# SUBMITTING A RESEARCH PROTOCOL INFORMATION for the College of Business & Management

**The following information explains the IRB forms, process for submission and approval process for research protocols.**

- **Most educators will submit the following IRB forms:**
  - **Human Participants Research Protocol**
  - **Informed Consent Form** *(Permission to work with* ***protected population and minors****. Includes* ***a parent/guardian letter*** *requesting permission to for child for participate in study)*
  - **Affiliation Agreement**
  - **Research Completion Form**

  **The Cooperative Research Agreement is completed ONLY if you are working with multiple agencies, or multiple school districts, NOT multiple schools within the same district.**

- **Most Doctoral Students will submit the following IRB forms:**

  **Live human subject research**
  - **Human Participants Research Protocol**
  - **Participant Information Statement (Non-protected population, non-survey research)**
  - **Informed Consent in Survey Research (Survey research only, non-protected population, and in place of Participant Information Statement)**
  - **Research Completion Form**

  **Non-living human subjects/no human subjects**

Send **(2) hard copies** and one e-copy of your protocol to:

**Liz Regimbal, Assistant Professor**
**Chair CBM IRB Advisory Committee**
**Cardinal Stritch University**
**Mailing Address: 11010 Prairie Lakes Drive Suite 300**
**Eden Prairie, MN 55344**
**1-800-347-8822 ex. 8807 (O)**
**(952) 943-0190 (F)**
**eeregimbal@stritch.edu**

Four hard copies and one e-copy of the protocol must be submitted no later than 7 days before a scheduled RAC meeting. A schedule of IRB meeting dates is available upon request supplied.

The RAC will make one of four decisions:

- Approve the protocol
- Conditionally approve the protocol contingent upon the completion of required changes
- Ask for clarifying information and review the protocol a second time
- Send the protocol to the Central IRB for further review (proposals that are federally funded and/or involve more than minimal risks, deception, protected populations, or sensitive topics are sent to the Central IRB for review).

## Complete IRB Training

An IRB training session must be completed. This training is required by the Federal Government's Office for Human Research Protections and Cardinal Stritch University. ***Training can be completed on-line at no cost by visiting On-Line IRB Training***. Most training programs allow you to save your answers in order to re-visit or complete training in multiple sessions. After successful completion of an IRB training program copy the computer-generated certificate that indicates a passing grade. Submit a copy of IRB certificate with your original IRB as verification that you passed training. **DON'T submit an IRB until the training program has been passed and an IRB training certificate has been earned. No research may begin until On-Line IRB Training has been completed and approved.** Any student, faculty member or visiting researcher must submit a copy of an IRB training certificate with their IRB protocol.

## Inform the IRB of any changes in your research

Promptly report

- Proposed changes in previously approved human research activities. The proposed changes may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
- Unanticipated problems involving risks to participants or others.
- Serious or continuing non-compliance with IRB regulations.

## Inform the IRB when you have completed your research

Submit a Research Completion Form stating that you have collected your data and you are no longer interacting with research participants. The form is included in the IRB packet.

Protocol #: _____ - _____ - _____
IRB use only

# Human Participants Research Protocol (HPRP)
# Institutional Review Board (IRB)
# Cardinal Stritch University

The following protocol must be submitted by:

- Any student, faculty member, or staff member of Cardinal Stritch University performing research involving human participants, regardless of where these participants are from and regardless of whether or not the research is federally funded, OR
- Any individual or institution performing research in which students, faculty, or staff at Cardinal Stritch University are participants, regardless of whether or not the research is federally funded.

The definition of research can be found in Definitions of Research on the IRB website located on the CSU Homepage.

**STOP! You must complete electronic IRB training and attach a hard copy of the training certificate with your IRB. *NO* IRB training certificate, *NO* review of your proposal! *NO* EXCEPTIONS! To complete the training go to the National Institute of Health, Office of Human Subjects Research for the Computer-Based (CBT) for NIH IRB members. The training is FREE, completely online, and will allow you to print a certificate of completion. You can also electronically save a copy of the IRB training completion certification. A hard copy is required when your IRB.**

## IRB Training Website: National Institute of Health
http://phrp.nihtraining.com/users/login.php

**INSTRUCTIONS**

- **Please fill out this form completely. Answer each question in the space following each question. Do not submit your full research proposal or chapter two.**

- **Do not begin recruitment of participants or data collection until you receive an approval letter from the Institutional Review Board.**

