions.

**How does the IRB reach a decision?**

IRB decisions are based upon a risk/benefit analysis. The IRB will review your proposal to determine whether: 1) risks to participants are minimized, 2) risks are reasonable in relation to anticipated benefits, 3) selection of participants is equitable, 4) informed consent is sought from each participant, and 5) informed consent is appropriately documented. Additionally, as appropriate the IRB will determine whether: 6) data collection is monitored to ensure participant safety, 7) the privacy and confidentiality of participants is protected, and 8) additional safeguards are included for vulnerable populations.

**How do I fill out the form?**

Follow the line-by-line instructions below to add the requested information. For the eIRBForm.doc, enter the requested information from within Microsoft Word and attach consent forms and any related appendices (survey items, interview questions, scripts, debriefing statement) to the end of the eIRB form.

**1. INSTRUCTIONS: GENERAL INFORMATION**

Each project must have a unique title. If you are modifying an existing approved IRB proposal, please indicate that here.

The principal investigator is usually a faculty or professional staff member and must take primary ethical responsibility for the project. If the project is a class assignment, this is usually the course instructor.

The co-investigator(s) are other researchers involved in the project. For a class assignment, this is often the student or students carrying out the project.

If you are a student submitting an IRB proposal, at least one faculty or staff member at SMCM must be listed as a co-investigator on your project. It is expected that you will consult with that faculty or staff member about your proposal and that they will review and provide feedback on your IRB submission forms **before** you submit them for review.

If you are receiving external funds to support the project, please indicate this in the “Funding Agency” area. If the research is not funded, please indicate “n/a.” This is particularly important if you are seeking or have obtained grant funding from a federal agency (NIH, NSF, etc.).

The type of review requested at St. Mary’s can be either an expedited review or a full review. If neither is specified, the full IRB will review the proposal. In the case of an expedited review, at least one member of the IRB reviews the proposal and consults the full IRB if necessary. Expedited reviews can only be requested for research that either 1) involves minor changes in approved research, or 2) involves **minimal risk** AND falls into particular categories of research, including but not limited to: research on individual or group characteristics of behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

For the complete list of research categories that may qualify for expedited review, see: <http://www.hhs.gov/ohrp/policy/expedited98.html> ). “Minimal risk” means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**2. INSTRUCTIONS: OBJECTIVES OF PROPOSED PROJECT**

What are the goals of the research? What are you trying to learn or accomplish? A short list of objectives is usually sufficient for this section, but if foundational information or external references would help the IRB to evaluate your methodology or the importance of your topic, please include that information in sufficient detail. Also be sure to define any theories or concepts that someone outside of your field of study might not be familiar with.

**3. INSTRUCTIONS: DESCRIPTION OF HUMAN PARTICIPANTS**

Please provide as much information as possible; for example, number, age, sex, how they will be obtained (including selection criteria and recruitment procedure if applicable), and whether the participants will be students or some other special category. Note that in some research designs (e.g., naturalistic observation, ethnography) it is impossible to specify exactly who the participants will be. In these cases it is appropriate to give a more general description (e.g., people who will interact with a librarian at the circulation desk). In any case, be as specific as possible. Information about the potential participants is very important in how the IRB evaluates the ethical considerations of the research project. If you plan to use prisoners as your research population, you must indicate that clearly here. You must also indicate clearly if your research involves the recruitment or use of minors. Also keep in mind that if you plan to interact in any way with staff, administrators, or students in public school systems, there are additional stages of review that are required through the public school section, so be sure to make note of your plans to obtain this approval in this section.

**4. INSTRUCTIONS: SUMMARY OF RESEARCH AND DATA GATHERING PROCEDURES**

Provide a description of your research project in language that a non-expert can understand. Include a detailed explanation of the procedure you will follow in collecting data and interacting with participants. The IRB needs to clearly understand the method you will utilize and how the data will be recorded/collected, so err on the side of including more rather than less detail.

**5. INSTRUCTIONS: LOCATION OF PROJECT**

Provide a brief statement of where the research project will take place. For some research projects a description of that location may be important (e.g., the location of the project influences who participates in the project).

**6.** **INSTRUCTIONS: CONFIDENTIALITY SAFEGUARDS**

The best way to protect participants’ identity is if the research is anonymous. Anonymous means that it is impossible to identify any particular individual’s data—that no identifying information is collected. If participants will be anonymous state that here (and please ensure that it is clear how/why they will be anonymous from your description in part 4).

