Institutional Review Board Handbook

The Department of Juvenile Justice (DJJ) Institutional Review Board (IRB) reviews research proposals that involve DJJ youth and staff, making recommendations to the Secretary's designee to either accept or reject the research proposal. Studies requiring IRB review are those that will have direct contact with youth or staff, with access to individualized information, or that occur within a DJJ facility or program – whether operated by the State or local government entity. All research for the purpose of generalized knowledge requires approval by the IRB prior to implementation. Research proposals shall be limited to the study of (1) possible causes, effects, and processes of incarceration and criminal behavior, (2) incarceration or supervision as institutional structures, (3) conditions particularly affecting incarcerated or supervised youth as a class, and (4) practices that have the intent and reasonable probability of improving the health or well-being of the subjects. The IRB consists of Florida Department of Juvenile Justice staff members, including staff from the Bureau of Research and Data Integrity, staff from each program area (Prevention, Probation, Detention, and Residential), and staff from the Offices of Health Services, General Counsel, and Inspector General. The United States Department of Health and Human Services 45 C.F.R. 46.116 (Protection of Human Subjects) was the model for DJJ IRB policies.

The Institutional Review Board Handbook contains directions for the principal investigator (P.I.) regarding the submission(s) of an IRB proposal to perform research. The principal investigator is the person who is directing/conducting the research project and must be qualified by experience/training to protect the well-being of the subjects in the study. For the IRB to be able to make an informed decision, the application packet must include a detailed description of what the study will entail, including safeguards for youth. Clear and concise communication of this information will help facilitate review by the IRB. If the Director does not receive the required information or the information received is not in the correct form, the Secretary's designee will reject the proposal and the investigator must submit a new application. All directions, forms, deadlines, and the IRB meeting schedule are available on the IRB Web site (http://www.djj.state.fl.us/research/irb-requests).

IRB Proposal Packets are due at least one month prior to the quarterly IRB meeting. The IRB will not review incomplete packets. If the IRB Director receives the packet after the stated deadline or it is incomplete until after the stated deadline, then the IRB will review the proposal at the next quarterly meeting. If the IRB Director receives an incomplete packet and does not receive the

remaining required materials within 90 days, then the Secretary's designee will reject the proposal and the principal investigator will need to resubmit the application packet.
Send IRB Proposal Packets to:

Director, Institutional Review Board
Florida Department of Juvenile Justice
2737 Centerview Drive, Suite 1200
Tallahassee, Florida 32399-3100

DJJ will not accept emailed IRB submission(s)s. Reports, grant applications, or IRB applications for other agencies will not suffice in place of the required information in the specified format.

I. Mandatory Items: Project Cover Sheet, Introductory Questionnaire, Protecting Human Research Participants Certificate, Protocol for the Proposed Research

II. Mandatory if applicable to the specific proposal: Research Acknowledgement Form, Data Request Form, University Institutional Review Board or Agency Human Subjects Board letter of approval, proof of completed background checks, Informed Consent and/or Assent Forms, instruments, Sponsor's protocol, and other documents including brochures on drugs or appliances.

The Institutional Review Board will review the proposal and issue a letter from the Secretary's designee in a timely manner.

I. Upon approval by the Board, the P.I. will receive a conditional approval letter, which states the conditions of the approval decision, as well as a Privacy and Security Agreement (PSA). DJJ will issue a final letter of approval once all the conditions are met, including the return of a signed Privacy and Security Agreement. The Privacy and Security Agreement will expire one year from the signature date on the final approval letter. DJJ will notify the principal investigator at least 30 days prior to the date of expiration to inquire about an extension. The principal investigator may request in writing a modification to the approved proposal.
II. If the Secretary's designee requests additional information from the principal investigator to facilitate a decision and does not receive a response within 90 days, then the proposal will be rejected and the principal investigator will need to resubmit the proposal packet.
III. Upon rejection by the Board, the principal investigator may appeal the decision in writing to the Secretary's designee within 30 days. The Secretary's designee will issue a letter of response within 30 days of receipt of the written appeal.

Mandatory Items

I. Project Cover Sheet and Introductory Questionnaire

The purpose of the project Cover Sheet and the introductory questionnaire is to ensure that the IRB has standard information about all protocols submitted. The principal investigator must sign the project Cover Sheet. If the principal investigator is a student, then the supervisory chairperson must sign the project Cover Sheet.