- **Please submit <u>two hard copies</u> and <u>one e-copy</u> to the IRB College Advisory Committee Chair: Contact Information:**
  **Liz Regimbal, Assistant Professor and RAC Chair.**
  College of Business & Management 1-800-347-8822 ex.8807or eeregimbal@stritch.edu

- **The Chair of the RAC will contact you and the research advisor via e-mail within 24-48 hours after the committee has met. Every attempt is made to contact graduate students the same day of the IRB meeting. A hard copy of the decision letter will be sent through the U.S. Postal Service for documentation of the RAC decision. If the RAC has a large amount of protocols to review, it may take longer to individually contact each graduate student.**

- **Note that the principal investigator (YOU) other investigators (Research Assistant, Teacher's Aide, etc., identified below), and the major advisor are the only individuals who may have access to data containing the names or identities of the participants. IRB approval is needed for others to have access to this information.**

# Human Participants Research Protocol (HPRP)
# Institutional Review Board (IRB)
# Cardinal Stritch University

**1. Principal Investigator**

Name _____

Address (full) _____

**Street**

_____

**City** **State** **Zip Code**

Phone _____

Email address _____

Department **(Example) Graduate Education, Doctoral**

Student _____ Faculty _____ Staff _____

**Other Investigator(s) (Complete only if additional researchers are involved in the project)**

Name _____

Address _____

Phone _____

Email address _____

Department _____

Student _____ Faculty _____ Staff _____

**Major Advisor (if applicable)**

Name _____

Address _____

Phone _____

Email address _____

Department _____

**2. Project Title** _____

Application date

Beginning and end dates of project **(NOTE: The beginning date of a research project must be a date occurring after the IRB meeting has taken place. Example: If you are submitting your proposal for a January 16th IRB meeting, the beginning date of the research must be listed after January 16th.**

Funding source: Personal, grant (state source), etc.

**3. Participants**

a. Describe the pool of participants

1) Gender (if one gender, justify your exclusion of the other)

2) Age

3) Race/ethnic group (if excluding specific people of color, justify their exclusion).

4) Number/sample size

5) Physical and mental health (if a study requires that participants are to be in good health, indicate how this will be determined).

6) Protected populations

a) Do the participants belong to any of the following protected populations? **Check all that apply or place NA on the line if the category doesn't apply.**

(1) _____ Minors (17 years or younger)
(2) _____ Persons with mental disabilities
(3) _____ Persons with _____learning, _____emotional, _____cognitive disabilities
_____ Aspergers Syndrone, _____ Autism, _____other health impaired
(check all that apply)
(4) _____ Prisoners
(5) _____ Pregnant women and fetuses
(6) _____ Any individual who might not be capable of making an informed decision concerning participation. Please explain.

b) If the participants are from a protected population, justify the necessity of their participation.

**(1)** Why are you using a protected population?

(2) What prevents you from using a non-protected population?

(3) Does the protected population in the research sample participate in "normal classroom activities" with few adaptations? _____ Yes _____ No

(4) Does the protected population in the research sample have a current Individualized Educational Plan (IEP) that specifies participation in "normal classroom activities"?
_____ Yes _____ No _____ Unsure

(If multiple categories of disabilities or more than one student with a diagnosed disability are present in the principal investigator's classroom please respond to question four for each participant in the space).

**NOTE: IRB proposals that include children or adults with a diagnosed disability such as autism, seizure disorder, etc., are required to submit the proposal to the individual college Research Advisory Committee (RAC) who in turn will submit the proposal to the Central IRB Committee. This adds an additional step to the IRB and will delay the approval process. Plan accordingly. The Chair of the Research Advisory Committee will assist in the submission of the IRB proposal to the Central IRB Committee and will also represent the proposal. You do not have to appear before the Central IRB Committee.**

b. Participant recruitment

1) Affiliation of participants relates to institutions, agencies, schools, hospitals, or the general public (from where you will recruit your participants). If recruiting from any institution other than Cardinal Stritch University, complete an Affiliation Agreement, even if you are employed at that institution.

2) Describe how participants will be contacted and recruited.

3) If applicable, include copies of recruitment materials, such as advertisements or flyers.

c. Will you be using archival data (data that have already been collected)?
No ____ Skip to the next question.
Yes ____

1) Describe the source of the data.

2) If another institution approved the original IRB protocol, please give the name of that institution and include a copy of their approval letter.

