Rockford College
Institutional Review
Board Policies

(Originally Developed Fall 1999)
(Revised Spring 2002 by Stuart Tousman, Ph.D.
Associate Professor of Psychology, IRB Chair)
POLICIES AND PROCEDURES FOR RESEARCH INVOLVING HUMAN SUBJECTS

It is morally and ethically imperative that the rights and welfare of research subjects be protected. In accordance with federal, as well as state regulations, Rockford College has established the Institutional Review Board for the Protection of Human Subjects (IRB) and the following policies and procedures for research involving human subjects, or data or materials derived from humans. Safeguarding the rights and welfare of human subjects utilized in research protects not only the individual subject, but also the researcher and the institution sponsoring the research project.

The IRB has been charged with implementing these policies and procedures, which are applicable to any research project, either funded or unfunded, originated at or supported by Rockford College, if it involves humans as subjects, or data or materials derived from humans. This would include all research involving Rockford College students, personnel, or facilities. All research projects will be held to the standards for federally funded projects set by the Code of Federal Regulations, 45 CFR 46 (March 8, 1983), and the Federal Policy for the Protection of Human Subjects: Notices and Rules (June 18, 1991). Research can not be initiated by faculty, staff or students before it is reviewed and approved in writing by the IRB.

Research, as defined in the federal policy, means "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". Research protocols for such projects must be reviewed and approved by the IRB to assure that the rights and welfare of human subjects are protected and that appropriate methods of obtaining informed consent will be utilized.

The IRB review will ascertain if subjects will be placed at risk. The review shall ascertain whether:

1. Potential risks to the subject are clearly identified.
2. Risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant approval of the research project.
3. Rights and welfare of all subjects will be adequately protected.
4. Adequate explanation of the potential risks and safeguards, as well as benefits, are given to the subjects and legally informed consent will be obtained by adequate methods in accordance with the provisions outlined in Appendix C.
5. Any exceptions are consistent with federal and university guidelines.

Engaging in research involving human subjects, data or materials without the approval of the IRB violates Rockford College policy. Data on human subjects must not be collected until the IRB approves the project in writing.
To help researchers fulfill their responsibility, the IRB has developed the following procedures. These procedures are intended to facilitate progress from an initial research request to final protocol approval.

A. **Assigning an IRB Consultant/Reviewer**
   Contact the Chair of the IRB to have a member assigned to your project. The IRB consultants/reviewers will assist faculty and staff, and answer their questions. Student initiated research must be directed by a faculty or staff research sponsor.

B. **Determining Level of Review**
   Research involving human subjects (or data or material derived from human subjects) will be reviewed at either the exempted, expedited, or full board level. To determine a protocol's review level, use the checklists in Section B.

C. **Preparing Your Protocol**
   After you have determined your proposal's review status, begin preparing the IRB review protocol, which appears in Section C. The IRB review protocol should not be as lengthy or comprehensive as funding or dissertation proposals. However, most material for the IRB protocol can be extracted from those proposals.

D. **Submitting the Protocol**
   The procedure for submitting the protocol depends on whether the primary researcher is a faculty/staff or student. Faculty or staff should submit typed protocols requesting exempted, expedited, or full board review directly to the assigned IRB consultant/reviewer. The consultant/reviewer will review the materials and either (1) return the request to the researcher with suggestions for clarification or change, or (2) send the request and his/her recommendation on to the IRB Chair.
   
   Students must submit research proposals to the faculty member in their department for corrections and/or editing and approval. We recommend that faculty member share the proposal with other members of their department for approval. When final, typed copies must be submitted by the sponsor to the IRB consultant/reviewer and should include the faculty member's recommendation of the project. From that point, the procedure will be the same as for faculty/staff research, except that all IRB communication will be directed to the student's research sponsor.
   
   If exempted status has been requested and the consultant/reviewer agrees, the decision will be immediate. Requests for expedited review will be sent to one other IRB member for consideration; those for full board review must be considered during a scheduled monthly meeting of the IRB, with the principal investigator in attendance.

E. **Results from the IRB Review**
   The IRB has the authority to approve, require modifications needed to secure approval, or disapprove research projects. It is anticipated that most protocols will be approved with only minor or no modifications. However, if a project is disapproved, you will be notified in writing and given reasons for the decision. You would then have an opportunity to respond to the IRB in writing or in person.
   
