

VIII. OVERVIEW OF IRB INVOLVEMENT

Approved IRB 12/13/2013

Operating definitions: a) Research: a systematic investigation designed to develop or contribute to generalizable knowledge; b) an activity involving intervention or interaction with a human subject that would only occur given the research purposes.

<i>Not Generalizable Research</i>				<i>Generalizable Research</i>		
<i>No IRB action</i>		<i>IRB as needed</i>	<i>Review</i>	<i>Review and Approve</i>		
	Administrative Assessment Activities	Class-Based Learning Activities	Research of Limited Scope	Exempt from Annual Review	Expedited Review	Full Review
DESCRIPTION	Data collection within the scope of duty of an office, academic unit or recognized student organization of the university.	Data collection serves the purposes of student learning objectives of a course. Minimal risk. Private.	Sensitive topics: Class research, non-StMU program evaluations, quality improvement activities, or pilot studies	Minimal risk; 5 categories, such as de-identified survey, interviews, or existing data; normal educational practices	Minimal risk 10 categories, such as modifications, existing data, voice recordings, moderate exercise	Greater than minimal risk; Vulnerable population
EVAL	Activity consistent with Marianist ideals for human dignity, specifically informed consent, voluntary participation, and minimal risk.			Proposals must meet 11 federally regulated criteria for approval.		
INFORMED CONSENT	Provide a brief oral or written informed consent to include the purpose and duration of the activity, the responsible person to answer informational questions, and the supervising office (Dean or Vice President) to direct any complaints.		Oral or written statement of the purpose and duration, researcher's contact information, and IRB contact information	Full written informed consent, original signature. <ul style="list-style-type: none"> o May request a waiver for original signature. o May request a waiver for elements of informed consent Voluntary participation may be compromised through dual roles (i.e. instructor/ researcher; counselor/ researcher) or undue incentives (linking participation to grade; excessive compensation).		
MINIMAL RISK	Minimal risk means that the potential for discomfort or harm encountered in the research is not greater than that experienced in daily activities. Social and behavioral research may involve various types of harm or discomfort, ranging from economic, legal, physical, to psychological, social or moral. Personal disclosures about possibly illegal activity, stigmatized behavior, or embarrassing information are greater than minimal risk. (National Science Foundation, <i>What is Minimal Risk?</i>)					Examples of greater than minimal risk: criminal acts, stigmatized behavior
IRB INVOLVEMENT	IRB not involved	IRB only involved if: a) greater than minimal risk; b) concerns from participants	IRB approval will be granted if proposal meets limited criteria; report to next IRB meeting.	IRB approval granted if proposal meets 11 criteria; report to next IRB meeting.	IRB approval granted if proposal meets 11 criteria; report to next IRB meeting.	IRB approval will be granted upon review by all members and majority vote.
TIME	IRB not involved	Undefined	Deadline: 1 st of month; IRB response by the end of the month	Deadline: 1 st of month; IRB Response by the end of the month		Deadline: 1 st of month; Time to review: 2 months.

IX. NOT GENERALIZABLE RESEARCH

(Approved by IRB Nov. 22, 2013)

§ 9.01 The Federal IRB guidelines define research as “a systematic investigation designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d)). A second operating definition of research activities is “The intervention or interaction with a human subject would not ordinarily take place, but for the research purposes.” Several types of data collection conducted at the university are for other purposes, such as student learning activities, program evaluation, and outcome assessment.

§ 9.02 Consistent with the Catholic mission of the university, all research data collection activities must uphold fundamental ideals of human rights, specifically the rights of voluntary participation, informed consent, privacy, and minimal risk. This policy is to specify under what conditions data collection falls within the scope of authority of IRB-HS to protect human subjects.

