

**SOCIAL AND BEHAVIORAL SCIENCES**

**UNIVERSITY OF CALIFORNIA, SAN DIEGO  
INSTITUTIONAL REVIEW BOARD**

**APPLICATION**

**PROJECT NUMBER** \_\_\_\_\_

\_\_\_\_\_  
**Signature of Department Chair** **Date**

\_\_\_\_\_  
**Signature of Faculty Advisor, if appropriate** **Date**

\_\_\_\_\_  
**PRINCIPAL INVESTIGATOR (Print or Type Name)**

\_\_\_\_\_  
**Signature of PI** **Date**

\_\_\_\_\_  
**Mail Code** \_\_\_\_\_ **E-Mail** \_\_\_\_\_

\_\_\_\_\_  
**PI's Status—e.g., Prof, Asst. Prof, Student, etc.**  
**Degree or Employment Status:** \_\_\_M.D. \_\_\_Ph.D. \_\_\_Master  
\_\_\_Graduate Student \_\_\_Undergraduate Student \_\_\_Other (explain) \_\_\_\_\_

\_\_\_\_\_  
**Mailing Address (Students Only)** \_\_\_\_\_ **Phone #** \_\_\_\_\_ **Fax #** \_\_\_\_\_

\_\_\_\_\_  
**Student I.D. #** \_\_\_\_\_

\_\_\_\_\_  
**Department:** \_\_\_\_\_ **Contact Person** \_\_\_\_\_ **Phone#** \_\_\_\_\_

\_\_\_\_\_  
**Is PI: Salaried** \_\_\_\_\_ **Non-Salaried** \_\_\_\_\_ **Contact Person's e-mail:** \_\_\_\_\_

**Other Investigators:** \_\_\_\_\_ **Project History: NEW** \_\_\_\_\_ **If NOT New, Please Provide:**  
**Previous Project Number:** \_\_\_\_\_  
**Expiration Date:** \_\_\_\_\_  
♦ **Be sure to include a summary of experience with this project to date (see Section #5). Also, explain any differences between this submission and the previously approved project**

**Project Title:** \_\_\_\_\_ **Indicate Whether Funded:**  
**Yes** \_\_\_\_\_ **No** \_\_\_\_\_ **Pending** \_\_\_\_\_  
**Funding Agency** \_\_\_\_\_  
**UCSD Contract/Grant #** \_\_\_\_\_

**Indicate Whether Project Will Involve:**

	<b>Yes</b>	<b>No</b>
<b>Subjects Under 18</b>	_____	_____
<b>Mentally Disabled</b>	_____	_____
<b>Mentally Retarded</b>	_____	_____
<b>Prisoners/Incarcerated Individuals</b>	_____	_____
<b>University Facilities</b>	_____	_____
<b>VA Facilities</b>	_____	_____

**This Is A Face Page ONLY:**  
*Submit 2 copies of the collated application including this Face Page to:*  
*Human Research Protections Program (0052)*  
*University of California, San Diego*  
*La Jolla, CA 92093-0052*  
**For Assistance Call (858) 455-5050**

## ATTENTION STUDENTS AND FACULTY SUPERVISORS

### IF THE P.I. IS A STUDENT:

The Faculty Supervisor MUST indicate Knowledge and Approval of this protocol by signing this form.

*I certify that this project is under my direct supervision and that I am responsible for ensuring that all provisions of approval are complied with by the investigator.*

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Faculty Supervisor (Print or Type)

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Signature

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DATE

**Prepare The Remainder Of This Application, *In Non-Technical Wording*,  
By Following The Outline Given Below.**

**ALL 16 Sections Must Be Addressed:**

Applications Containing *Unedited* Portions Of Grant Proposals Will Not Be Accepted For Review. *Concise*, but complete, responses are requested. If possible, the application should not exceed 3 - 5 typed pages, excluding the consents and bibliography (10 or 12 point type, single spaced and single sided).

**SIGNATURES:**

Applications That *Have Not Been Signed* By The Principal Investigator, Faculty Supervisor And The Department Chair *Prior* To Being Submitted To The Human Subjects Office *Will Be Returned*.