**4. Brief description of the project**: Please fill in requested information after each heading. Use as much space as needed. Do not submit a separate description/proposal. Include one or two scholarly references where appropriate. Please make sure a description and purpose of the intervention is clearly described (if appropriate).

a. **Purpose and hypothesis**: State the purpose and/or hypothesis of your study.

b. **Data**: Describe information to be gathered. Provide definitions of unfamiliar terms with a scholarly reference if applicable.

c. **Procedure**: Describe how data will be collected and recorded (what will participants be required to do?). **Be specific when working with a protected population. Provide examples of tally sheets, or any record keeping forms used for data collection. Please label each data collection form.**

d. **Personnel**: Describe personnel interacting with the participant(s).

1) Roles of the personnel.

2) Qualifications of the personnel

e. **Location**: Describe the location where the participant involvement will take place.

f. **Time**: State the total amount of time required of each participant.

g. **Deception:** Will deception be involved?

No _____ Skip to the next question.
Yes _____

1) Describe the deception.

2) Justify the use of deception.

3) How and when will participants be debriefed about the deception?

g. **Sensitive topics:** Does the study involve any sensitive topics that might adversely affect the participant's reputation, character, or employment (e.g., sexual or illegal behaviors)?
No _____ Skip to the next question.
Yes _____ Please describe

- If the study involves a sensitive topic and the participant could be identified, a signed Informed Consent Form must be submitted.
- If the researcher believes that information collected from a participant could have adverse effects on the participant if the researcher is compelled by a legal agency to reveal that information, a *Certificate of Confidentiality* should be filed (http://hhs.gov/ohrp/humansubjects/guidance/certconf.pdf )

h. **Confidentiality**: Does your study use protected populations or deal with sensitive topics?
No _____ Skip to the next question.
Yes _____

1) Can individual participants be identified by name, appearance, or by some other means?
No _____ Yes _____

2) Are your data
Anonymous _____ Confidential _____

Note that **anonymous** data have no identifying information that can link the participants to their data (the researcher will not know the participants' identities), whereas **confidential** data means the researcher may know the participants' identities but the participants' data will not be shared with anyone except in aggregate or group form.

3) Describe specific procedures to be used to ensure the anonymity or confidentiality of the individual participant's data.

4) How will the information obtained from the participants be used? That is, what information will be accessible to others (e.g., discussed in a class, presented at a conference or submitted for publication)?

i. **Records:** How will participants' records be stored and safeguarded?

1) Discuss how you will handle the data *during* your study (e.g., where will it be stored?).

2) Discuss how you will handle the data after the *completion* of your study (e.g., where will it be stored?).

Note

- Identifiable data need to be securely stored for a period of at least **three years** after completion of research.
- Secure storage consists of locked desks, cabinets or rooms to which individuals other than the principal investigator do not have access.

j. **Risks**: Will the participants be subjected to physical, psychological, social, legal, or economic risks, immediate or long-range, that are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests?

No _____ Skip to the next question.

Yes _____

1) Describe these risks.

2) Describe the necessity of such risks.

3) Describe the alternative research methods that were or will be considered.

4) Describe why alternative research may not be feasible.

k. **Benefits**

1) Describe the benefits to the participants to be gained from this research (please state if there are none).

2) Describe the benefits to society as a whole to be gained from this research (please state if there are none).

3) If there are risks associated with your study, describe why you believe the value of the information to be gained outweighs the risks.

l. **Surveys and interview questions:** Will you be giving a survey or asking interview questions?

No _____ Skip to the next question.

Yes _____

1) Attach a copy of any survey, questionnaire, test instrument, or interview questions to be used in your research. Provide the web-site for on-line surveys.

2) If a copy cannot be attached, please explain.

m. **Summary of test or instruments used in preliminary screening of participants:** Will you be performing a preliminary screening in order to choose participants?
No _____ Skip to the next question.
Yes _____

1). Describe all instruments used in screening of participants. ), **Insert copies, not originals, of pre and post tests, and/or any validated, criterion referenced, formative assessment, used as a data collection tool. Please state the origin of any test instrument used in the study, i.e., teacher-prepared, researcher-prepared, American Testing Service (ATS).**

2) Describe how these instruments will be used in your research.

n. **Cooperating institutions**

1) Will you be conducting research at an institution other than Stritch (e.g., a school or hospital)?
No _____ Skip to the following question.
Yes _____
a) Attach a copy of an Affiliation Agreement on that institution's letterhead.
b) For school-based research, provide a signed approval form from the principal or other authorized person on that school's letterhead in addition to the *Affiliation Agreement Form*.