§ 9.03 OHRP Guidance indicates that an intent to publish is not a sufficient criteria for determining whether a data collection activity involves research. Planning to publish a project of limited scope, such as a program evaluation, customer satisfaction, or quality improvement study, does not necessarily mean that the project fits the definition of research. People seek to publish descriptions of nonresearch activities for a variety of reasons if they believe others may be interested in learning about those activities. Conversely, program evaluation or quality improvement studies that use a systematic methods to increase the generalizability of the study may involve research. Please consult the IRB if you have any questions about a planned data collection activity.

(OHRP Guidance: <http://answers.hhs.gov/ohrp/categories/1569>)

A. ADMINISTRATIVE ASSESSMENT ACTIVITIES

(Approved by IRB Nov. 22, 2013)

§ 9.04 When the data collection is within the scope of responsibility of a professional or an office on campus, it is not subject to IRB review under 45 CFR 46.102(d). This includes program evaluation or needs assessment activities of university offices, academic programs or departments, and recognized student organizations. The university employee conducting the data collection and his or her supervisor will be responsible for the administrative assessment activity within the structure of the appropriate Vice President supervising the office. In the case of student organizations, the President of the organization and the faculty sponsor will be the responsible parties within the structure of the Dean of Students and the Vice President for Student Development. Examples of Administrative Assessment Activities are assessment of program activities, outcomes assessment of student learning activities or student evaluations of teaching effectiveness.

§ 9.05 Assuring Voluntary Consent

Data collection should be anonymous, or if not feasible, should protect participants' privacy, and should be consistent with FERPA requirements. Participation should be voluntary, and non-participation should not disadvantage anyone in any way. The project should have a brief informed consent, to include the purpose of the assessment, the duration of the activity, the university office and person responsible for the data collection activity, and how to contact the responsible person's university supervisor. The informed consent may be in writing or oral.

An example of written information:

Turner Luce in the Office of University Animal Control wants to know how much you like the cats on campus. This survey should take you about 2 minutes. If you have questions about this assessment activity, please contact Dr. Lois Steem, Director of University Animal Control at lsteem@stmarytx.edu or 436-1234.

An example of oral information:

Hi. Would you like to take our survey on the cats on campus? I'm Turner Luce from the Office of University Animal Control. The survey should take you about 2 minutes. If you have any questions about this survey, you can contact Dr. Lois Steem, Director of University Animal Control at lsteen@stmarytx.edu or 436-1234.

§ 9.06 Assuring Minimal Risk

Information obtained in the data collection activity should be minimal risk. Minimal risk means that the probability for harm or discomfort—that is the potential for negative effects—is no greater than those ordinarily encountered in daily life. Harm or discomfort

may be physical, psychological, or social; other harms may be economic, legal, or moral. Administrative Assessment Activities should not need to address behaviors that participants consider private, sensitive topics, stigmatized behavior, or illegal behavior. These topics include private behavior in which an individual can reasonably expect that no observation or recording is taking place; personal behavior such as sexual identity or sexual practices; protected information such as health, disability status, or mental health diagnosis; violence, criminal activity, illegal behavior; personal history that may elicit embarrassment or shame. If the Administrative Assessment Activity has a need to know these types of information about human participants, then the data collection needs to minimize risks through sound research methods and needs to be reviewed and approved by the IRB.

§ 9.07 IRB Review

Review of Administrative Assessment Activities does not fall under the scope of the St. Mary's University IRB, rather falls within the scope of the Vice President under which the organization or staff member resides. For example, academic assessment activities fall under the appropriate Dean and the Vice President for Academic Affairs, program assessment activities of university offices fall under the Vice President for Business and Finance, and program assessment activities of student organizations fall under the Vice President for Student Affairs.

All Administrative Assessment Activities should indicate, orally or in writing, the purpose of the assessment, the duration of the activity, the university office and person responsible for the data collection activity, and how to contact the responsible person's university supervisor.

University staff may obtain an opinion from the IRB that the proposed data collection activity is minimal risk, but IRB will not review and approve the activity (email IRBCommitteeChair@stmarytx.edu). If results of the administrative assessment are later submitted for professional publication, it is possible that the publisher asks for an IRB approval letter. In this case, the IRB can only provide a statement that this activity does not meet the definition of generalizable research, therefore 45 CFR part 46 does not apply.