If the participants will not be anonymous, describe how the confidentiality of the participants’ responses will be maintained. For example, the researcher might protect confidentiality in various ways including, but not limited to, having all data stored on a password protected computer only accessible by the researcher, removing identifying variables before data analysis is conducted, destroying documents or materials at the conclusion of data analysis, etc. If responses are to be audio or video recorded, this must be clearly described and how those recordings will be gathered, stored, and destroyed should be described.

If confidentiality cannot be safeguarded, please explain in detail why the information cannot be kept confidential.

A description of all confidentiality provisions must also be explained to the participant in detail in the informed consent process.

**7. INSTRUCTIONS: DESCRIPTION AND ASSESSMENT OF ANY POTENTIAL RISKS**

Assess any potential risks—physical, psychological, social, legal, or other—and assess the likelihood and seriousness of such risks. If your methodology involves potential risks, describe alternative methods, if any, that were considered and why they will not be used. Also describe any steps you are taking in the research process to minimize or offset the risks (for example, risks related to asking about stigmatizing behaviors may be offset by having responses collected anonymously; risks related to vulnerable populations may be offset by exclusion criteria for the study). This section may also need to include risks related to confidentiality or lack of confidentiality.

This risk assessment is directly related to the type of review requested in section 1. An expedited review should be requested if the research entails less than minimal risk. A full review should be requested if the risks exceed that criteria.

FOR IN-PERSON RESEARCH DURING THE COVID-19 PANDEMIC: All participants should also explain any procedures they will use in in-person research to minimize the risk of COVID-19 transmission. Please see the IRB website COVID-19 information for additional details about what should be included and how to address this in the consent form.

**8. INSTRUCTIONS: DESCRIPTION OF CONSENT PROCEDURES**

Include how and where informed consent will be obtained. Attach a copy of the consent form that you will use as an appendix to the proposal (see below for more information on the required elements of consent forms). If the researcher wants to request a waiver of documented consent or a waiver of consent entirely, based on federal guidelines, justification for the wavier must be clearly stated using information from the federal guidelines. These guidelines can be found at [46.116 of the Code of Federal Regulations](https://www.ecfr.gov/cgi-bin/text-idx?SID=3f2b3382a0154e83cd328932d46ad3d4&mc=true&node=se45.1.46_1116&rgn=div8).

Consent form templates are available on the website at <http://www.smcm.edu/irb/forms/>. It is HIGHLY encouraged that you use one of the SMCM provided templates to help make sure all required elements are present. Templates are provided for in-person studies (where the researcher interacts face to face with the researcher) as well as for online studies (where the participant agrees to participate on a computer). These templates can be modified as needed, and some suggested language to accommodate different types of studies is included in the templates. If the templates do not meet the needs of your project well, feel free to consult with the IRB chair for information on how to make sure your consent form meets federal regulations.

Parental consent is usually required for participants under the age of 18. If parental consent will be needed, an explanation of how parental consent and child assent will be collected must be described. A parental consent form template is provided at <http://www.smcm.edu/irb/forms/>. Depending on the age of the child, a traditional consent form can be used for the child (an older child that can understand the formal consent form language), or oral consent can be obtained from younger children after a brief description of the project and their rights (e.g., that they can stop anytime, that only you will see their answers).

FOR IN-PERSON RESEARCH DURING THE COVID-19 PANDEMIC: Consent forms for in person studies must include the following statement of COVID risk:

*To participate in this study, you must appear in person. The evidence to date suggests that COVID-19 and its variants are most easily spread through person-to-person contact. Although the researchers have safeguards in place to reduce the likelihood of transmission, it may still be possible to become infected. In signing this consent form, you acknowledge that you understand this risk and wish to participate.*

Debriefing is the process of letting participants know more about the study after they have participated. This is particularly important if the researcher used deception about the true purpose of the research during the informed consent process, or if the participant would benefit from having more information or resources related to the project after they participate (e.g., the contact information of local resources related to topics addressed in the study). If debriefing procedures will be used, describe them in this section of the proposal (see below for information on debriefing).

**9. INSTRUCTIONS: DESCRIPTION OF THE POTENTIAL BENEFITS**

The benefits of research may include benefits to the individual participant, investigator(s), and to society in general which may result from this research, but the most important benefit is usually related to the value of the research itself to scientific knowledge. The benefit of the research is weighed against the risks of the research to determine a cost-benefit assessment of the project, so this explanation is particularly important the higher the risks are.