**WHO CAN APPLY:**

Only UCSD salaried Faculty, Staff, or UCSD Students may act as *Principal Investigator* on research projects involving human subjects. However, non-salaried individuals may act as co-investigators on such projects.

**CAUTION:**

The Regents of the University of California may *NOT* indemnify the PI if the individual is engaged in research involving human subjects without IRB approval and something should go wrong. Deviation from the approved protocol, in the form of modifications/changes, *WITHOUT PRIOR REVIEW* and approval by the IRB may also place the researcher at risk of losing UC indemnification.

1. **FACILITIES** where the study will be carried out.
2. Estimated **DURATION** of the study.
3. **SPECIFIC AIMS**. Provide a precise statement of the specific aims (goals) for this protocol. Emphasize those aspects that justify the use of human subjects.
4. **BACKGROUND AND SIGNIFICANCE**. Provide a succinct discussion of relevant background information and the rationale for the current study.
5. **PROGRESS REPORT/PRELIMINARY STUDIES**. If this is a **renewal application**, a brief **summary of past experience to date** with this protocol must be provided including any untoward effects on the subjects. List any publications that have emanated from this protocol. Renewal applications must be revised from the original application to reflect any changes in the research design and other areas and must describe the progress made since the original application.
6. **RESEARCH DESIGN AND METHODS**. Describe the research design and the procedures to be used to accomplish the specific aims of the project. Define in clear terms exactly what will be done to the human subjects. Where appropriate, identify the sources of research material obtained

from individually identifiable living human subjects in the form of records or data. Indicate whether new data will be obtained specifically for the purposes of this research, or if existing records or data will be used.

Provide a precise, but brief, description of the methods for data collection, data analysis and data interpretation. **Inclusion of women and minorities** must be addressed in all research protocols. For example, what is the study population and how/where will subjects be recruited? What percentages of women and minorities make up the demographic area under study and what percentage will be in your study? If inclusion of women or minorities is inappropriate, the scientific rationale must be explained and justified.

7. **HUMAN SUBJECTS.** Describe the characteristics of the proposed subject population, including their number, age, **sex, ethnic background** and health status. Identify the criteria for inclusion and exclusion of any subpopulation. Explain the rationale for using special subjects, if any, such as pregnant women, children, or institutionalized individuals who are likely to be vulnerable.

Describe how human subjects will be contacted in the first instance and by whom, what they will be told, and how they will be selected for participation.

8. **INFORMED CONSENT:** Describe the plans for recruitment of subjects and the **consent procedures** to be followed, including the circumstances under which consent will be obtained, who will seek it, and the methods of documenting consent. The text of all communications with prospective subjects (advertisements, flyers, letters, etc.) must be submitted for review and approval by the IRB **prior** to their use in the study.

*Follow The Enclosed Standard UCSD IRB Format In Preparing The Consent. (See Explanation Regarding IRB Approval To Use ORAL Consent, Further On In This Packet of Information Under Behavioral Research)*

9. **POTENTIAL RISKS.** Describe and assess any potential or known risks - psychological, physical, social, legal or other, and assess their likelihood and seriousness. If the potential for subjects to become upset, require psychological, or medical attention, as a result of the research procedures, a means of supplying this attention must be addressed. E.g., Is there a loss of confidentiality of the identity of the subjects? Is there a loss of confidentiality about the information given by the subjects? Is there potential emotional stress? Does the research create potential social stigmatization, physical damage to subjects such as potential abuse, legal action by authorities if the responses become known outside of research?
10. **RISK MANAGEMENT.** Describe the procedures for protecting against or minimizing any potential risks, including **risks to confidentiality**, and assess their likely effectiveness. Specify steps to be taken to guard the anonymity of subjects and/or the confidentiality of their responses, and who will have access to the data. If there will be a key to coded information, describe the means of protecting the key. Indicate what personal identifying indicators, if any, will be kept on subjects. Specify procedures for storage and ultimate disposal of personal information.

The Human Subjects Committee does not require that researchers destroy their human subjects data at the completion of their research. If the project is funded, researchers should contact their funding agency who may have specific requirements for retention or disposal of records.

