FLORIDA DEPARTMENT OF JUVENILE JUSTICE PROCEDURE

Title: Institutional Review Board (IRB) Research Proposal Review Process Procedures

Related Policy: FDJJ – 1609.01

I. DEFINITIONS

Assent - The juvenile's affirmative agreement to participate in research. Mere failure to object shall not be construed as assent.

Assent Form - A form that describes the project's purpose, methodology, benefits, and any potential or recognized risks to the participants and asks for the juvenile's signature should she/he agree to participate in that project. This form is approved by the IRB during the application review.

Consent - The juvenile's parent(s) or legal guardian(s) affirmative agreement to allow their child to participate in research. Mere failure to object shall not be construed as consent.

Data Request Form - A form to be used when requesting Department of Juvenile Justice data that cannot be found through the Department's research website (http://www.djj.state.fl.us/research) or publications. Based on the nature of the request, an analyst from Research and Planning will be assigned to contact the Principal Investigator and discuss the data. Completions of data requests with tight deadlines are contingent on Department deadlines and business rules regarding Department priorities.

Department Research - Grant proposals or research projects written or conducted by DJJ units or by them in partnership with other research organizations, which require direct contact with juveniles and/or use of confidential data about the participants.

Informed Consent Form - A form that describes the project's purpose, methodology, benefits, and any potential or recognized risks to the participants and is signed by the juvenile's parent(s) or legal guardian(s).

Institutional Review Board (IRB) -A review board consisting of professionals from inside the Department that reviews research proposals studying juveniles in the Department's custody and evaluates the potential risks and benefits to participating juveniles and the Department. Representatives of Research and Planning, General Counsel, Health Services, and Inspector General offices are mandatory members of the board. The board will look at all aspects of a research study to determine risk and the researcher's plan to diminish risks.

Institutional Review Board Handbook – A document that discusses and details the requirements for constructing the Research Protocol, Informed Consent Form, and Assent Form.

Introductory Questionnaire - A questionnaire containing specific questions about the research proposal submitted with the review application.

Minimal Risk - The probability and magnitude of physical, psychological, or emotional harm that is normally encountered in the daily lives or in routine medical, dental, or psychological examination of healthy

individuals.

Potential Risk - Any physical, psychological, or emotional harm that might result from the research involving the juveniles as participants.

Principal Investigator - The person who is directing and/or conducting the research project and requesting the subjects' participation and the IRB review.

Privacy and Security Agreement (PSA) - A legal document containing the parameters of the study (data sharing and duration) to be signed by the principal investigator and the Department Secretary's Delegate.

Research - A systematic investigation designed for gathering and analysis of information to develop or contribute to generalizable knowledge.

Research Acknowledgement Form – All research involving collecting new data from a DJJ program, facility or affiliated organization must include a Research Acknowledgement Form for all entities participating in the research. This form will define any needs the researcher may have to acquire data from the entities. The IRB branch liaison will use this form to contact programs, facilities or affiliated organizations and inform them of the researcher's intent. An Acknowledgement Form is the Department's approved form to fulfill this requirement. Researchers wishing to obtain archival data do not need a Research Acknowledgement Form.

Research Project Cover Sheet - A form that identifies the research project title, principal investigator, reason for conducting research, and supporting or funding institution submitted as part of the review application.

Research Protocol - A 3-5 page single-spaced typewritten summary of the research design and methodology that provides the IRB with information about the research plan and its potential risks and benefits to the participants. This research plan is submitted with the review application.

Research Subject - A juvenile in the care and custody of DJJ who agrees to participate in a proposed research project or a DJJ employee/contract employee who agrees to participate in a proposed research project.

II. STANDARDS/PROCEDURES

A. Scope and Relevancy of Research Proposals and Researcher's Qualification:

1. Research that exposes human subjects to an unreasonable risk of harm shall not be conducted.

2. Subjects must not be exposed to any risk that can reasonably be avoided. The principal investigator has the primary responsibility for protecting subjects from being harmed by participation in a study.

3. Individuals who propose to conduct research involving human subjects must be qualified by experience and/or training to protect the well-being of the subjects of their research.

4. DJJ encourages conducting scientific research that contributes to our knowledge about juvenile delinquency, that improves the juvenile justice system, and that benefits DJJ's commitment to public safety and effective treatment of the juveniles in its custody.

5. Research proposals, based on a sound theoretical foundation, must present viable research questions to be investigated by qualified researchers and/or research organizations in order to be considered for review by the IRB. The IRB shall be authorized to review and to approve or disapprove, and to state conditions for, the conduct of any research involving a human subject or subjects, in accordance with the policies and procedures stated herein. In certain circumstances, the IRB shall solicit advice from others who are especially qualified to represent the views of a particular subject population. IRB members shall not participate in the approval of projects in which they are involved or have a conflicting interest.

