

**SAMPLE IRB PROPOSAL DOCUMENT**

*This document was prepared for informational purposes only.*

*Do not rely solely on this sample packet for information regarding the Institutional Review Board's policies/protocols/regulations. Download the full DJJ IRB Handbook and review it thoroughly prior to submitting a proposal.*

*Direct any questions to:*

***IRB Director***

***Department of Juvenile Justice***

***Office of Research and Data Integrity***

***2737 Centerview Drive***

***Tallahassee, FL 32399***

***Telephone: (850) 717-2633***

***Email: [IRB.Director@djj.state.fl.us](mailto:IRB.Director@djj.state.fl.us)***

FLORIDA DEPARTMENT OF JUVENILE JUSTICE



Institutional Review Board
Cover Sheet

Project Title: An Analysis of Factors Contributing to the Utility of Foot-Powered Automobiles

Name of Principal Investigator: Frederick Flintstone, Ph.D. Title: Assistant Professor

University/Research Institution: University of Bedrock

Department: Mechanical Engineering

Mailing Address: 5678 College Loop, Suite A, Bedrock, Bedrock 12345

Email Address: fredflintstone@u.bedrock.edu Telephone #: (123) 456-7890

Purpose of this study? [x] Dissertation [ ] Thesis [ ] Grant [ ] Other: [ ]

I approve this protocol for submission to the Institutional Review Board.

Dissertation/Thesis Chairperson

Date

Co-Investigators:

What are the research questions?

The following items have been included in the application packet (N/A, if not applicable):

- Introductory Questionnaire
5-page Research Background and Protocol
Research Acknowledgement Form for the DJJ program(s) involved (Above Dotted Line Only)
Copies of all forms/instruments
University/Agency Human Subjects Approval Letter
Data Request Form

The principal investigator has read the Institutional Review Board handbook: [ ] Yes [ ] No

The undersigned accepts the responsibility to comply with Federal, State, and Department of Juvenile Justice policies related to the protection of the rights and welfare of human subjects.

Signature of Principal Investigator

Date

2737 Centerview Drive • Tallahassee, Florida 32399-3100 • (850) 488-1850

http://www.djj.state.fl.us

FLORIDA DEPARTMENT OF JUVENILE JUSTICE



Introductory Questionnaire  
Institutional Review Board

Name of Principal Investigator: Frederick Flintstone

Project Title: An Analysis of Factors Contributing to the Utility of Foot-Powered Automobiles.

1. Characteristics of the research (check all that apply):

- Archival Data Study Method (requires Data Request Form)
  - Identified Data
  - De-identified Data
- Non-Archival Data Study Method
  - Survey/Questionnaire
  - Intervention
  - Experimental
  - Behavioral or Psychological Study
  - Exercise or Nutrition Study
- Deception of Subjects
- Use of Impaired Subjects\*
- Collection of Physical Specimens (e.g., blood, urine, hair)
- Use of Placebos
- Non-Approved Indication for Approved Drug
- Non-Approved Dose for Approved Drug
- Experimental/Marketed Drug: IND # \_\_\_\_\_
- Experimental/Marketed Drug: IND Exempt
- Other, please specify: \_\_\_\_\_

\*Impaired subjects include those who have physical or mental limitations which restrict their ability to understand, or who are dependent on the individuals who may be consenting for them. The subjects include, but are not limited to, people who are in one of the following categories: mentally or emotionally impaired, illiterate, or those who require certain care. Some subjects are permanently impaired by definition of their circumstances; others are temporarily impaired.

2. Where did this study idea/request originate?

- At the Florida Department of Juvenile Justice
- At another State of Florida agency (please specify): \_\_\_\_\_
- An academic institution (please specify): \_\_\_\_\_
- A research institution (please specify): \_\_\_\_\_
- From a grant proposal
- Other (please specify): \_\_\_\_\_

2737 Centerview Drive • Tallahassee, Florida 32399-3100 • (850) 488-1850

<http://www.djj.state.fl.us>

*The mission of the Department of Juvenile Justice is to increase public safety by reducing juvenile delinquency through effective prevention, intervention and treatment services that strengthen families and turn around the lives of troubled youth.*

3. Is financial or material support required for this study?  Yes  No (If No, skip to #5)

Source of Funding:	<u>Applied for</u>	<u>Obtained</u>	
Grant Institution	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	(please specify) _____
NIJ	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	
OJJDP	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	
BJA	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	
DJJ	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	
State of Florida	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	
University	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	(please specify) _____
Other	<input type="checkbox"/> Yes	<input type="checkbox"/> Yes	(please specify) _____

4. Expected dates of the study: Start Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ End Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

5. Expected location(s) of the study? (please specify)

(Researcher fills out **top portion** of Research Acknowledgement Form at this time)

_____	Research Acknowledgement Form Filled Out	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	<i>Signature Obtained (DJJ Process)*</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____	Research Acknowledgement Form Filled Out	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	<i>Signature Obtained (DJJ Process)*</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____	Research Acknowledgement Form Filled Out	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	<i>Signature Obtained (DJJ Process)*</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