11. **POTENTIAL BENEFITS.** Discuss those benefits to be gained by the individual subject, as well as those benefits that may accrue to society in general. If there is no direct benefit to the subject, this must be stated.
12. **RISK/BENEFIT RATIO.** Discuss why the risks to subjects are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks.
13. **BIBLIOGRAPHY.** List several relevant articles, if applicable, that the IRB Committee can use to provide necessary background for the protocol.
14. **OTHER FUNDING.** Indicate whether this project is supported by federal, state, or another source. Provide the UCSD grant number and inclusive dates of support. **If you have indicated on the face sheet that there is NO funding support for this project, you will need to explain just how the project is to be supported.**
15. **CONFLICT OF INTEREST. PRINCIPAL INVESTIGATOR'S STATEMENT OF ECONOMIC INTEREST (Form 730-U).** This should be filled out by all investigators involved with "non-government" research or research funded by monies in any form from private sources. The **original 2-sided** copy of this form, signed in **blue ink**, must be included with the application package to the Human Subjects Committee.

The Principal Investigator, co-investigators or any other individual who is responsible for the design, conduct or reporting of research or educational activities, will be required to disclose financial interests related to the research.

16. Copies of questionnaires,\* survey instruments, testing instruments that are **not** part of standard clinical or educational practice, must be submitted with the application.

**Requirement To Report Any Unanticipated Problems Involving Risks To Human Subjects Or Others.** The IRB, the regulatory and appropriate institutional officials must be promptly informed of any unanticipated problems involving human subjects or others. Please note that this application package includes a **UCSD Research Subjects Injury Report**. You are to use this form to report any incidents of injury or other adverse effects experienced by UCSD subjects to the IRB. This must be done no later than 10 working days after first becoming aware of the problem. ***An Adverse Reaction Is Any Serious And/Or Unexpected Or Unusual Effect Associated With A Procedure In Subjects Or Others.***

*If you have any questions about the consent form requirements, or any other portion of this application, please call the Human Research Protections Program Office for assistance at 858-455-5050.*

## ***FREQUENTLY ASKED QUESTIONS CONCERNING HUMAN SUBJECTS RESEARCH***

The review of research involving human subjects at UCSD is a collaborative process intended to result in mutually acceptable research procedures which accomplish the investigator's scientific objectives while protecting the rights and welfare of the subjects. The Human Subjects Committee tries to be as flexible as possible and reviews each protocol as a separate case, and every attempt is made to take into account all factors in determining the outcome of the review. The regulatory charge of the IRB is the protection of Human Subjects. However, the IRB also has an educational role and responsibility, and advocates consultation at all stages of the research process.

### ***What Is Human Subjects Research?***

This is defined by the regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge which involves obtaining *data* from a living individual whether through *intervention* [e.g., blood draw], manipulations of the subject or the subjects environment for research purposes. *Interaction* includes communication or interpersonal contact between the researcher and the subject [e.g., interviews], or from identifiable private information [e.g., private records, observations]." *The regulations extend to graphic, written, or recorded information derived from individually identifiable human subjects.*

Private information includes information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

Pilot studies and screening tests may constitute "research." Indirect activities such as analysis of data from people particularly if there is a plan to publish the results (or be a co-author), constitutes human subjects research.

A person may also be a "human subject" when a researcher obtains data about the person from a third party.

Research does not include: (a) instruction, (b) surveys for evaluating the performance of faculty, staff, and students, or other studies for institutional use only, (c) student course work or undergraduate honors theses, ***unless they are to be made available to the public or used by other researchers.***

### ***Why Must It Be Reviewed?***

The purpose of the review is to determine whether subjects are at risk, whether the potential benefits of the research outweigh the risk, and whether adequate provision has been made to obtain informed consent. Risk is defined as exposure to the possibility of harm, whether physical, psychological, sociological, or other, to a participant in a research activity.