If participants have complaints about the administrative assessment activity, the supervisor should report the complaint to the St. Mary's University IRB-HS within 48 hours. The complaint will be reviewed in light of criteria for informed consent and minimal risk with human subjects, and the appropriate university administrator will be informed of the IRB determination.

B. STUDENT LEARNING ACTIVITIES (CLASS PROJECTS)

(Approved by IRB Nov. 22, 2013)

§ 9.08 When the data collection serves the purposes of student learning objectives, the activity is pedagogy, not generalizable research (45 CFR 46.102(d)). This includes class assignments designed to engage students with people and problems outside the classroom, such as research activities, service learning assignments, and audio or video interviews.

The class instructor who makes the assignment will be responsible within the structure of the Academic Department, Dean, and Vice President for Academic Affairs for the conduct of the student learning activities. This is consistent with the Marianist principle of Subsidiarity (Faculty Handbook, 1.6.9) in which “Every effort is made to locate the decision-making process as close as possible to those who will be required to carry out or act on the decision.” Toward that end, this policy statement is to provide classroom instructors the information they need to decide what class projects may proceed without IRB review. However, if instructors have questions about how to apply the guidelines, they can contact the IRB Chair at IRBCommitteeChair@stmarytx.edu.

Data collection activities for purposes of student learning objectives must uphold fundamental ideals of human dignity, specifically the rights of informed consent, voluntary participation, privacy, and informed consent. Data collection in student learning activities cannot utilize any vulnerable population, such as children or adolescents (under 18), prisoners or probationers, or pregnant women.

The class instructor must make a determination that each student learning project meets the following criteria:

1. minimal risk;
2. anonymous data collection;
3. voluntary participation;
4. oral or written informed consent;
5. has no vulnerable population (children, prisoners, or pregnant women);
6. and is not intended for publication outside the university.

If the Student Learning Project meets these criteria, explained in more detail below, the instructor may supervise the activity without IRB involvement. Any Student Learning Project that does not meet these criteria must be reviewed by IRB as a Project of Limited Scope.

§ 9.09 Assuring Informed Consent

The project should have a brief informed consent to include the purpose of the data collection, the duration, the class title and instructor responsible for the assignment, and how to contact the instructor's Dean. The informed consent may be in writing or oral.

An example of written information:

Dr. Marge Innovera's class, Statistics for Life Applications, wishes to survey people about their irrational fears of statistics and spiders. The survey will take about 5 minutes. Don't worry, you won't be exposed to statistics or spiders during the survey. If you have any questions about this study, please contact Dr. Marge Innovera, College of Arts and Sciences at minnovera@stmarytx.edu or (210) 436-1234.

An example of oral information:

Hi. We're doing a survey to learn more about irrational fears of statistics and spiders. We are in Dr. Marge Innovera's class, Statistics for Life Applications. The survey will take about 5 minutes. Don't worry, you won't be exposed to statistics or spiders during the survey. If you have any questions about this study, please contact Dr. Marge Innovera, College of Arts and Sciences at minnovera@stmarytx.edu or (210) 436-1234.

If the purpose of the research activity may bias the participant's responses, then the students can provide a partial information, oral or written, before the data collection AND a complete written explanation after completion of the data collection.

An example of partial oral presentation:

Hi. We're doing a survey to learn more about people's reactions to controversial topics. We are in Dr. Marge Innovera's class, Statistics for Life Applications. The survey will take about 5 minutes. If you have any questions about this study, please contact Dr. Marge Innovera, College of Arts and Sciences at minnovera@stmarytx.edu or (210) 436-1234.

Written information with full information provided after study:

Thank you for participating in our survey about reactions to controversial topics. This project is an assignment of Dr. Marge Innovera's class, Statistics for Life Applications. The purpose of this project is to compare people's irrational fears of statistics and spiders. If you have any questions about this study, please contact Dr. Marge Innovera, College of Arts and Sciences at minnovera@stmarytx.edu or (210) 436-1234.