   Some projects approved by the IRB may be subject to further review by College officials. The Dean might agree with the approval of a project. However, if the project is federally funded, they could not approve of a project that had been disapproved (See 46.112 of 45 CFR 46).
Section B

DETERMINATION OF APPROPRIATE LEVEL OF REVIEW

The initial step in the preparation of your research protocol involves determining the appropriate level of review. The principal investigator (and the sponsor if the principal investigator is a student) are asked to make an initial recommendation as to the appropriate level of review. Assistance may be obtained from your assigned IRB consultant/reviewer. This is a tentative recommendation; the consultant/reviewer and/or the IRB Chairperson may require a level of review different from your recommendation.

What follows are descriptions of the categories of research which qualify for exempted, expedited, and full review. Beginning with exempted research, please read the description and complete the checklist. Continue through the descriptions until you reach the level of review for which your project qualifies.

I. EXEMPTED RESEARCH

Generally, research which does not propose to disrupt or manipulate subjects' normal life experience, or incorporate any form of intrusive procedures, may be declared exempted from expedited or full board review (Title 45 CFR 46, March 8, 1983, and the Federal Policy for the Protection of Human Subjects, June 18, 1991). Major considerations when determining if an exempted level of review is appropriate include level of risk and the presence or absence of deceptive procedures.

MINIMAL RISK means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Projects involving more than minimal risk must be presented for full board review. Further, any degree of deception disqualifies a study from exempted review.

A. CHECKLIST FOR EXEMPTED REVIEW LEVEL

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
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<tbody>
<tr>
<td>1. It is clear that the nature of the proposed research fits one of the categories listed in section I.B. of this appendix.</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>2. No implications for criminal or civil liability, employability, or damage to subject's financial standing or reputation would exist if data were known outside of the study.</td>
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<tr>
<td>3. The research does not employ a protected group as subjects (eg. fetuses, pregnant women, prisoners, mentally handicapped, minors in a</td>
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</table>
The study does not present more than a MINIMAL RISK to subjects.

The study does not involve DECEPTION.

Appropriate informed consent procedures will be followed.

"Yes" answers to all of the above are required to qualify for a recommendation for exempted review.

B. RESEARCH ACTIVITIES ELIGIBLE FOR EXEMPTED REVIEW

1. Exemption For Education
   Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods is exempted. (Individuals under the age of 18 constitute a protected class. Consequently, many projects involving minors will require full board review. However, some of these exemptions are applicable to research with minors. Exemption 1 applied to research with minors.)

2. Exemption For Research Involving Educational Tests
   Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) is exempted, unless (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (Applies to research with minors).

3. Exemption For Survey Or Interview Procedures
   Research involving survey or interview procedures is exempted unless (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (Does not apply to research with minors).

4. Exemption For Research Involving Observation of Public Behavior
   Research involving observation is exempted unless (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (Applies to research with minors only when the investigator(s) does not participate in the activities observed.)
5. Exemption For Research Involving Elected or Appointed Public Officials or Candidates for Public Office
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempted under exemption #2, #3, and #4 above is exempted if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

6. Exemption For Collection Or Study Of Existing Data
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens is exempted, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

7. Exemption for Research and Demonstration Projects Conducted by or Subject to Approval of Federal Departments or Agencies
Research and demonstration projects which are conducted by or subject to the approval of department or agency heads are exempted if they are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs, (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

8. Exemption for Taste/Food Quality Evaluation and Consumer Acceptance Studies
Taste and food quality evaluation and consumer acceptance studies are exempted if, (i) wholesale foods without additives are consumed; or (ii) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
II. RESEARCH ELIGIBLE FOR EXPEDITED REVIEW

In general, research may qualify for expedited review if it is judged to involve no more than minimal risk, does not include intentional deception, does not employ sensitive populations or topics, and includes appropriate informed consent procedures. (The Statement of Assurance provided by the institute to the US Department of Health and Human Services provides additional information.) As defined earlier,

**MINIMAL RISK** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

The greater the probability of harm or discomfort, the greater the responsibility of the researcher to provide safeguards for the protection of subjects' safety and well-being. In studies qualifying for expedited review, the description of the subject's performance should not be misleading or untruthful. However, there are times when full disclosure would jeopardize the procedure. For example, subjects might not be informed of the actual purpose of certain procedures. No more than such mild deception can be tolerated in an experiment or research study submitted for expedited review. Any intentional deception involving misleading or untruthful information provided to the subjects must be considered in a full board review.