II. Protecting Human Research Participants Certificate

All investigators, **including the principal and co-investigators**, must complete the Protecting Human Research Participants on-line course and submit the completion certificate with the IRB proposal packet. The course is offered free of charge by the National Institute of Health Office of Extramural Research (http://phrp.nihtraining.com/users/login.php).

III. Format of the Protocol

For most protocols, three to five single-spaced, typewritten pages should be sufficient to provide the IRB with the information it needs. A good rule of thumb is to write the protocol for a person with a graduate degree not in your field. Discuss scientific issues at the level of sophistication of an article in Scientific American.

a. Project Title:

It is essential that all documents dealing with research protocol are identified using a consistent title. This assures proper filing and retrieval of all correspondence.

b. Investigator(s):

Identify the principal and co-investigators. Students should identify their supervisory chairperson and committee members. **All investigators**, including the principal and co-investigators, who have access to juveniles, their parents, department employees or contract providers, or who have access to confidential information **must undergo background screenings at their expense**. Indicate in your protocol and the introductory questionnaire whether a background screening will be necessary for your study **and** which investigators will require one. The investigators must follow the Florida mandated reporter laws and include in the protocol a plan on how to respond to disclosures of abuse.

c. Abstract:

The abstract should be a concise one- to two-paragraph summary of the study, including the study's purpose, background of the issue, significance of this study, and the research plan.

d. Specific Aims:

This portion of the protocol should specify the purpose of the study and the information needed to complete it. Provide a description of what you expect to learn from the project.

e. Background and Significance:

This portion of the protocol should provide background information for your project, including a brief literature review. Also, explain why your project is a logical scientific next-step and why that step is important to take. Describe how this knowledge will contribute to the base of information about delinquency and youth.

f. Research Plan:

The research plan should be the primary focus of the protocol. It should include descriptions of the following elements:

i. The sample inclusion and exclusion criteria
ii. The study procedure (i.e. what you intend to do in your study)
    1. If you are studying treatments, explain how the treatment differs from the care the participant would receive if not participating in the study.
    2. If you intend to conduct a longitudinal follow-up on the participants after the sampling has closed and the research interventions are completed, you must state this intention in the protocol. Provide a description of how you intend to track participants and protect confidentiality.
iii. A sample protocol or flow chart for an individual participant (flowcharts/diagrams are encouraged)
iv. The data analysis process
v. The role of each investigator with regard to contact with participants and description of the skills/qualifications/relevant training received of all the investigators
vi. Brief descriptions of all instruments, including surveys, questionnaires, or other forms that will be used during the study. You must provide a copy of all instruments needed for the study in the exact format participants will see them.

g. Potential Risks:

You shall not conduct research that exposes human subjects to an unreasonable risk of harm. You must not expose subjects to any risk that is reasonably avoidable. The principal investigator has the primary responsibility to protect subjects from harm caused by participating in the study.

i. Describe the physical or psychological risks that may result from participation in this research protocol.
ii. Describe any security issues with regard to the safety of juveniles, investigators, program staff, and others. Explain how common or uncommon each risk is, using statistical data when available.
iii. Explain how these risks are minimized.

h. Potential Benefits:

i. Describe the potential benefits of the research to the participants. If there are no direct benefits to them, then make that statement. Describe any potential benefits to their families, the Department, and society in general. Explain why the benefits outweigh the risks.
ii. Explain how this research will directly benefit the Department juvenile justice staff or the youth served.

i. Potential Financial Risks:

Describe any financial risk to the participants that may result from participation in this research protocol. If the exact dollar amount is unknown, estimate the costs that the participant may incur.

j. Potential Financial Benefits:

Describe any potential financial benefits of the research to the participants. If there are no direct financial benefits to them, then make that statement. Include any direct compensation, free service, medication, etc.

k. Conflict of Interest:

Describe any conflict of interest that exists or may appear to exist as it relates to any of the investigators and this protocol. A conflict of interest exists if there is potential benefit to the investigator(s) beyond the professional benefit from academic publication or presentation of the results. If an investigator is a Department or contracted provider employee, then include a description of the position, duties, and the possible conflict this creates with acting as an investigator in the study. Please be aware that a DJJ employee or the employee of a contracted provider cannot act as an investigator for a project in the facility where they work.