§ 9.10 Assuring Voluntary Participation

Participants should be free to decline participation without loss of benefits outside the research activity. Linking participation in data collection activities with grades, attendance, or an alteration of course assignments violates this criteria of voluntary participation.

Voluntary participation in the data collection activities may be compromised by undue inducement to participate or by a dual role of the researcher. Instructors must insure that the solicitation to participate in the data collection activity does not compromise the potential participants' ability to agree or disagree to participate.

Undue Inducement. Inducements are offers that get people to do things they may not otherwise do. The data collection activity should not have monetary inducements or product inducements of a value greater than \$3.00 (or equivalent to a cup of coffee) per participant. Random drawings for products or services of a value greater than \$3.00 requires IRB review as “Research Activity of Limited Scope.”

If the data collection activity uses an inducement, the research activity must assure that participants may withdraw from participation and still receive the incentive. Participants who start the study, by agreeing to the informed consent (oral or written) and starting the data collection, then quit the data collection activities for whatever reason, must still receive the incentive.

Dual Role. If the data collection occurs in a social service treatment context, including medical care, mental health care or provision of social services, the person asking for participation and consent in the data collection cannot be involved in the patient's treatment.

§ 9.11 Assuring Privacy

A range of information is considered private or personally identifiable: name, ID number (school- or government-issued), date of birth, mother's maiden name; HIPAA protects health-related information and FERPA protects educational records. Use of any of these types of information in the data collection creates a need to protect private information and must be reviewed by IRB.

Inadvertent disclosure: In classroom based surveys, care should be taken to avoid “inadvertent disclosure” based on demographic information. Given St. Mary's demographics, a classroom survey that includes 7 categories of demographics can easily identify the one or two minority subjects:

Demographic	St. Mary's %	Est. Class of 30	
Hispanic	55.8%	17	
White, non-Hispanic	25.9%	8	
International	6.9%	2	
African-American	3.7%	1	
Asian/Pacific Islander	2.6%	1	
American Indian/ AK Native	0.4%	1	
Other	3.7%	1	

Source: 2013 St. Mary's University Profile

Better to collect demographic categories of Hispanic; White, non-Hispanic; and Other. If the classroom based project has a need to know other demographic categories, the proposal

must be reviewed by IRB as a Project of Limited Scope. Internet surveys access a different population, and do not have the same concerns for inadvertent disclosure.

Class projects can utilize a range of procedures to protect participant privacy:

Anonymous data: the most complete protection of participant privacy is an anonymous survey, in which the subject identity is not known at data collection. No identifying information nor information subject to inadvertent disclosure is collected.

Anonymous Interview data: The students must assure the instructor that they will only interview people they do not previously know. Interviews may use note-taking or audio recording for the data collection; video recording permits identity disclosure.

De-identified data: the original data collection included some forms of identifiable information, but the source, not the researcher, stripped the data file of all identifiable information. An example of this is: non-profit service information is maintained on an Excel database; the non-profit representative saves no fields with identifying information. Class-projects can utilize “source de-identified” data without IRB review.

Researcher anonymized data: the original data has identifying information, but the researcher only records data that is not identifiable. An example of this is a review of paper records of a non-profit agency. Class projects that need to use this data must have a confidentiality protocol that is reviewed and approved by IRB.

§ 9.12 Assuring Minimal Risk

Information obtained in the data collection activity should be minimal risk. Minimal risk means that the probability for harm or discomfort—that is the potential for negative effects—is no greater than those ordinarily encountered in daily life. Harm or discomfort may be physical, psychological, or social; other harms may be economic, legal, or moral. Examples of each type of risk can assist the instructor in guiding student projects:

- physical harm: Will it bruise or draw blood?
- psychological harm: Will asking this information traumatize someone?
- social harm: Will this information embarrass someone?
- economic harm: Can someone lose money because of this information?
- legal harm: Can someone get arrested because of this information?
- moral harm: Can someone's reputation be damaged because of this information?