2) Will you be conducting research in cooperation or in partnership with another institution?
No _____ Skip to the next question.
Yes _____
a) Attach a copy of a Cooperative Research Agreement on that institution's letterhead.
b) Note that the principal investigator is responsible for ensuring that all collaborating institutions operate under Stritch's IRB guidelines.

**5. Information given to participants:** All potential participants *must* be given a written explanation of the study, including participant expectations, risks, benefits, and the participant's right to withdraw without penalty. Individuals must also understand that participation in research is voluntary. This allows potential participants to make an informed decision about whether or not to participate in the research. Depending on the type of research, **one** of the following three forms must be provided to the participant. Please include a copy of the appropriate form with your protocol. Explanations and examples are provided with each type of form. The following forms are not required in cases where data have already been collected (i.e., existing or archival data).

**a.** Participant Information Statement**.** This is the most commonly used form. The rights and expectations of the participants must be described. Signatures are not required. This form is used when the research does not require one of the following two forms.

**b.** Informed Consent Form**.** This is similar to the *Participant Information Statement*. However, in addition to providing information on the rights and expectations of the participants, a signature is required from the participant or the participant's parent, legal guardian, or legal representative (**if the participant is a minor or is unable to understand his or her involvement in the resea**rch). This applies in cases where the research entails

- Sensitive topics (e.g., illegal or sexual behaviors)
- Protected populations
- Audiotaping or videotaping participants
- The possible identification of the participant (directly or indirectly) when disclosure of their responses outside of the research could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.

**c.** Informed Consent in Survey Research**.** This is also similar to the *Participant Information Statement* and is used for research involving anonymous or confidential surveys. Participants need not sign a consent form so as to avoid establishing an unnecessary link between the participants and their data. This is especially important when a survey deals with sensitive topics that may place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation. Informed consent is obtained by including the following statement:

"Filling out this survey indicates that I am giving my informed consent to be a participant in this study."

However, surveys given to minors or individuals not able to make an informed decision whether or not to participate must first be approved (via signature) by a parent, guardian, or legal representative.

Note that for each of the above three forms, the participant must be provided with a copy of the document and the researcher must also keep a copy.

**6. Study Completion:** The IRB must be informed, in writing, once all data have been collected (Research Completion Form).

**7. Principal Investigator Assurance:**

I have read the Stritch Standards for the Protection of Human Participants of Research, including the obligation to obtain informed consent from participants, when appropriate, and I will comply.

Signed _____ Date _____
Principal Investigator (student, faculty, or staff)

Signed _____ Date _____
Major Advisor (if applicable)

IRB approval is for a period of 12 months. In the event that the research is not completed within the 12 month period, the protocol must be resubmitted to the IRB. Significant changes or additions must also be submitted.

# AFFILIATION AGREEMENT

Cardinal Stritch University
Institutional Review Board

The following form is to be used if you will conduct research at an institution other than Stritch (e.g., a school or hospital). That institution will provide access to participants but is not a partner in the research. The *Affiliation Agreement* establishes that the institution is giving permission to you, the researcher, to conduct a study using that institution's students, employees, previously collected data, facilities, etc.

If that institution is actively engaged in the research project (e.g., collecting data, disseminating information, etc.), then you will instead complete and submit a Cooperative Research Agreement.

Submit an original signed copy of the *Affiliation Agreement* on the institution's letterhead. For school-based research, provide a signed approval form from the principal or other authorized person on that school's letterhead in addition to the *Affiliation Agreement* form.

In the following form, please replace **underlined** material with the appropriate information.

# AFFILIATION AGREEMENT FORMAT

Letterhead of Institution

**Affiliation Agreement**: Name of school/agency/company is giving permission to name of researcher, title (student, faculty, etc.) from the college/department at Cardinal Stritch University, to conduct research at name of school/agency/company

**Nature of the Research Project**: The researcher will conduct a study on title of study. Provide a brief description of the research project. The researcher will require access to data, participants, or other resources necessary to conduct this research.

**Contact Person at Name of school/agency/company**: The contact person at your organization with whom the researcher is to communicate regarding the research project is

Contact person's name and title
Address
Telephone number
E-mail address.