\*Refer to DJJ's IRB Handbook for the specific process on obtaining signatures for the Research Acknowledgement Form

6. Describe any significant relationship between the investigator(s) and any of the participants in the study. Check all that apply:

- Researcher/Participant
- Teacher/Student
- Contract or Department Provider/Delinquent
- Health Care Provider/Patient
- Employer/Employee
- Friend or Family
- Other (please specify) \_\_\_\_\_

7. Are you currently or have you ever been employed by the Florida Department of Juvenile Justice or a DJJ provider?  Yes  No

If **yes**, explain any possible conflicts of interest or explain why this situation will not result in a conflict of interest. \_\_\_\_\_

\_\_\_\_\_

8. Describe the youth assent/parent consent process?

---

---

---

9. Participant Information

9a. Estimated number of participants \_\_\_\_\_ Age Range: \_\_\_\_\_ to \_\_\_\_\_ years of age

9b. Describe participant types (e.g., normal controls, habitual offenders, sexual offenders)

---

---

---

9c. Are participants selected based on gender?  Yes  No If yes:  Males/ Females  
If **yes**, specify reason. \_\_\_\_\_

---

---

9d. Are participants selected based on race/ethnicity?  Yes  No

If **yes**, specify races/ethnicities: \_\_\_\_\_

If **yes**, specify reason: \_\_\_\_\_

---

9e. Describe the plan for dealing with youth who cannot read or are developmentally disabled.

---

---

---

10. If you are planning to interact with youth or staff at a DJJ facility or property where they may receive information about possible abuse of a youth, how do you plan to comply with Florida Statute 39.201 regarding mandatory reporting?

Incidents of abuse will be reported to 1-800-96ABUSE

Other (please explain): \_\_\_\_\_

11. In the event of a psychological or medical emergency, plans for management are:

Normal provisions of the DJJ program.

On-site physician with emergency medications and equipment provided by investigators.

Public or community emergency services (e.g., 911).

Other (please explain): \_\_\_\_\_

12. Will any services, tests, medical procedures, etc., be performed that are in addition to the routine rehabilitative regimen or overlay services for the participants, including drug testing?

Yes     No        (If **No**, skip to #13)

12a. Who will have access to the results? \_\_\_\_\_  
\_\_\_\_\_

12b. If the study involves pharmacological intervention, will any of the drugs, devices, etc., be given to the participants free of charge? If so, please specify. \_\_\_\_\_  
\_\_\_\_\_

12c. Who or what agency will pay for them? \_\_\_\_\_

13. All individuals, including the principal and co-investigators, who will have access to juveniles, their parents, department employees, or contract providers or individuals who will have access to confidential information must undergo background screenings. Please identify **all individuals** who will require background screenings **and your time frame** to complete DJJ background checks on each individual. *\*Background Screenings submitted to the Department without the title of the IRB submission and the email address of the principal investigator included on the documentation will be discarded. Please refer to DJJ's IRB Handbook for the specific process.*

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

14. What measures will be taken to protect the confidentiality of the information (e.g., tapes, pictures, personal documentation) obtained? Specifically address how the principal investigator will store, handle, and destroy the information.

14a. During the research study: \_\_\_\_\_  
\_\_\_\_\_

14b. After completion of the research study: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

15. Will research participants be compensated?         Yes     No (If **No**, skip to #16)

15a. Reimbursement of Expenses?     Yes         No

If **yes**, specify the expenses for which the participant will be reimbursed.

\_\_\_\_\_

15b. Monetary Compensation?  Yes  No If yes, amount: \$\_\_\_\_\_

If monetary compensation is provided, a pro-rated payment is required. Please outline the amount and schedule of all payments. If a pro-rated payment scheme is not applicable, an explanation must be provided below.

---

---

Given the group of participants you will recruit, could the monetary compensation unduly influence a subject to participate in this study or remain in this study when other factors in the subject's health/environment would keep the subject from doing so? (Please specify).

---

---

16. Is there an oversight committee that reviews safety data for this research study?

Yes  No If yes, please specify: \_\_\_\_\_

---

Updated 4/18/14

# RESEARCH PROTOCOL

## **Research Protocol: An Analysis of Factors Contributing to the Utility of Foot-Powered Automobiles**

### Contents

<b>Research Protocol: An Analysis of Factors Contributing To The Utility of Foot-Powered Automobiles .....</b>	<b>1</b>
<b>Project Title.....</b>	<b>2</b>
<b>Investigator(s).....</b>	<b>2</b>
<b>Abstract .....</b>	<b>2</b>
<b>Specific Aims .....</b>	<b>2</b>
<b>Background and Significance .....</b>	<b>2</b>
<b>Research Plan.....</b>	<b>2</b>
<b>Potential Risks.....</b>	<b>3</b>
<b>Potential Benefits.....</b>	<b>3</b>
<b>Potential Financial Risks.....</b>	<b>3</b>
<b>Conflict of Interest.....</b>	<b>3</b>



### **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.

### **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.

### **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.

### **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.

### **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.

### **Research Plan:**

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

- The sample inclusion and exclusion criteria
- The study procedure (i.e. what you intend to do in your study)
  - If you are studying treatments, explain how the treatment differs from the care the participant would receive if not participating in the study.
  - 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.