Mandatory Items (if applicable to specific proposal)

I. Research Acknowledgement Form : If the proposal involves a Department of Juvenile Justice program, the principal investigator must clearly identify every program, facility or organization that will be involved in the research on the Introductory Questionnaire (question 5). Following receipt of the completed IRB proposal, the IRB Director will notify the program area (Residential, Prevention, Probation, Detention, Health Services or Executive Services) liaison to review the request. Program liaisons will have 14 business days to review the proposal. **Researchers shall NOT contact programs prior to the Department's review of the research proposal; doing so could compromise IRB approval.** The principal investigator must fill out the Research Acknowledgement Form for each program, facility or organization that will be involved in the research (principal investigators must only complete the portion above the dotted line). The program liaison is responsible for contacting the IRB Director within the 14 business day period to confirm review of the proposal. The Researcher can begin to contact the locations listed on the Introductory Questionnaire upon notification from IRB Director or Program Area Liaison. The Research Acknowledgement Form states that the program Director understands the purpose of the study, the procedures, and any requirements placed on the program, such as access or staff time. Program Directors reserve the right to deny researchers access to the program. Studies that require a Research Acknowledgement Form will not be granted final approval until the signed Research Acknowledgement Form is received from each program, facility or organization listed on the Introductory Questionnaire.

II. Data Request Form: If the proposal involves data under the stewardship of the Department of Juvenile Justice that cannot be obtained via published reports on the Department's web site (i.e. individual level charge and placement data, etc.); the principal investigator must complete and submit a data request form. Details include at minimum; a description of information required, data variables specific to the research request, analytic approach, relevance to the juvenile justice field, and projected time frames for completion are necessary. An analyst responsible for fulfilling the data request will contact the Principal Investigator to discuss the parameters of the data or analysis requested and time allotted to complete the data request. Completions of data requests with tight deadlines are contingent on Department deadlines and business rules regarding Department priorities.

III. University Institutional Review Board or Agency Human Subjects Board letter of approval: The principal investigator must provide a University or Agency Human Subjects Approval Letter from a Board that complies with all federal requirements prior to the start of the study. If the letter cannot be acquired until approval from the Florida Department of Juvenile Justice and this is the only issue preventing approval by the IRB, then a conditional letter of approval can be issued. This issue must be addressed within the Introductory Questionnaire.

IV. Proof of completed background checks: **All investigators** must provide proof of completed Florida Department of Juvenile Justice background checks **prior** to final

approval. Instructions on how to conduct a background screening and the forms needed to make the request can be accessed through this link: http://www.djj.state.fl.us/services/support/OIG/BSU. If you have a question, you may inquire by sending an email to: generalbsu@djj.state.fl.us or by calling (850) 921-6345. **Background screenings performed by other agencies are not acceptable in place of the Florida Department of Juvenile Justice background screening**. The Institutional Review Board cannot waive the cost of the background screenings. Researchers **must** include the title of their IRB submission(s) and the email of the principal investigator in Section B of the appropriate background screening documentation. Any documentation submitted without a title to reference, will be discarded.

V. Instructions for Preparing an Informed Consent or Assent

a. The purpose of the Informed Consent and Assent is to provide the information necessary for the youth and parents/guardians to make an informed decision. The Department requires full disclosure of the research process to the youth and their guardians with rare exceptions. If you desire an exception to full disclosure in your consent or assent forms please include a rationale in the appropriate sections of your research protocol. The forms should be clear, concise, and written at the sixth grade reading level. They should include a brief narrative description of the purpose, procedures, risks, and benefits of the intended research. Informed consent and assent forms provided by the sponsor of a protocol must be adapted to IRB standards.

b. Researchers are required to obtain both informed assent from the youth and the informed consent of the parent/guardian. The IRB rarely grants exceptions. If you desire an exception for both the youth assent and parental consent, please include a rationale in the appropriate sections of your research protocol. Assent is a child's affirmative agreement to participate in research. Consent is the parent, legal guardian, or legal representative's agreement for the child to participate in research. The dual assent and consent requirements are necessary because subjects under the age of 18 cannot legally agree to participate in a study without the additional approval of their legal guardian or representative. Assent and consent are two separate processes both designed to inform potential subjects about the research and acquire their agreement to participate in the study. Researchers should consider the age, psychological state and the maturity of the minors enrolled in the study to determine if the participants are capable of providing assent. Mere failure to object will not be considered assent. Subjects who are 18 or older can legally consent to research. Therefore, informed assent is not required for these research participants.