**Contact Person at Cardinal Stritch University**: The contact person at Stritch with whom our organization is to communicate regarding the research project is

Your name and title
Address
Telephone number
E-mail address.

**Confidentiality of Data**: The researcher has agreed to protect the confidentiality of data collected. Participants will not be individually identifiable.

**Report**: The researcher will share a copy of the final report with our organization upon our written request.

**Questions:** If there are any questions or concerns regarding this project, please notify in writing and mail to the following address:

Liz Regimbal, IRB Chair CBM Advisory Committee
Cardinal Stritch University
11010 Prairie Lakes Dr. Suite 300
Eden Prairie, MN 55344
1-800-347-8822 ex.8807
eeregimbal@stritch.edu

# AFFILIATION AGREEMENT
# EXAMPLE

School District of Waukesha
222 Maple Avenue
Waukesha, WI 53186
262-970-1015

Dear xxxxxxxxx

The Doctoral Department of Cardinal Stritch University appreciates your willingness and cooperation for allowing Joan L. Whitman to conduct research at your facility, School District of Waukesha.

**Nature of the Research Project**: The research activities are considered part of the normal instructional process. The researcher will conduct a study on and involves the following provide a brief description of the research project. The researcher will require access to data, participants, or other resources necessary to conduct research.

**Contact Person**: The contact person at your organization with whom the researcher is to communicate regarding the research project is contact person's name, title, address, telephone number, and e-mail address.

**Confidentiality of Data**: The researcher has agreed to protect the confidentiality of data collected and participants will not be individually identifiable.

**Report**: The researcher will share a copy of the final report with your organization upon written request.

If there are any questions or concerns regarding this project, please notify in writing and mail to the following address:

Liz Regimbal, IRB Chair
Cardinal Stritch University
11010 Prairie Lakes Drive Suite 300
Eden Prairie, MN 55344
1-800-347-8822 ex 8807
eeregimbal@stritch.edu

Thank you for your cooperation.

_____ Date _____
Signature of Research Student

_____ Date _____
Signature of Official of Cooperating Organization

_____ Date _____
Signature of Faculty/Staff/Faculty Advisor

1-20-10 jlw

# Informed Consent Form Information

## Introduction

Whenever you perform research involving human participants, you must let them know what you expect them to do as well as their rights and responsibilities as participants. That is, all potential participants *must* be given a written explanation of the study, including participant expectations, risks, benefits, and the participant's right to withdraw without penalty. Individuals must understand that participation in research is voluntary. You must also allow potential participants to ask questions to clarify their role in the study. This allows potential participants to make an informed decision about whether or not to participate in the research.

Depending on the type of research, one of the following three forms must be provided to the participant, unless the data have already been collected (e.g., archival data). Please include a copy of the appropriate form with your protocol. Explanations and examples are provided below.

**a.** Participant Information Statement**.** This is the most commonly used form. It is completed when the research does not involve sensitive topics, protected populations, illegal behaviors, or audio/video taping of participants' behaviors. Although the rights and expectations of the participants must be described, signatures are not required.

**b.** Informed Consent Form**.** This is similar to the *Participant Information Statement*. However, in addition to providing information on the rights and expectations of the participants, a signature is required from the participant or the participant's parent, legal guardian, or legal representative (if the participant is a minor or a person unable to understand his or her involvement in the research). This form must be completed in cases where the research entails

- Sensitive topics (e.g., illegal or sexual behaviors)
- Protected populations
- Audiotaping or videotaping of participants
- The possible identification of the participant (directly or indirectly) when disclosure of their responses outside of the research could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.

**c.** Informed Consent in Survey Research**.** This is also similar to the *Participant Information Statement* and is used for research which involves anonymous or confidential surveys. Participants need not sign a consent form so as to avoid establishing an unnecessary link between the participants and their data. For example, if asking questions about the participant's use of illegal drugs, the researcher would want to avoid any possibility of the survey's respondents being identified. Informed consent is obtained by including the following statement:

"Filling out this survey indicates that I am giving my informed consent to be a participant in this study."

However, surveys given to minors or individuals not able to make an informed decision whether or not to participate must first be approved (via signature) by a parent, guardian, or legal representative.