Federal and State regulations require that the rights and welfare of all subjects involved in research be protected. Since UCSD is a recipient of federal and state funding, the institution has a Multiple Project Assurance agreement with the Department of Health and Human Services to review and

approve **ALL** research involving human subjects. The agreement covers any and all research involving human subjects in any way, and does not recognize any exemptions as part of its institutional agreement.

### ***Who Reviews It?***

In compliance with Federal and State regulations, the University has authorized an Institutional Review Board (IRB), more commonly known as the Human Subjects Committee, to review **ALL** research involving human subjects. This is a campus-wide committee composed of a group of diverse individuals whose aim is to protect human subjects and promote ethically sound research. It is their responsibility to assure that research design is such that participants are protected, risks are minimized and expected benefits are maximized, and that consent procedures are adequate.

They consist of faculty, administrative staff, and at least one non-institutional member, which meets monthly to review all human subjects research. Copies of the applications are distributed to all members of the Committee prior to the meeting for review and discussed at each meeting.

### ***Who Must Submit An Application?***

Any faculty, staff, student, or individual who conducts research involving human subjects under the auspices of the University.

### ***When Does It Have To Be Submitted?***

Each application has a listing of the due dates and meeting dates for the calendar year. These applications require the signature of the investigator, sponsor, and Department Chair **PRIOR** to submission.

### ***What Happens If Research Is Conducted Without Approval From The IRB?***

Engaging in research involving human subjects without prior IRB approval will place the researcher at risk such that the Regents of the University of California may not indemnify him/her if something should go wrong. Deviation from the approved protocol, in the form of modifications/changes, **Without Prior** review and approval by the IRB may also place the researcher at risk of losing UC indemnification.

In addition, graduate students in pursuit of an advanced degree must have human subjects approval **before** the research is begun. Research involving human subjects that is conducted **without** the approval of the Human Subjects Committee may seriously jeopardize the awarding of the degree. In addition, using data already collected may be disallowed.

If human subjects research is begun without approval, upon discovery of the error the investigator must stop the research and notify the IRB office immediately. The investigator must then submit a protocol to the Human Subjects Committee along with a detailed explanation as to why the protocol

was not submitted at the appropriate time. If the investigator is a student, a detailed letter from her/his faculty advisor must accompany the materials submitted to the Human Subjects Committee. Conducting further research without approval may jeopardize research funds, data already collected, or disallow a thesis.

### ***What Is The Consent Process?***

Upon review and approval of the research project involving human subjects by the IRB, the IRB will send the PI a ***stamped approved*** copy of the consent. The subject must sign a stamped approved copy of the consent, any other document not approved by the IRB is not considered acceptable. The PI can make copies of this document for each participant to read, and then sign ***prior*** to enrollment in the study. An individual should also be on hand to discuss any questions the subject might have with regard to the study. No investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent, approved by the IRB, of the subject or the subject's legally authorized representative.

### ***When Does IRB Approval Expire On A Project?***

IRB approval for an approved Human Subjects research project is good ***ONLY*** for one year (365 Calendar Days) from the date of approval. Continued approval beyond that period is contingent upon submission of an IRB Monitoring Form or resubmission of the protocol for review and re-approval by the UCSD Human Subjects Committee. *As a courtesy*, these forms are sent to the PI approximately 6 to 8 weeks before the project is due to expire.

### ***Where Can One Get Assistance?***

The Human Subjects Program Office acts as a liaison between the University community and the IRB. Individuals are encouraged to contact the office staff at (858) 534-4520 to discuss any concerns they may have in submitting their protocols for review, as well as any questions they may have of the Committee's responses to their protocols.

### ***What Are The Responsibilities Of The Investigator?***

Research investigators have a fundamental responsibility to safeguard the rights and welfare of the individuals participating in the research activities.



**UNIVERSITY OF CALIFORNIA, SAN DIEGO  
AUDIOTAPE RECORDING RELEASE CONSENT FORM**

As part of this project, an audiotape recording will be made of you during your participation in this research project. Please indicate below the uses of these audiotape recordings to which you are willing to consent. This is completely voluntary and up to you. In any use of the audiotapes, your name will not be identified. You may request to stop the taping at any time or to erase any portion of your taped recording.