c. Informed consent/assent is a process, not just a form. Information is presented to enable persons to voluntarily decide whether to participate. The design of the procedure(s) used in obtaining informed consent/assent is to educate the possible participants in terms they can understand. Therefore, write the informed consent/assent language and its documentation (especially explanations of the

study's purpose, duration, experimental procedures, alternatives, risks, and benefits) in "lay language" (i.e. understandable to the people asked to participate). The researcher must assess the participant's comprehension of the research project. The purpose of the written presentation of information is to document the basis for consent/assent and for the participant's future reference. The P.I. should revise the consent/assent process and forms when deficiencies are noted or when additional information will improve the consent/assent process. The IRB must approve all changes prior to implementation of the changed research process and the revised consent/assent process and forms.

d. Informed consent/assent cannot include language that waives or appears to waive any of the participant's legal rights. In addition, no language may release or appear to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

e. For protocols involving measuring, treating, or examining a participant that includes more than minimal risk, the Department IRB requires that the investigator directly involved in the research obtain informed consent/assent. The principal investigator must determine the risk to the participant and record it in the Introductory Questionnaire and Research Protocol. The IRB will review the principal investigator's assessment of risk to the participant and communicate in the approval letter any changes to this section. You shall not conduct any research that exposes human subjects to an unreasonable risk of harm. Subjects must not be exposed to any risk that can reasonably be avoided. The principal investigator has the primary responsibility to protect subjects from harm due to participation in the study.

f. The original consent/assent form, signed by the investigator, the participant or participant's legal guardian, or any other authorized representative of the participant, and a witness, must be placed in the participant's file. In addition, duplicate copies must be provided to the participant or participant's authorized representative, and placed in the experimental record of each participant.

g. Following the assent/consent process, participants that assent to participate and parents/guardians who consent for their youth to participate must retain a copy of the assent or consent form. You can accomplish this requirement in two ways: (1) provide additional copies of the assent/consent forms or (2) design the assent/consent forms so the signature page separates from the assent/consent form, which the participant and parents/guardians then retain.

h. Preparation of the Text:

    i. Do not copy information from this research protocol directly into the relevant sections of the informed consent/assent. Making this information understandable to juveniles and their parents or guardians usually requires

the investigator to rewrite the entire informed consent/assent at a sixth grade reading level.

ii. Sentences should be short and to the point. Avoid empty words (e.g., use "like" instead of "along the lines of," use "because" instead of "for the reason that"). Avoid difficult words (e.g., use "show" instead of "indicate," use "end" instead of "terminate").

iii. In almost all cases, the second person (i.e., you, your) should be used when writing the informed consent/assent ("As part of this research, you will be asked to….." or "Before taking the test, your hearing will be checked.") In parental consent forms, use the third person when referring to the participant (i.e., your child). If the researchers will be using combined assent and parental consent forms, then use the second person (i.e., you).

iv. Use lay terms at all times. Only include a technical term, with the definition or description, if it is important to the research. Use parentheses only when appropriate.

i. Elements of the Informed Consent/Assent Format:

i. Name of Participant: Enter the name of the research participant.

ii. Title of Research Study: The title must be identical to the title on the protocol, the project Cover Sheet, the informed consent/assent form, and any abstract submitted to the IRB.

iii. Principal Investigator's Name, telephone number, and email address.

iv. Sponsor of the Study: Enter the name of the study sponsor or grant institution (if applicable).

v. The Purpose of the Research: This section should contain a brief description of the purpose of the research and the selection criteria for participation. Only relevant background information should be included. For example, "We do not know the best way to help teenagers understand how they have hurt the victims of their actions. This project will help us learn more about your understanding and attitudes towards people you may have hurt in the past." A review of the literature is not appropriate.

vi. Informed Consent/Assent Procedure: Describe the procedure for obtaining informed consent and assent. Attach any written materials used for this process.

vii. Procedures for this Research:

1. This section should include a brief, but informative, description of the research procedures and what the participant will likely experience. The type and frequency of all tests, follow-up events, etc., should be included along with the expected duration of the participant's participation. It should be clear which part(s) of the protocol are experimental and which are not.

2. If the study is a randomized protocol, explain it as follows, "You will be divided into groups by chance, like the flip of a coin, so that we can give you a different treatment."

3. If the protocol is either a single or a double blind method, explain it as follows, "To see how well this new program works, no one will know which group you are in, unless there is a problem. Then we will report the group to which you belong."

4. If blood samples are required, state the amount needed in teaspoons, as well as milliliters. Specify any other needed specimens in appropriate measures, easily understandable by the participant.

5. If deception is essential to the research, a statement must be included to inform the potential participant of this. For example, "As part of this study it may be necessary to trick or deceive you. This trick or deception will in no way cause you any harm. After finishing the study, we will explain the trick or deception to you."