**Note that in each case, the participant must be provided with a copy of the document and the researcher must also keep a copy.**

# Participant Information Sheet

## Required Information

**When to use this form:**

- Complete this form if your research involves minimal risks to your participants (i.e., 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).
- Rather than using this form, complete an Informed Consent form if your research involves
  - Sensitive topics (e.g., illegal or sexual behaviors)
  - Protected populations (minors 17 years of age or younger, persons with mental disabilities, persons with developmental disabilities, prisoners, pregnant women, fetuses, any individual who might not be capable of making an informed decision concerning participation).
  - Audiotaping or videotaping of participants
  - The possible identification of the participant (directly or indirectly) when disclosure of their responses outside of the research could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.
- Complete an Informed Consent in Survey Research form if participants will fill out a survey or questionnaire.

The form can be altered to fit your needs, but the following information MUST be included:

- General information
  - Title of the project
  - Date
  - Your name
  - Your affiliation with the university (student, faculty, staff)
  - The names of other people with whom the participant will interact
  - Purpose of the study
- Procedure
  - What you expect the participant to do
  - Time commitment of the participant
- Confidentiality or anonymity
  - A statement telling the participant whether or not you will ensure anonymity (no one, not even the principal investigator, will know the participant's identity) or confidentiality (the principal investigator or specified others may know the participant's identity, but that identity will not be revealed to others). Unless it is not possible, it is a good idea to ensure one or the other.
- Risks
  - Description of potential risks, physical or psychological, involved in the study. If there are no foreseen risks, state so.
- Benefits
  - A statement of the potential benefits of the study to the participant (if there are none, state so)
  - A statement of the potential benefits of the study to society (if there are none, state so).

- Voluntary nature of participation
  - The participant may withdraw from the study at any time
  - If doing so, there will be no penalty or adverse effects
  - Data collected up to this point can be destroyed if the participant requests this to be done.
- Use of information
  - A statement discussing what will be done with the information gathered. For example, will the results be presented at a conference, submitted for publication, or simply used for classroom.
- Who to contact if there are questions, concerns, or complaints. This will include
  - Your name, e-mail, and phone number (for students, we suggest you list your Department's contact information rather than your personal information)
  - Your instructor's e-mail, phone number, and address
  - The IRB chair's e-mail, phone number, and address (this is followed by a statement that all complaints will remain confidential)

    Liz Regimbal, IRB Chair CBM Advisory Committee
    11010 Prairie Lakes Drive Suite 300
    Eden Prairie, MN 55344
    1-800-347-882 ex 8807
    eeregimbal@stritch.edu

- A statement that the research has been approved by the Cardinal Stritch University's Institutional Review Board for the Protection of Human Participants for a period of 12 months and the date of that approval.

Note:

- The *Participant Information Statement* must be written in a language that can be understood by someone with a sixth grade education
- One copy must be given to the participant and a second copy must be kept for the principal investigator's records.

# PARTICIPANT INFORMATION STATEMENT EXAMPLE

## OBSERVATIONAL SKILLS OF MILWAUKEE POLICE OFFICERS

January 15, 2008

My name is Dr. Mai Vang. I am a faculty member in the Department of Psychology at Cardinal Stritch University. I am conducting a study on the observational skills of Milwaukee police officers.

Procedure: You will be asked to watch a 3-minute video clip depicting activity in a convenience store. Following the video, you will be asked six questions concerning what you observed in the video. The study should require no more than 20 minutes of your time.

Confidentiality: All responses to the questions will remain confidential (i.e., I will not reveal your responses). To ensure confidentiality, do not include your name on the answer sheet.

Risks: I do not anticipate this study will cause any type of risk, psychological or otherwise.

Benefits: Although this study probably will not benefit you directly, this research will help psychologists understand observational skills in trained observers.

Participation is Voluntary: If you are not comfortable with this study, please feel free to stop at any time. Your answers to the questions will be destroyed upon your request and you will not be penalized in any way.

Use of Your Information: My goal is to present the results of this study at a scientific meeting. Only aggregate (combined) data from all participants will be used, and in no case will any names be associated with this study.

Contact Information: If you are interested in the results of this study (which should be completed by May 15, 2009), or if you have any other questions, concerns, or comments on this project, please contact:

Dr. Mai Vang
Department of Psychology
Cardinal Stritch University
6801 N. Yates Rd., Box 2134
Milwaukee, WI 53217-3985
414-410-9991
mxvang@stritch.edu

If you have any complaints about this study, please call or write:

**Fill in the name of the current IRB chair from the College you are attending here:**

_____Liz Regimbal_____

Although your name may be asked, all complaints are kept in confidence.