- |    |   |          |
|----|---|----------|
| 1. | The audiotapes can be studied by the research team for use in the research project.           | _____    |
|    |   | Initials |
| 3. | The audiotapes can be used for scientific publications.                                       | _____    |
|    |   | Initials |
| 4. | The audiotapes can be reviewed at meetings of scientists interested in the study of<br>_____. | _____    |
|    |   | Initials |
| 5. | The audiotapes can be reviewed in classrooms to students.                                     | _____    |
|    |   | Initials |
| 6. | The audiotapes can be reviewed in public presentations to non-scientific groups.              | _____    |
|    |   | Initials |
| 7. | The audiotapes can be used on television and radio.   | _____    |
|    |   | Initials |

You have the right to request that the tape be stopped or erased during the recording.

You have read the above description and give your consent for the use of audiotapes as indicated above.

Signature	DATE	Witness	DATE
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## BEHAVIORAL RESEARCH

The terms "behavioral research" or "the behavioral sciences" may be used to refer either to **studies of the behavior of individuals, or to studies of the behavior of aggregates such as groups, organizations, or societies.** The *broad objective* of the behavioral and social sciences is to establish a body of demonstrable, replicable facts and theory that contributes to knowledge and the amelioration of human problems. Most behavioral research involves no physical intervention and no physical risk.

The scopes and diversity of research in these areas is quite broad. Theories and methods vary both across and within disciplines. Some investigators do their research in a lab, others perform survey research, observational studies of small group experiments. Often times there are overlaps within a specific discipline.

Behavioral research involving human subjects **generates data** by means of **questionnaires, observation, studies of existing records, and experimental designs involving exposure to some type of stimulus or intervention.** Many variations of these basic methods are used. Questions may be in person, on the telephone, by means of a questionnaire, etc. Records studies may be public, (e.g., vital statistics, motor vehicle registrations, or court records) or non-public and sensitive (e.g., medical or educational records in which subjects are identified). Experimental studies may be conducted in public or private settings or labs. Intervention in such studies range from the innocuous to the significant.

### RESEARCH INVOLVING PSYCHOLOGICAL INTERVENTION

If the subject(s) of the proposed research will be exposed to any psychological intervention such as contrived social situations, manipulation of the subject's attitudes, opinions or self-esteem, psychotherapeutic procedures, or other psychological influences, the following must be provided:

1. Identify and describe *in detail* the PSYCHOLOGICAL INTERVENTION.
2. Identify and describe *in detail* the BEHAVIOR expected of subject(s) and the context of the behavior during the psychological intervention.
3. Describe how DATA resulting from this procedure will be gathered and recorded.
4. Identify anticipated and possible psychological, or social CONSEQUENCES of this procedure for the subject(s).
5. Indicate the investigator's competence and identify her/his QUALIFICATIONS, by training and experience, to conduct this procedure. *If the PI lacks these qualifications, a qualified co-investigator must be named.*

## RESEARCH INVOLVING DECEPTION

If the protocol involves **DECEPTION** (false information given to subjects, false impressions created, or information relating to the subjects' participation is withheld from subjects) a detailed description as to how subjects will be *debriefed* must be provided.

The researcher must provide the participant with information about the nature of the study and attempt to remove any misconceptions that may have arisen. Where scientific or humane values justify delaying or withholding this information, the researcher incurs a special responsibility to monitor the research and to ensure that there are no damaging consequences for the participant.

Where research procedures result in undesirable consequences for the individual participant, the researcher has the responsibility to detect and remove or correct these consequences, including long-term effects.

In research involving deception, debriefing is required to compensate the research subjects for having been denied at least some powers of self-determination and for having been deliberately misinformed; debriefing procedures thus should be designed to provide subjects with (1) satisfaction from having contributed to science or society, and (2) new knowledge that will be of educational or therapeutic value to them. In addition, subjects should receive other benefits or reparations: (3) dehoaxing - entails giving the subject whatever explanation or evidence is necessary to convey the truth about the research and to clear up any misunderstandings. (4) desensitizing - involves the detection and removal of any undesirable emotional consequences of research participation. Desensitizing should be designed to "alter subjects' feelings concerning the way they behaved or were treated in the study so that they are restored to a state of emotional well-being." (5) restoration of confidence in science, (6) information on ways risk was anticipated and circumvented, (7) an opportunity to ask questions, and (8) an opportunity to withdraw one's own data.