**CONSENT FORM INFORMATION**

**Your proposal must include a consent form that has been made specifically for your study, but you may use our templates and include your own study details on it.**

**The templates for signed consent, online consent, and parental consent can be found on the IRB Website at** [**https://www.smcm.edu/irb/forms/**](https://www.smcm.edu/irb/forms/)

**The consent form should be included as Appendix A in your IRB proposal document.**

**The following information should be included, if relevant, in your consent form**.

See <http://www.hhs.gov/ohrp/policy/consentckls.html>

1. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. a description of any reasonably foreseeable risks or discomforts to the subject;
3. a description of any benefits to the subject or to others which may reasonably be expected from the research;
4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

There are certain situations where additional information or alterations to the above requirements are possible.

See <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116> sections b, c, and d.

Please also note the requirements for documentation.

See <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117>

**RESEARCH WITH CHILDREN:** If the research involves children, both assent of each child and permission of the parents may be required.

Please refer to <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.401>

Signed consent forms must be retained by the principal investigator for 3 years from the date of research completion and a copy of the consent form should be provided to the research participant.

See: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117>

**DEBRIEFING YOUR PARTICIPANTS\***

A student’s experience as a participant should be a positive educational one. This does not mean that we have to design studies so that they are “fun” for the participants, but rather that our procedures should include a debriefing stage (at the end of your study) in which participants are told (a) the purpose of the study, (b) the relation of the purpose to the conditions that they participated in (if an experiment), and (c) the overall results and conclusion drawn from the experiment (or where and when information about results will be available in the future). This information should be written in a general way (i.e., not laden with jargon). Ideally, participants will receive this information immediately after their participation has ended unless it is not possible to give such complete information immediately (because of possible contamination, multiple-session experiments, etc.). In such cases, participants should be informed (during the experimental session) of exactly where/when such information can be obtained. Also, for in person research rather than simply providing debriefing information on a slip of paper (that is likely just to be thrown away) you should attempt to verbally debrief the participants. This is especially important in studies where there was risk to the participant (to ensure they are okay) or where deception was used (to explain the deception and the need for it).

**Some examples:**

Example 1

Thank you for participating in the study entitled “Ideal Balance of Power in Intimate Relationships, Self-Esteem, and Academic Achievement.” This research seeks to examine the relationship between how closely a person’s intimate relationships match their ideal intimate relationships (in terms of balance of power) and academic achievement. A third variable, global self-esteem, will also be studied in relation to these concepts. If you are interested in discussing the research further please contact Researcher X at xXXXX or at researcherX@smcm.edu.

Example 2

You have just participated in a study called, “Freedom of Choice: Blessing or Burden? The relationship between choice set size, maximization propensity, and post-decision regret.” As the title suggests, I am specifically looking at the correlation between the amount of choices presented to individuals, the inclination of individuals to optimize or simplify when faced with decisions, and the amount of regret experienced as a result of these factors. If you would like further information, please contact Researcher X at researcherX@smcm.edu. In addition, the results of my SMP will be presented on either May 2 or May 3 at the Psych SMP poster session.

Example 3

In the preceding experimental study you were given controversial material regarding the religion of Gnosticism for the purposes of measuring how students react to religious beliefs which differ from their own, and for the purposes of measuring whether a participant’s religious belief would be influenced by conflicting beliefs. Participants were also asked to respond to a Satisfaction with Life scale to determine whether life satisfaction had any relationship with the incorporation or rejection of religious ideas.

As stated earlier, all information that was given regarding the religion of Gnosticism is academically sound. Information about Gnosticism was written by the researcher, but based off of the work of religious scholar Elaine Pagels1. For more information regarding Gnosticism, other texts can be found at the campus library2. If you have questions or comments about the study, feel free to contact the researcher at researcherX@smcm.edu or at XXX-XXX-XXXX.

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 Pagels, Elaine. (1989). *The Gnostic Gospels*, New York, NY: Vintage Books.

2 Franzmann, Majella. (1996). *Jesus in the Nag Hammadi Writings*, Edinburgh, Scotland: T&T Clark.

 And Robinson, James M. (Ed.). (1990). *The Nag Hammadi Library* *in English*, San Francisco, CA: Harper San Francisco.

**Always include at the end of your statement**

If you have questions about your rights as a participant you may contact the Chair of the Institutional Review Board of St. Mary’s College of Maryland, at 240-895-4359 or irb@smcm.edu, or 18952 E. Fisher Rd., St. Mary’s City, MD 20686.

“Debriefing your participants” was adapted from Sieber, J. E. (1999). What makes a subject pool (un)ethical? In G.D. Chastain & R.E. Landrum (Eds.), *Protecting human subjects: Departmental subject pools and institutional review boards* (pp.43-63). Washington, D.C.: American Psychological Association.