Thank you for your cooperation.

1-20-10 jlw

This research project has been approved by the Cardinal Stritch University Institutional Review Board for the Protection of Human Research Participants on January 12, 2009, for a period of 12 months.

**INSTITUTIONAL REVIEW BOARD (IRB)**

1-20-10 jlw

# RESEARCH COMPLETION FORM

The Research Completion Form must be submitted to the IRB Research Advisory Committee in your college after data have been collected for your study. This form will be filed with your original IRB once it is received. Please follow the directions for completion of the Research Completion Form.

**Research Completion Form Directions:**

1. Complete both sides of the Research Completion Form immediately after all data have been collected for your study.

2. Provide your original signature and, if applicable, obtain your research advisor's signature.

3. Mail, fax, or e-mail (with electronic signatures) the original Research Completion Form to
   Liz Regimbal, Assistant Professor
   College of Business & Management
   11010 Prairie Lakes Drive Suite 300
   Eden Prairie, MN 55344
   1-800-347-8822 ex 8807(Office)
   (952) 943-0190 (Fax)
   eeregimbal@stritch.edu

4. Reminder, the Research Completion Form should be submitted immediately after data collection is completed, and not after you have finished writing the research document.

5. Note that you have 12 months to collect your data. If more time is needed, a new IRB Human Participants Research Protocol (HPRP) will be required.

6. Please contact the chair of your IRB Research Advisory Committee if any questions arise.

## Research Completion Form

1-20-10 jlw

**Directions: Submit the Research Completion Report with original signatures after data have been collected.**

**Submit to: College Advisory Committee Chair at the College where the IRB was approved.**
College of Business & Management Liz Regimbal eeregimbal@stritch.edu

**Principal Investigator** _____
**Department** _____
**Phone** _____
**E-mail** _____

**Project Title** _____

**Project Completion Certification**

I certify that as of today's date, data collection with human participants is no longer taking place for the project titled above. Therefore, the IRB protocol can be officially completed/terminated at Cardinal Stritch University.

| **Signature of Principal Investigator** | **Printed Name** | **Date** |
|---|---|---|
| | | |

| **Signature of Research Advisor/ Supervisor** | **Printed Name** | **Date** |
|---|---|---|
| | | |

**For Office Use Only**

**IRB Advisory committee**

**Original Disposition: Exempt Expedited Full Review**

**Original Approval Date:** _____/_____/_____

**IRB Termination Date:** _____/_____/_____

1. **Provide a brief description of the results obtained in the study.**

2. **Have any articles been published using the results of this study?**
   _____ YES _____ NO

3. **Participant Recruitment**
   Total number of participants enrolled:
   Total number of participants completed the project:

4. **Adverse Events**
   Have any adverse events occurred during the data collection period?
   _____ YES _____ NO

   If YES, how many?

   Describe these events:

   **Were adverse events reported to the IRB or the department where the research originated?**
   _____ YES _____ NO

5. **Changes in Research Protocol**
   Were changes made in the procedure, recruitment of participants, or interaction with participants after IRB approval?
   _____ YES _____ NO Minor changes were made that were not reported to the IRB because they did not change the level of risk and/or had no impact on the willingness of participants to engage in the research.
   _____ YES _____ NO Major changes were made. These were reported to and approved by the IRB.
   _____ YES _____ NO Major changes were made. These were NOT reported to or approved by the IRB.

   Please describe these changes: _____

6. **Completion/Termination Rationale**
   Please check all applicable reasons for completion or termination of the IRB protocol and provide an explanation if necessary.

   _____ a. data collection completed
   _____ b. thesis/research paper written using collected data
   _____ c. student did not complete data collection in 12-month time period
   _____ d. student is graduating
   _____ e. funding was not received to complete data collection
   _____ f. other (explain)

Please submit completed **original** form to the College Advisory Committee representative where your IRB was approved.

1-20-10 jlw

# CARDINAL STRITCH UNIVERSITY
# INSTITUTIONAL REVIEW BOARD
# CHANGES IN RESEARCH

This form must be completed when

- A change has been made in the study's procedures, design, and recruitment of participants, surveys or any other aspect of the study that could affect the ability or willingness of participants to make an informed consent to participate in the study.
- Unanticipated problems have occurred in the collection of data.
- Data collection was terminated to avoid exposing participants to apparent or immediate hazards (e.g., physical, psychological, or legal risk).
- Researchers have not complied with procedures approved by the IRB.