1. Describe **in detail** the **DECEPTION** involved, including any instructions to subjects or false impressions created.
2. **JUSTIFICATION.** Explain **in detail** why deception is necessary to accomplish the goals of the research. Care should be taken to distinguish cases in which disclosure would invalidate the research from cases in which disclosure would simply inconvenience the PI.
3. Describe **in detail** the plan for **DEBRIEFING** subjects. Clarify when and how subjects will be debriefed? Attach a copy of any debriefing statement.
4. Justify why the proposed subject population is suitable for such a study.

## RESEARCH INVOLVING SCHOOL PERMISSION

Schools do not have the authority to give consent for children to participate in research; ***only parents or legal guardians have that authority***. Permission from the school district, however, must be obtained before conducting research in schools within the district.

In most cases, Principals and teachers do not have the authority to grant permission for research to be

conducted in a school; such permission must come from the school district. Although this permission will usually come from the superintendent, in some districts another individual or committee has been given the authority to grant permission. *Investigators should check with the district office to determine the appropriate procedure for obtaining permission.*

Proof of that permission in the form of a letter from the school district must be submitted to the IRB in writing, and whenever possible, the permission should be on school district letterhead. Provisional approval of the research project can be given by the IRB pending receipt of permission by the school district. The research cannot begin, however, until written proof is received by the IRB.

### **RESEARCH IN A FOREIGN COUNTRY**

The political or social climate in a foreign country may be such that normal methods for protecting the confidentiality of research data and the identity of subjects are not adequate. Researchers should address this problem in their protocols. The procedures employed may not be any less stringent than those required by the Human Subjects Committee for research in this country, even if those customary in the foreign country are less restrictive.

*Should a situation arise that the PI is not at UCSD when conducting the research at the time continued approval of resubmission of a protocol is due, it is **still incumbent upon the PI** to see that all materials are submitted to the Human Subjects Program Office in a timely manner.*

**The continuation of research after expiration of IRB approval is a violation of regulation 21 CFR 56.103(a). "If the IRB has not reviewed *and approved* a research study by the study's current expiration date, i.e., IRB approval has expired, research activities should stop. No new subjects may be enrolled in the study."**

### **OBSERVATIONAL STUDIES**

This usually involves **fieldwork, or ethnographic research**, involving observation of and interaction with persons or groups being studied in the group's own environment, often for long periods of time. Since field work is a **research process that gains shape and substance as the study progresses, it is difficult, if not impossible, to specify detailed contents and objectives in a protocol.** Often a **waiver of informed consent** is given for this type of research. However, the investigator should supply the IRB with *a copy of the types of questions or issues that will be discussed with the subjects.*

Researchers should discuss the following: (1) what type of activities will be observed, (2) whether or not they will participate in the activities observed, (3) describe the public locations where the research will conduct these observations, (4) whether or not the research will have any direct contact or interaction with subjects. If yes, this should be described, (5) whether the data will be recorded anonymously. If not, will a key code be used, who will have access to the data, (6) will videotaping/audiotaping be done; will photographs be taken? If yes, describe the confidentiality measures to be taken including storage, safeguarding measures.

Research involving the observation (including observation by participants) of public behavior, must also make clear whether the responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects. In addition, whether the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; or the

research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

### INVOLVEMENT OF PUBLIC OFFICIALS AS SUBJECTS IN RESEARCH

Researchers should discuss whether the individual is appointed, elected, or candidates for public office? What is their public official title(s), and/or role(s)? How many subjects will be recruited? What procedures will they be involved in? Public observations? Survey/Interviews? For surveys/interviews, a copy of the survey/interview schedule or list of questions should be attached. If the subjects will be surveyed or interviewed, will their **responses** be recorded? Identified on tape? Anonymously? Will the subject(s) be tape recorded? videotaped? Will a key code be used to protect the identifiable data? Will follow-ups be conducted? Who will have access to the data? Describe the confidentiality measures (including storage/safeguarding measures). Will the subject's identity be disclosed in final reports or publications? *A copy of the proposed consent form or consent script should be provided for review and approval by the IRB.*