6. Except as provided herein, no research project involving contact with the juveniles in the Department's custody and/or access to confidential information about them is authorized without the IRB review and the permission of the Secretary or the Secretary's delegate. This shall include research conducted by DJJ and provider employees, as well as, outside researchers.

7. Investigators shall explain to their subjects, prior to their participation, the objectives of the research, the procedures they will follow, and the potential risks and benefits. Individuals shall not use a subject unless they are satisfied that the individual or those legally responsible for the individual consent to participation freely and with understandings of the consequences. The IRB may not require certain procedures and may stipulate additional information or procedures to protect the subjects.

8. Investigators shall respect the privacy of subjects and protect confidential information given to them. They shall advise subjects in advance of any limits upon their ability to ensure that the information will remain confidential.

9. Subjects shall not be induced or coerced to participate by means or circumstances that might affect their ability to decide freely.

10. It shall be made clear to all subjects that they are free to withdraw from active participation in the research at any time and without prejudice to their interests.

11. Instructors who assign or supervise research projects and exercises conducted by students are responsible for ensuring that the students are qualified and to safeguard the well-being of the subjects.

12. Prior to entry into a facility or having contact with a youth, the researcher must present the Program Director/Superintendent the completed background check and IRB letter of approval.

13. Due to the age (youth) and incarceration/supervision status of the potential subjects at DJJ, the IRB has additional requirements for researchers to include:
    a. A youth's ability to weigh the risks of the research against the value of any possible advantages of participation must not be affected by the magnitude of the possible advantages. This includes advantages as compared to the general living conditions, medical care, food quality, amenities, and opportunities for earnings that exist in the facility
    b. The process of selecting research subjects must be fair to all incarcerated or supervised youth. Unless the Principal Investigator provides the IRB with justification in writing for following some other procedures, control subjects shall be selected randomly from the group of available incarcerated or supervised youth who meet the characteristics needed for that particular research project.
    c. The information must be presented in an age-appropriate manner.
    d. Extensive evaluation and consideration shall be given to the issue of mandatory reporting by the Investigators. A clear, concise plan must be presented regarding how researchers will be trained regarding mandatory reporting statutes and the plan for calling in allegations of abuse.
    e. The participation of youth shall require active parental or guardian consent, except in the case of de-identified, archival data requests.
    f. The proposed research shall be limited to the following: 1) Study of possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk, and no more than inconvenience to the subjects; 2) Research on conditions particularly affecting incarcerated youth as a class; 4) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

14. The IRB review is conducted based on the US Department of Health and Human Services guidelines, Protecting Human Research Subjects, Institutional Review Board Guidebook, published by the Office for Human Research Protections (OHRP).

15. Requests from state and federal government agencies for existing data and information collected by the Department for program management and evaluation purposes are not subject to IRB review if they are used for the same purposes by those agencies. The Department shall receive and assign those requests to the related units for appropriate responses.

16. Research and evaluation conducted by the Bureau of Research and Planning are deemed necessary for DJJ's management purposes and the daily operation of its units and are not subject to IRB review.

17. Data collection and data analysis conducted by the Department units for program management and reporting on their daily operations are not subject to IRB Review.

18. Projects that use data on human subjects gathered in earlier projects or by DJJ in which individual identifiers are present require IRB review. Two possible situations exist that may qualify for an exemption from full review (a desk review by the Secretary's delegate is still required): 1) Someone who has legitimate access to the records gathers the data and gives the investigator only redacted data (all identifiers have been removed) , or 2) Research requests involving only the use of secondary, de-identified data.

B. Procedures for Requesting DJJ's Approval of Research Proposals Involving Juveniles as Research Subject:

1. The IRB uses the following criteria to review all completed research applications:
    a. Does the research study include a clear and concise research design, sampling process, data collection process, and analysis plan? Each of these areas are critical in determining if the risks of participation will result in outcomes that are valid and meaningful.
    b. The risks to the subjects are minimized.
    c. Risks to the subjects are reasonable in relation to anticipated benefits.
    d. Selection of subjects is equitable.
    e. Informed consent is sought from each prospective participant and his or her legal guardian, and the procedure is properly documented.
    f. Adequate precautions have been taken to protect the privacy and confidentiality of subjects and their information.

Application Process:

1. Complete a Project Cover Sheet and Introductory Questionnaire.

2. Complete a research protocol, assent and consent forms, include all research instruments to be used, and Research Acknowledgement Form (if applicable). For data requests, specific data elements must be identified using the Data Request Form.