This form does not need to be completed when

- Changes or problems are minor and
- Are extremely unlikely to affect a person's willingness to participate in the study and
- Do not involve physical, psychological, or legal risk greater than was originally approved by the IRB.

If you have questions regarding the applicability of this form, please write or call your College IRB Research Advisory Committee chair (IRB Members).

Date of changes, unanticipated problems, termination of data collection, etc.:

Describe the changes that were made:

Describe the reason for the changes that were made:

Name of Principal Investigator: _____ College _____

Signature: _____ Date: _____

Name of Advisor: _____

Signature: _____ Date: _____

Return this form to the chair of your College's IRB Research Advisory Committee (IRB Members) prior to making any protocol revisions or, if changes are immediately needed to safeguard participants, within five working days of the change.

**FOR IRB USE ONLY**

College RAC _____ College RAC Chair _____

Decision:

_____ Approve
_____ Ask for Additional Information
_____ Send to Central IRB

College RAC Chair signature _____ Date _____

# IRB Definitions
# Cardinal Stritch University

1. **Affiliation Agreement** is an agreement between the researcher and institution/agency where the researcher is employed and will conduct research with human subjects.

2. **Cooperative Research Agreement** is an agreement between two or more different institutions/agencies to conduct research with human subjects.

3. **Competence** involves the use of procedures and techniques used only by qualified and/or experienced researchers, with care being taken to protect the welfare of the participants.

4. **Dependent variable** means the variable, or event that is being measured; the variable that is affected by the manipulation of the independent variable (e.g., the number of correct answers on a test, the answers to a survey question).

5. **Deception** is involved when participants are not informed about the risks of research in order to gain cooperation from the subjects. (Note; care must be taken to identify research in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the investigator).

   **An alternative definition of deception** means that participants may not be fully aware that they are involved in the research. The deception by a researcher for the purpose of securing participant's cooperation and/or to prevent potentially biased reporting of data by the participant is allowable provided that all of the following conditions are met:

   1) Deception is necessary due to lack of alternative procedures for data collection not involving deception;
   2) The deceptive procedures will not place participants at significant financial, physical, psychological, or social risks;
   3) Careful debriefing whereby the participants are fully informed of the nature and purpose of the deception will follow the data collection/experiment.

6. **Exempt research** includes those activities in which there is minimal participation of human participants as defined in OPPR Report 455 CRF Section 46.101.

7. **Expedient research** is that which involves no more than minimal risk to the participant or for which a previously approved protocol requires minor changes. Approval is obtained from the IRB Chair or designated IRB member.

8. **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** protects against the misuse or disclosure of the participants health records and personal information.

9. **Human participant** means a living individual with whom an investigator (faculty, staff, or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (45 CFR 46.102).

10. **Informed consent** is a statement of agreement to be signed by the participant and/or his/her parent or legally authorized representative in whom s/he expresses a willingness to participate in the experiment detailed in the document.

11. **Independent variable** means the variable, or treatment that is manipulated by the research (e.g., if the different tests are given to different groups of participants, the type of test would be the independent variable).

12. **Institution** means any public or private entity or agency including federal, state, and other agencies.

13. **Instrument(s)** is a measuring device for determining the present value of a quantity under observation. Examples of an instrument might be questionnaires or surveys.

14. **Interaction** includes communication or interpersonal contact between investigator and participant.

15. **Intervention** includes both physical procedures by which data are gathered (for example venipuncture) and manipulations of the participant or the subject's environment that are performed for research purposes.

16. **Legalized authorized representative** is an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to allow participation in the procedure(s) involved in the research.

17. **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.

18. **Private information** includes information about the behavior of an individual that occurs in a situation and will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the participant is available to the investigator or associated with the information) in order to obtain information to constitute research involving human participants.

19. **Protocol** is a plan for scientific experiment or treatment.

20. **Research** means a systematic investigation, including methodology development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of these regulations, whether or not they are supported or funded under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

21. **Research proposal** is a written plan for the proposed research investigation containing basic information related to the area being researched.

22. **Sensitive or protected population** includes minors (17 years of age or younger), persons with mental retardation, people with mental disabilities, persons with developmental disabilities, older people (65 and over), prisoners, pregnant women and fetuses, or any individual who might not be capable of making an informed decision concerning participation (e.g., persons with mental illness or psychiatric disability) as defined by the code of federal regulations 45.CFR.