A. CHECKLIST FOR EXPEDITED REVIEW LEVEL

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
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<td></td>
</tr>
<tr>
<td>2.</td>
<td>No implications for criminal or civil liability, employability, or damage to subjects' financial standing or reputation would exist if data were known outside of the study.</td>
<td></td>
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<tr>
<td>3.</td>
<td>The research does not employ a protected group as subjects (eg. fetuses, pregnant women, prisoners, mentally handicapped, or minors).</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>The study does not present more than a MINIMAL RISK to subjects.</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>The study does not involve INTENTIONAL DECEPTION such that misleading or untruthful information is provided to subjects.</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Appropriate informed consent procedures will be followed.</td>
<td></td>
</tr>
</tbody>
</table>

"Yes" answers to all of the above are required to qualify for a recommendation for expedited review.
B. **Research Activities Eligible For Expedited Review**

The following sections present examples of research activities that may be reviewed through expedited review procedures. This list was established by the secretary of Health and Human Services, and will be amended as appropriate through periodic publication in the Federal Register.

1. Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

3. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject’s privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, w-rays, microwaves).

4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

6. Voice recordings made for research purposes such as investigations of speech defects.

7. Moderate exercise by healthy volunteers.

8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
III. RESEARCH REQUIRING FULL BOARD REVIEW

The following categories of research require full IRB approval:

1. Projects for which the level of risk is determined by P.I., IRB consultant/reviewer, or IRB Chair to be greater than minimal.

2. Projects which involve the intentional deception of subjects, such that misleading or untruthful information has been provided.

3. Projects which involve sensitive or protected populations; e.g., minors, prisoners, fetuses, mentally retarded, mentally disabled, test subjects for new drugs or clinical devices, pregnant women, illegal behavior, legally incompetent persons.

Research that is judged to involve more than minimal risk, intentional deception, or a protected population must be presented to the entire review board for discussion and consideration of approval or non-approval. The board schedules monthly meetings to accommodate such requests as well as to conduct other business. Individuals intending to conduct research involving more than minimal risk with special populations such as children, prisoners or institutionalized patients, or planning to use procedures that are personally intrusive, stressful or potentially traumatic (physical, psychological or moral) should request full board review.

IV. DECEPTION POLICY

Intentionally misleading or providing untruthful information to subjects is not considered to be a desirable procedure. All other possible alternative research strategies should be explored and eliminated before settling on a deceptive approach. Should a researcher choose to implement a deceptive strategy, it will be necessary to provide a clear justification of the procedure to the reviewers as well as additional measures to protect subjects.

Justification must address:

1. Alternative research methods that would not require the adoption of deceptive practices (e.g., role playing, gaming approaches, simulation strategies, etc.).

2. The social value of the research being conducted. Though social value is not a total justification, it is necessary to demonstrate increased benefit to offset the increased subject risk where deception is involved.

3. Steps taken to further insure subject safety. Deception is taking advantage of the subject's willingness to participate and thus renders the unwary subject vulnerable to increased psychological or physical harm. Steps must be taken, and clearly explained, to protect against harm to the subjects.

4. Debriefing: Where deception is used, thorough debriefing of the subjects is essential. Upon completion of participation, the deceptive practice must be disclosed to the subjects and reasons for the deception provided. It is necessary to insure that the subject have every opportunity to complete their participation in a similar emotional, physical and cognitive state as when they started. Therefore, deceptions with potential long-term negative implications for subjects should be avoided.
Section C

IRB Review Protocol/Study Description

A. Research Question

Provide a brief statement of the question(s) being asked and the supporting rationale. Notice that the statement is brief and expresses not only the research question but the theoretical rationale behind the question. Some projects will undoubtedly require a bit more explanation, but a complete literature review is not necessary for IRB review purposes.