3. If the Principal Investigator is affiliated with a College, University, or any agency that has an IRB, they must submit a letter of approval (or exemption) from the organization's IRB with the application to the DJJ IRB.

4. Send one (1) copy of the completed proposal via the mail to the IRB at:
    IRB Director
    Florida Department of Juvenile Justice
    Knight Bldg, First Floor
    2737 Centerview Drive
    Tallahassee, Florida 32399-3100

5. The IRB Director shall review the research protocol and/or assign a board member to review the research proposal to assess the design, methodology, and potential risks for the participating juveniles.

6. The assigned board member will review the proposal and make a recommendation to present it to the entire Board or to return it to the researcher. If the proposal is recommended to be heard by the IRB, the IRB Director (or assigned board member) will present a summary of the proposal during the IRB meeting.

7. The Board shall discuss the potential risks of the research project and ensure that the research participants who choose to participate are well protected and are not exposed to more than minimal risks. The Board shall also consider the project's benefits to the Department in promoting its commitment to public safety and effective treatment for the juveniles.

8. The IRB will review the proposal and will ask questions and give feedback to the Secretary or the Secretary's delegate.

9. The Secretary or the Secretary's delegate will review the proposals independently and make a decision to either accept or reject the proposal. Acceptance of the proposal constitutes approval for the study to be conducted.

10. A letter will be sent to the researcher soon after the IRB meeting with the results of the Secretary's or Secretary's delegate's decision. If approved, the letter will include the following statements:
    a. All information obtained from DJJ is confidential except as provided in this notice. It may not be disclosed to any person, business, government agency, or other entity unless the disclosure is authorized in writing by DJJ. If DJJ does permit disclosure of such information, the Department reserves the discretion to place conditions on such disclosure.
    b. You may not disclose any information that could reasonably lead to the identification of any individual youth. All data resulting from this research project must be published in aggregate form.
    c. Any person working on this research project must agree to be bound by these conditions concerning confidentiality of information.

11. If the proposal is rejected and the researcher chooses to resubmit, they must complete a new application.

12. The researchers must:
    a. Present the IRB with a completed DJJ background screen (as determined by the IRB).
    b. Provide the IRB with a list of facilities or programs (on the Introductory Questionnaire) where they wish to conduct research. DJJ will be responsible for coordinating the contact between the researcher(s) and facilities or programs intended to be involved in the research. Researchers should **not** independently contact programs prior to discussing the research with the Department's IRB director.
    c. Present the IRB with signed Research Acknowledgement Forms, after DJJ has established contact with the program/organization within which the subjects reside or are supervised (if dealing with youth in facilities) or that is participating in the research.

d. Sign a Privacy and Security Agreement (PSA) once the proposal is approved.

13. The IRB approval only lasts for one calendar year from the date of approval. The principal investigator will be notified one month before the termination of research approval. The researcher must submit a time-limited request for continuation and any modifications prior to the one-year date.
    The application for continuation must include a detailed summary of progress and expected completion date.

14. The principal investigator shall be required to submit a copy of the final report published on the authorized research project to the Department. The final report shall be given to the IRB for review 90-days before being submitted for publication.

15. All IRB members will complete annual continuing education related to IRB issues.

16. The Director of the IRB will maintain an online list of current research projects.

C. Modifications of Research Design and Methodology:

1. The IRB must authorize any changes or modifications to the approved research design and methodology. The principal investigator is responsible for securing such authorization prior to implementing changes in the research design. The principal investigator shall report to the IRB Director any and all problems or changes (anticipated or unanticipated) involving risk to the subjects or others.
2. Any unauthorized deviation from the approved research plan discovered during the project's implementation may result in suspension or termination of the research project.
3. The principal investigator must report to the IRB Director any serious or continuous noncompliance with IRB regulations or human subjects protocol.
4. Any violation or deviation from IRB requirements, approved research protocol, or human subjects protocol may result in termination of departmental approval.

III. RESPONSIBILITY AND DUTIES

A. Institutional Review Board (IRB):

1. Review research proposals from researchers both within and outside of DJJ.
2. Make recommendations to the Secretary or Secretary's Designee to accept or reject research proposals based on a thorough review by Board members.
3. Make recommendations for changes to proposals to best protect the youth in DJJ.
4. Monitor ongoing research projects and review final products (articles, books).
5. Meet at least quarterly as a Board to review research proposals.
6. Review all surveys and needs assessments developed by DJJ staff or provider staff to assess potential risks to youth, facilities, and families.

IV. ATTACHMENTS

Attachment 1 - Project Cover Sheet

Attachment 2 - Introductory Questionnaire
Attachment 3 - Institutional Review Board Handbook
Attachment 4 - Research Acknowledgement Form
Attachment 5 – Data Request Form