Classroom Learning Activities should not need to address behaviors that participants consider private, sensitive topics, stigmatized behavior, or illegal behavior. These topics include private behavior in which an individual can reasonably expect that no observation or recording is taking place; personal behavior such as sexual identity or sexual practices; protected information such as health, disability status, or mental health diagnosis; violence, criminal activity, illegal behavior; personal history that may elicit embarrassment or shame. If the Classroom Learning Activity has a need to know these types of

information about human participants, then the data collection needs to minimize risks through sound research methods and needs to be reviewed and approved by the IRB.

§ 9.13 IRB Consultation

University instructors may obtain an opinion from the IRB that the proposed student learning activity meets the four criteria of adequate informed consent, voluntary participation, anonymous, and minimal risk, but IRB will not provide an approval letter for Student Learning Projects. (email IRBCommitteeChair@stmarytx.edu). If the Student Learning Project does not meet the four criteria, then the student and instructor must apply for IRB Review as a Project of Limited Scope.

If results of the student learning activity are later submitted for professional publication, sometimes the publisher asks for an IRB approval letter. In this case, the IRB can only provide a statement that this activity does not meet the definition of research, therefore 45 CFR part 46 does not apply.

If student class assignments must address sensitive topics that are inherently higher risk or must maintain identifiable private information, then students will need to complete the IRB Application for Research of Limited Scope.

If student projects are in fulfillment of an Honor's/Master's thesis or Doctoral dissertation, then students will need to complete the IRB Application for Proposal Review.

IRB Class Projects Policy

Class assignments intended to engage students with people and problems outside the classroom do not require IRB review and approval if they meet all the following criteria:

1. minimal risk;
2. anonymous data collection;
3. voluntary participation;
4. oral or written informed consent;
5. has no vulnerable population (children, prisoners, or pregnant women);
6. and is not intended for publication outside the university.

Class projects that meet all these criteria may proceed under the supervision of the course instructor. The instructor may request a consultation in cases that are unclear if the class project meets the criteria (email IRBCommitteeChair@stmarytx.edu). Class projects that, due to the nature of the subject matter or procedures, do not meet one or more criteria should complete an IRB Application for Proposal Review.

This is a summary of the IRB policies and procedures for class projects; instructors and students should consult the full policy at § 2.08-- § 2.16 of the IRB Policies and Procedure Manual.

Minimal risk: The probability of harm or discomfort is no greater than those ordinarily encountered in daily life. Harm or discomfort may be physical, psychological, or social; other harms may be economic, legal, or moral. Examples of each type of risk can assist the instructor in guiding student projects:

- physical harm: Will it bruise or draw blood?
- psychological harm: Will this activity evoke distressing memories?
- social harm: Will this information embarrass someone?
- economic harm: Can someone lose money because of this information?
- legal harm: Can someone get arrested because of this information?
- moral harm: Can someone's reputation be damaged because of this information?

Informed consent: The project should have a brief informed consent, oral or in writing, to include the purpose of the data collection, the duration, the class title and instructor responsible for the assignment, and how to contact the instructor. Providing the instructor's business card in an interview or contact information on an internet survey is sufficient contact information.

Anonymous: The data collection activity will not collect any form of personally identifiable information, such as signature, name, phone number, email address, government or university issued ID number, or date of birth. Classroom-based surveys should avoid "inadvertent disclosure." Given St. Mary's demographics, a classroom survey that includes detailed demographics (more than Hispanic, Anglo, and Other) can easily identify the one or two African-American or Asian subjects in the class. Class projects that utilize existing data should consult the IRB Policy on Class Projects.

Voluntary participation: Participants should be free to decline participation without loss of benefits outside the research activity. Linking participation in data collection activities with grades, attendance, or an alteration of course assignments may compromise voluntary participation and will require IRB review. Inducements of a value greater than a cup of coffee will require IRB review.