6. If the protocol involves an investigational drug, the following statement must be included **verbatim**: "You have been informed that because this study involves articles regulated by the FDA (Food and Drug Administration), the FDA may choose to inspect records identifying you as a participant in this investigation."

7. You must include your intention to conduct a longitudinal follow-up on the research participants in the informed consent/assent. For example, "After you have completed your part in this study, we will continue to contact you about your progress as part of our normal follow-up."

viii. Potential Health Risks or Discomforts:

1. The following statement must be included **verbatim** at the end of this section: "If you wish to discuss these or any other discomforts you may experience, you may call the Principal Investigator listed on this form."

2. State any potential health risks or discomforts so that the participant can understand the meaning of the risks. For example, if a drug will decrease white blood cells, it should be included that this could result in possible infection.

3. The relative risk for an adverse effect of a drug, diet, or treatment must be included. Whenever possible, use quoted or calculated statistical data. For example, Drug X has resulted in nausea and vomiting in 1 out of 10 participants, headaches in 1 out of 20 participants, and death in 1 out of 100,000 participants.

    a. If specific statistics do not exist, classification into "uncommon" or "frequent," etc. is acceptable.

    b. If the procedures include venipuncture (puncturing of a vein), the following statement must be included **verbatim**: "The risks of drawing blood from a vein include discomfort at the site of the puncture, possible bruising and swelling around the puncture site, rarely an infection, and, uncommonly, faintness from the procedure."

    c. If the investigation procedures utilize radiation or radioactive material, the informed consent/assent must include the appropriate statements regarding risk or discomfort and state that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus if the participant becomes pregnant) that are currently unforeseeable.

ix. Potential Health Benefits to You or to Others:

1. The initial statement should state whether there is a direct benefit to the individual participant. It is important that expected benefits are not overstated, or appear as if you are trying to coerce the participant to take part in the research.

2. If some randomly selected participants will receive a placebo treatment, you must state that those individuals may not benefit directly from this study. If there is no benefit to the individual participant, but a possible benefit to participants, to medical knowledge, or to society, please indicate this. If participants will receive more than standard care, include that information in this section.

x. Potential Financial Risks:

1. If a financial risk exists for the participant or the participant's family, you must clearly describe the risk to them. Estimate the cost of the additional procedures, medications, etc. that participation may incur, if the exact dollar amount is unknown.

2. This statement must be included **verbatim** in the risks section of the informed consent/assent form when applicable: "You will be charged expenses as a result of participating in this study. All or a portion of these charges may not be covered by your insurance plan. You or your family will have to pay installments based on your verified ability to pay. Any questions about these charges should be discussed with the principal investigator of the study."

3. In some cases, the sponsor of the research will agree to pay for any additional costs because of the protocol or because of adverse events caused by the protocol. These statements should be included in this section. For example, "The sponsor will pay for any immediate care and/or treatment beyond what is covered by the juvenile justice program or personal health insurance. You or the participant will not incur any additional costs because of participation in the research. This agreement to provide free medical treatment does not include treatment for any injury/illness that is not the result of the research."

xi. Potential Benefits to You or to Others:

1. The initial statement should state whether there is a direct benefit to the individual participant. It is important that expected benefits are not overstated, or appear as if you are trying to coerce the participant to take part in the research.

2. Include in this section if participants will receive free or more than standard care.

3. Clearly describe any direct compensation given, including when and how they will receive this compensation. Any payment made to the participant must be pro-rated.

xii. Compensation for Research-Related Injury:

1. If the principal investigator or sponsor will provide compensation for research-related injury, then the following statement must be included **verbatim**: "In the unlikely event you sustain a physical or psychological injury which is proximately caused by this study:____ professional medical, ____ professional dental, or _____ professional

consultative care will be provided by _____ without charge."

2. Place any statements provided by the sponsor about research-related compensation in this section of the informed consent/assent.

3. The Florida Department of Juvenile Justice does not provide compensation for research-related injuries.

xiii. Conflict of Interest:

1. Describe any conflict of interest that exists, or may appear to exist, as it relates to any of the investigators and this protocol. A conflict of interest exists if there is potential benefit to the investigator(s) beyond the professional benefit from an academic publication or other presentation of the results.