For example: “The study is designed to examine whether the personality trait of self-monitoring plays a role in the maintenance, stability, and satisfaction within romantic relationships. Snyder (1974) defines self-monitoring as ‘the extent to which individuals control and regulate their self-presentation’. Individuals who are said to be high in self-monitoring (HSMs) are more likely to control and change their behavior to fit what is considered to be socially desirable in a situation. Individuals who exhibit low self-monitoring (LSMs) are more likely to base their behavior on their true emotions, even if their actions or expressions are less socially desirable.”

B. Hypothesis(es)

Provide a clear statement of the research hypothesis(es) as related to the rationale and theory behind the study. Stating hypothesis(es) in the null form is of little help to reviewers.

For example: “Based on Snyder and Simpson’s (1984) findings for motivation in relationship formation, it is hypothesized that LSMs, who most likely formed their relationship based on intrinsic factors, will be more likely to maintain the relationship for intrinsic reasons, thus resulting in a more stable and satisfying union. Likewise, HSMs are predicted to maintain their relationship for more extrinsic reasons, resulting in a relationship that is less satisfying and less stable than the relationship of LSMs. It is also hypothesized that unions containing two LSMs will be more stable and satisfying than those containing two HSMs or one LSM and one HSM.”

C. Method

1. Participants
   a. Number of Subjects _____________.
   b. Describe relevant features of the subjects you will be using (e.g., sex, race or ethnic group, age range, general state of mental and physical health, etc.).

2. Materials
   a. Apparatus and stimuli
   b. Surveys, questionnaires, etc.

D. Procedures

1. Describe recruitment procedures and any material inducements given for
participation.

2. Note the location of the study. Be as specific as possible.

3. Describe all personnel, including name and affiliation with Rockford College.

4. Provide a step by step description of everything subjects will be asked to do in your study.

5. Very concisely, describe the type of data to be analyzed (e.g., categorical responses, interval level ratings, etc.) and the proposed statistical analysis.

E. Potential risks you can anticipate for subjects

1. Describe immediate risks, long term risks, rationale for the necessity of such risks, alternatives that were or will be considered, and why alternatives may not be feasible.

2. Describe any potential legal, financial, social or personal effects on subjects of accidental data disclosure. Though the potential for disclosure may be extremely remote, if a fire or bombing exposed your data, how would it affect subjects?

F. Expected benefits for subjects (if any) and/or society

The IRB is required to insure that the potential risks to subjects (however minimal) are clearly justified by the potential benefits of the research both to the subjects and to the current state of theoretical knowledge on the topic. You can assist this process by providing a statement clarifying the potential for new knowledge resulting from the study as well as any benefits directly to the subjects. Stating that "more research is needed on this topic" will be of little help. Please explain why more research will be a benefit.

G. Deception used in gathering data

Justify and support the use of deception in the project, particularly if subjects are being provided with any untruthful or misleading information. Realize that not providing complete information is minimally deceptive. Provide a detailed written description of the debriefing process.

H. Safeguarding subjects' identity

1. What uses will be made of the information obtained from the subjects? What elements of your project might be openly accessible to other agencies or appear in publications?

2. What precautions will be taken to safeguard identifiable records or individuals? How will confidentiality of data be protected?
# INFORMED CONSENT

## I. GENERAL REQUIREMENTS

No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

### A. BASIC ELEMENTS OF INFORMED CONSENT

Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purpose(s) 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 to receive for participation up to point of their termination.
B. ADDITIONAL ELEMENTS OF INFORMED CONSENT
When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

6. The approximate number of subjects involved in the study.

C. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

   a) programs under the Social Security Act, or other public benefit or service programs;
   b) procedures for obtaining benefits or services under those programs;
   c) possible changes in or alternatives to those programs or procedures; or
   d) possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration.

D. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

E. The informed consent requirements in these regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

F. Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

II. DOCUMENTATION OF INFORMED CONSENT

A. Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. **A copy shall be given to the person signing the form.**

B. Except as provided in paragraph (c) of this section, the consent form may be either of the following:
   1. A written consent document that embodies the elements of informed consent required by the Code of Federal Regulations. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
   2. A "short form" written consent document stating that the elements of informed consent required by the Code of Federal Regulations have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. **A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."**

C. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
   1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
   2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. Please see the following sample consent forms. Each contains the basic required elements for informed consent.