- A sample protocol or flow chart for an individual participant (flowcharts/diagrams are encouraged)
- The data analysis process
- The role of each investigator with regard to contact with participants and description of the skills/qualifications/relevant training received of all the investigators
- 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.

**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.

- Describe the physical or psychological risks that may result from participation in this research protocol.
- 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.
- Explain how these risks are minimized.

**Potential Benefits:**

- 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.
- Explain how this research will directly benefit the Department juvenile justice staff or the youth served.

**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.

**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.

**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.

FLORIDA DEPARTMENT OF JUVENILE JUSTICE



Research Acknowledgement Form  
Institutional Review Board

DATE: 03/02/2017

TITLE OF PROPOSED RESEARCH: An Analysis of Factors Contributing to the Utility of Foot-Powered Automobiles.

NAME OF PRINCIPAL INVESTIGATOR/ RESEARCHER: Frederick Flintstone, PhD

NAME OF ORGANIZATION/FACILITY: University of Bedrock

NAME OF PROVIDER/AGENCY: N/A

LOCATION ADDRESS: 5678 College Loop, Suite A

CITY: Bedrock STATE: Bedrock ZIP CODE: 12345

The following will be required of facility staff *(Check All That Apply)*:

Staff Time	Facility Resources	Other
<input type="checkbox"/> Completion of Forms or Questionnaires	<input type="checkbox"/> Audio-Visual Equipment	
<input type="checkbox"/> General Supervision	<input type="checkbox"/> Computers	
<input type="checkbox"/> Interaction with Youth & Researcher	<input type="checkbox"/> Internet Access	
<input type="checkbox"/> Mailing or Copying	<input type="checkbox"/> Postage	
<input type="checkbox"/> Obtaining Outside Counselor for Youth	<input type="checkbox"/> Printing or Copying	
<input type="checkbox"/> Parental Contact	<input type="checkbox"/> Securing Monetary Incentives	
<input type="checkbox"/> Records Maintenance	<input type="checkbox"/> Secure Storage of Research	
<input type="checkbox"/> Records Research	<input type="checkbox"/> Other (list)	
<input type="checkbox"/> Youth Counseling	<input type="checkbox"/> Other (list)	

Additional comments, questions, support, concerns, etc., regarding the proposed research: \_\_\_\_\_

By signing this Acknowledgement Form, I acknowledge that I am aware and approve of the proposed research project as listed above and the required staff time / facility resources needed:

FACILITY ADMINISTRATOR/CONTACT PERSON: \_\_\_\_\_

SIGNATURE & TITLE: \_\_\_\_\_

E-MAIL: \_\_\_\_\_ PHONE: \_\_\_\_\_

I do not wish to acknowledge the proposed research at this organization/facility

**Attach any/all applicable forms or instruments here.**

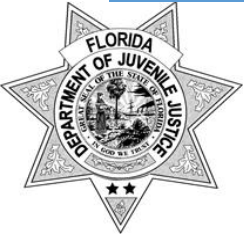
---

**Attach a copy of your university's IRB approval letter, or any other applicable human subjects study approval letters.**

---

# DATA REQUEST FORM

## FLORIDA DEPARTMENT OF JUVENILE JUSTICE



### Institutional Review Board Data Request Form

<b>SECTION 1: TO BE COMPLETED BY PRINCIPAL INVESTIGATOR</b>			
<b>Name</b>	Frederick Flintstone, PhD	<b>Contact Number</b>	(123) 456-7890
<b>Project Title</b>	<u>An Analysis of Factors Contributing to the Utility of Foot-Powered Automobiles.</u>	<b>Email Address</b>	fredflintstone@u.bedrock.edu
<b>Description of Information Required</b> <i>(Please include dates/timeframes for any analysis, and other specific indicators/categories required in the data)</i>			
<b>Purpose/Context</b> <i>(what the data is required for)</i>			
<b>Request Date</b>		<b>Required Date</b>	
<b>Format Required</b> <i>(Table, Map, Spreadsheet, Word etc) – please specify</i>			

<b>SECTION 2: TO BE COMPLETED BY DJJ RESEARCH AND DATA INTEGRITY OFFICE</b>			
<b>Time Estimate</b>		<b>Date Received</b>	
		<b>Assigned to</b>	
<b>Initial review comments</b> <i>(Discussion with PI – revisions required? Agreement to proceed? Can R&amp;DI provide the data? Etc)</i>			
<b>Work in progress comments</b> <i>(Additional notes and comments during production of data)</i>			

<b>SECTION 3: COMPLETION DETAILS</b>			
<b>Date Completed</b>		<b>Date Provided to PI</b>	
<b>Feedback from PI</b> <i>(If applicable)</i>			