### RESEARCH INVOLVING CHILDREN/ADOLESCENTS

If working with children and/or adolescents as subjects, an adolescent/child's "**assent**" will be needed. This should be written in wording appropriate to that age group. Consideration must also be given to the maturity and psychological state of the child.

Federal regulations define assent to mean "a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent." [45 CFR 46.202(b)].

In research conducted in schools, a clear indication in the consent/assent must also be given that this research is not part of the child's regular school program, is not being conducted under the auspices of the school, and the child's grade or continued enrollment will not be affected by her/his decision to participate.

In cases where there is inconsistency between the consent of the parent and the assent of the child, the following rule shall be followed: *a "NO" from the child overrides a "YES" from the parent, but a "YES" from the child does **not** override a "NO" from the parent.* Children should also be informed as to what to do if their parents did not give permission from them to participate.

### MINIMIZING COERCION INVOLVING CHILDREN

In conducting research on children, every attempt must be made to minimize coercion to participate. Researchers must remember that children are in a dependent relationship with adults and special care must be taken to ensure that the decision to participate as research subjects made by children is truly voluntary. The following factors should be taken into account when developing research procedures:

1. **Rewards.** Concrete rewards for participation may be used, but should not be so valuable within the value system of the child, as to outweigh legitimate reluctance to participate.
2. **Peer Pressure.** Care must be taken to minimize social pressure to participate, particularly peer pressure and fear of ridicule for not participating.
3. **Coercion.** Care must be taken to minimize the coercion implicit in requests to

participate from parents, teachers, or other adult authorities.

In general, researchers should refrain from having teachers or parents request children to participate in research.

Researchers should avoid using phrases such as "will you help me?" or "we would like your help with this" since children are not likely to refuse to help an adult. Rather, children should simply be asked if they want to participate.

### **RESEARCH INVOLVING TAPE/VIDEO RECORDINGS**

If you intend to video or tape record sessions, the consent must indicate that the recordings may be stopped at any time, and that portions and/or the entire tape/video may be erased at the subject's request. The consent should also state how the tape/video recording will be used by the researchers. *See Video and Tape Release Consent Form.*

### **RESEARCH INVOLVING QUESTIONNAIRES/SURVEYS/INTERVIEWS**

Consents should state that subjects have the right to refuse to answer any question or skip any question they chose not to answer. The PI should also state what procedures will be used to protect the confidentiality of the subject's responses. The investigator should provide copies of the questionnaire if they are not standard clinical assessment tools.

Where the investigator does not have specific questions, a listing of topics and generic questions should be provided for review and approval by the IRB.

### **ORAL CONSENT**

Regulations state that an "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."

However, listed below are situations when an *oral consent* may be used:

(a) A short form written consent document, reviewed and approved by the IRB, stating that the elements of informed consent 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. 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.

An oral consent may also be used under the following circumstances:

(b) 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

(c) 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.

*While documentation may be waived, all investigators must provide subjects with a written statement regarding the research. A copy of the oral script must be submitted to the IRB for review and approval.*

***THE INVESTIGATOR IS REQUIRED TO PROVIDE THE APPROPRIATE CONDITION FOR ITS USE AS WELL AS THE JUSTIFICATION.***

### **CERTIFICATE OF CONFIDENTIALITY**

Some research involving human subjects could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; or the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. In such cases, the IRB suggests that the investigator apply for a "Certificate of Confidentiality" from the Department of Health and Human Services (DHHS). The certificate protects researchers against being *compelled* to disclose the identity of their subjects in any legal proceeding.

Where appropriate, discuss provisions for ensuring medical or professional intervention in the event of adverse effects to the subject. Also, where appropriate, discuss the provisions for monitoring the data collected to ensure the safety of subjects.