INFORMED CONSENT

“Social Emotions”

I (print the name of participant:_______________________________) freely and voluntarily agree to participate in the research study entitled “Social Emotions” under the direction of Dr. Mark A. Jackson to be conducted in the Psychology Department of Rockford College.

I understand that while the study will be under the supervision of Dr. Jackson, other professional persons who work with him may be designated to assist or act in his behalf. I understand that the experiment will last approximately 30 minutes.

I understand that the purpose of this study is to explore various factors that determine social emotions.

I understand that the research procedure will be as follows; I will be asked to read a hypothetical scenario describing a person experiencing an event that might generate a social emotion. I will be asked to imagine what the person would be feeling and thinking and then to complete a questionnaire designed to measure my views.

I understand that there are no risks or benefits involved in my participation in this study. I have been told that every effort will be made to keep my responses strictly confidential. None of my responses will contain any identifying information.

I understand that I may withdraw my consent and discontinue participation at any time without receiving any negative consequences. I have been given the opportunity to ask questions concerning the procedure, and all questions have been answered to my satisfaction.

I understand that if I desire further information about this matter, I should contact:

Student’s Name  Dr. Stuart Tousman
Phone number  Phone number
e-mail  e-mail

I have read and understood the above.

Participant’s signature______________________________Date________________

Extra credit received for class____________________________________________

I have explained and defined in detail the research procedure in which the participant has agreed to participate, and have given him/her a copy of this informed consent form.

Experimenter’s signature___________________________Date________________
Debriefing

“Social Emotions”

Explanation of Study

Many social scientists have speculated about the nature of social emotions. One issue concerns the social emotion “humiliation”. However, empirical investigations regarding the humiliation experience are few. Theorists suggest that humiliation necessarily involves other people knowing of the experience (i.e., it is public) and is often felt to be undeserved. We are further exploring these possible distinctions. In this study, you either responded to one or more scenarios designed to elicit humiliation. With regard to the scenarios, some of them highlighted the public exposure of a particular action and others kept the action private. Additionally, the number of people who witnessed the incident was manipulated. We are expecting that the publicness of the action and the status of the agent will dramatically affect the degree of humiliation experienced.

We encourage you to stop by next semester and discuss the results of this study with us. We would be very happy to show you what our findings were.

We hope you enjoyed participating in this study. Your cooperation makes it possible for us to do valuable social research. If you have any questions, please feel free to contact us.

Dr. Stuart Tousman
Rockford College
(815) 226-4112


IRB Human Subjects Research Review
Rockford College
Research Description Coversheet Form

Original submission_____ Proposal Modification_____ Continuation_____  

A. Project code___________________________________________________________
   Example – Dan Jones, Fall 2001, Psych 495-A
   (other authors in parentheses after code)

B. Phone number/email of PI ______________________________________________

C. Project Title _________________________________________________________
   ______________________________________________________________________

D. Statement of assurance: I/We have read and will follow the Rockford College Policies and 
   Procedures for research Involving Human Subjects. Further, I/We will inform the IRB if significant 
   changes are made in the proposed study.
  _______________________________________________________________________
   (Signature of PI)   (Date)

E. Sponsor (if PI is a student)______________________________________________
   _________________________________________________________________
   Rank/Title     Department/Program      Phone
   ___________________________________________________________________
   Sponsor signature (indicating project approval)

F. Duration of project: From__________ To__________

G. Is federal or other extramural funding being sought? ______

H. Level of review requested:   Exempted_____ Expedited_____ Full Board_____  
   Rationale for level of review:
   Though this study involves working with human participants, it does not require the use of at risk 
   groups. It also involves very minimal deception. Therefore, I request that this study be expedited.
Rockford College
IRB DECISION FORM

(Researchers include this form before the coversheet)

Project Code.______________________________________________

Project Title ________________________________________________________________________

IRB committee form

IRB member name____________________________________________________

IRB Meeting Date____________

Individual comments about proposal:

Board Decision

Signature of Chair ________________________________________

_____ Rejection of proposed research, significant substantive changes necessary. Resubmit to IRB chair.
Comments:

_____ Conditional IRB approval: make changes to proposal and resubmit to IRB chair for expedited approval.
Comments:

_____ IRB approval pending advisor approval: IRB approves proposal but requests resubmission for faculty advisor review.
Comments:

_____ IRB approval to begin research