2. The IRB considers it a conflict of interest when Florida Department of Juvenile Justice employees or contracted employees act as an investigator for a study occurring within the same facility where they work, or that is conducted during regular work hours for which said employee is paid, unless prior authorization for on-duty compensation is provided in writing from the investigator's supervisor to the IRB.

xiv. Alternatives to Participating in this Research Project:

1. The following statement must be included **verbatim** within this section: "You are free to not participate in this study. If you choose to participate, you are free to withdraw your consent and discontinue participation in this research study at any time without this decision affecting your relationship to the people in your juvenile justice program or the investigators. If you have any questions regarding your rights as a participant, you may phone the Institutional Review Board (IRB) office at (850) 717-2633."

2. This section should include all the options the participant would have if the current protocol did not exist. If your protocol involves the treatment of participants, the following statement must be included **verbatim** at the end of this section, "Choosing not to participate in this study will in no way affect your care and treatment."

3. Placing "N/A" in this section is not an option.

xv. Withdrawal from this Research Study:

1. The following statement must be included **verbatim** within this section: "If you wish to stop your participation in this research study for any reason, you should contact _____ at _____. You may also contact the Institutional Review Board (IRB) Office at (850) 717-2633."

2. This section should include anticipated circumstances under which the investigator might terminate the participant from the study without regard to the participant's consent/assent.

3. This section should include the consequences of the participant's decision to withdraw from the research.

4. Placing "N/A" in this section is not an option.

xvi. Confidentiality:

1. The following statement must be included **verbatim** within this section: "_____ will protect the confidentiality of your records to the extent allowed by law. You understand that the Study Sponsor, the Department of Juvenile Justice, and the Institutional Review Board have the legal right to view your records."

2. Confidentiality ends when the youth discloses abuse to the investigator. The investigator must include in the consent and assent forms that they are mandated reporters and bound by Florida law to disclose if the youth reports being abused (F.S. 39.201). The investigators must follow the Florida mandated reporter laws and include in the protocol a plan for responding to disclosures of abuse.

xvii. HIV Testing:

1. Should your protocol involve HIV testing, you must provide information about the HIV antibody test. Include the following statements in the informed consent/assent form immediately preceding the "Signature Section." (Note: Change the verb tense used in this statement to conform to the rest of the informed consent/assent):

    a. "You have been provided with information about the HIV antibody test and have had the opportunity to ask questions about it. Someone will inform you of the test results in person and provide you with appropriate counseling for your individual circumstances. An appointment has been scheduled

for_____, 20__ at _____ am/pm, to conduct such post-test counseling."

b. The following statement must be included **verbatim** within this section: "By your signature, you acknowledge that you have been given all of the information you desire concerning the blood test that you freely give your consent to have this test performed, and that you authorize the recording of your test result in the research records. You further understand that we maintain these records in a confidential manner as provided by law and that the information is not released except as authorized by you, by order of a court, or as otherwise provided by law. You understand that Florida law authorizes releasing your positive test result to your sexual or needle-sharing partner(s) if you should refuse to do so."

xviii. Signatures:

1. Within this section, there must be a place for the name of the person acquiring assent/consent and the date acquired. The following statement must be included **verbatim** within this section: "The principal investigator or representative explained the nature and purpose of the above-described procedure, the benefits, and the risks involved in this research protocol."

2. On the consent/assent forms, there must be a place for the printed version of the participant's name, the signature of the participant, and date assent was acquired. The following statement must be included **verbatim** above the participant's signature line: "The principal investigator or representative explained the nature and purpose of the above-described procedure, the benefits, and the risks involved in this research protocol. You are agreeing to participate in this study."

3. On the parental consent forms, there must be a place for the printed version of the participant's name, the signature of the participant's parent or guardian, and the date parental consent was acquired. The following statement must be included **verbatim** above the participant's signature line: "The principal investigator or representative explained the nature and purpose of the above-described procedure, the benefits, and the risks involved in this research protocol. You are giving permission for your child to participate in this study."

VI. Instruments, forms, and other documents: The principal investigator must provide all instruments, forms, and other documents in the exact format used in the study. If you

modify the instruments, forms, or other documents after approval, then the principal investigator must acquire IRB approval prior to the use of these items.

VII. Sponsor's protocol: The principal investigator must provide the sponsor's protocol if it is a part of the study.

VIII. Information, including brochures, on drugs or appliances: If the study involves drugs or appliances, then the principal investigator must provide information, including the brochure, on these items.

Please contact the Institutional Review Board Director with additional questions. Contact information is available on the IRB Web site (http://www.djj.state.fl.us/research/irb-requests)