

KENT STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD
APPLICATION FOR APPROVAL TO USE HUMAN RESEARCH SUBJECTS

Move through this document using TAB or mouse. DO NOT USE THE ENTER KEY. Please type all information. HANDWRITTEN FORMS WILL NOT BE ACCEPTED. To check a box, double-click in the box.

Submit completed form with signatures and all required attachments to the IRB REVIEWER associated with your Department or College, or to: Office of Research Safety and Compliance, Research and Graduate Studies, 137 Cartwright Hall, Phone: 330-672-2704.

Project Title: 175 character limit (IMPORTANT: Please specify below if this application should serve as a replacement for a currently active protocol. Include active protocol number.) *Cost-Effectiveness Of Early Childhood Care And Education Services Pilot Study*

Principal Investigator

Name: Dr. Kristie Pretti-Frontczak

Department: Special Education

Address:

Email: kprettif@kent.edu

Phone:

- Status:** Faculty
 Doctoral Student
 Graduate Student
 Undergraduate Student
 Other: (Specify:)

- Project:** Faculty Research
 Student Dissertation
 Student Thesis
 Course Requirement: (Course #:
 Other : (Specify:)

KSU Faculty Co-Investigator(s) (Use additional sheets if necessary)

Name:

Department:

Address:

Email:

Phone:

- Status:** Faculty
 Doctoral Student
 Graduate Student
 Undergraduate Student
 Other: (Specify:)

Faculty Advisor (If PI is a student)

Name:

Department:

Phone:

Email:

Protocol Funding: Not-applicable Pending Awarded Federal: Yes No

Funding Agency: _____ If funded or pending, attach detailed information regarding proposal (including title).

Estimated Project Duration: Starting Date: 08/2011(But not before approval is obtained)
 Ending Date: 08/2013

KSU IRB USE ONLY

IRB Reviewer Determination	
<input type="checkbox"/> Level I – Exempt, Category _____	
<input type="checkbox"/> Level II – Expedited, Category _____	
<input type="checkbox"/> Level III – Full Board review	
<input type="checkbox"/> Disapproved	
_____ Primary Reviewer	_____ Date
_____ Secondary Reviewer	_____ Date

IRB Administration Action	
<input type="checkbox"/> Approved Level I – Exempt, Category _____	
<input type="checkbox"/> Approved Level II – Expedited, Category _____	
_____ Administrator, IRB	_____ Date
_____ Chair, IRB	_____ Date

AGENDA Date _____
Correspondence
E-mail approval _____
Date _____
E-mail notice of annual review _____
Date _____

Full Board Review Action		Meeting Date:	
<input type="checkbox"/> Approved	<input type="checkbox"/> Contingent Approval	<input type="checkbox"/> Tabled	<input type="checkbox"/> Disapproved
	<input type="checkbox"/> Contingencies Met	Date: _____	

Part I: Please answer the following questions by checking the correct response.

- Yes No 1. Will participants be identifiable to anyone other than the researchers through records, responses, or identifiers linked to the participants?
- Yes No 2. Could participants be at risk of criminal or civil liability, damage to employability or to financial standing, or undue embarrassment, if responses became known outside this research project?
- Yes No 3. Does research deal with sensitive aspects of participants' behavior, such as illegal conduct, drug use, sexual behavior, use of alcohol, or potential harm to self or others?
- Yes No 4. Does research involve the study of existing data? (If yes, please specify.)
- Documents, archives, and/or records Biological specimens
- 4.a. Is the database, archives, or record collection publicly available? Yes No
- 4.b. Are the subjects who provided the data individually identifiable? Yes No
- 4.c. Will any identifying information that may link your data to individuals be included in your research records? Yes No
- Yes No 5. Does the research involve audio, video, digital, or image recordings of participants? (If yes, please specify.)
- Video-taped Audio-taped Photographed Other: (Specify:)
- Yes N/A 6. Are participants free to withdraw at any time without penalty?
- Yes No 7. Is there deception of participants? (If so, answer questions in Part VII, #35-44)
- Yes No 8. Does the research deal with participants under the age of 18?
- Yes No 9. Will identifiable medical information be collected?
10. Does the research deal with any of the following vulnerable populations:
- | | | | |
|---|-------------------------------|---|----------------------------|
| <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Legally incompetent adults | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Traumatized or Comatose |
| <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Cognitively/Mentally impaired | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Economically Disadvantaged |
| <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Physically challenged | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Terminally ill |
| <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Pregnant women | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Prisoners |
11. Does the project involve: (If yes, also answer question #20 on page 4).
- | | | | |
|---|---------------------------------------|---|---------------------|
| <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Administering drugs | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Medical devices |
| <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Administering alcohol | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Invasive procedures |
| <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Administering nutritional supplements | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Drawing blood |
| <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Taking tissue samples | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No | Giving injections |
12. Are you collecting any portion of your data on-line? Yes No
13. Are you requesting a waiver of any elements of the consent process? Yes No
(If yes, answer questions in Part VIII, #45-46.)

Part II: Summary of Research

14.) **Describe the purpose and significance of the proposed research; include sufficient background information and the specific objectives of the study. Summarize the major hypotheses. (Use non-technical language that can be understood by someone outside the discipline.)**

The proposed research project is the pilot study component of a larger research project. The goal of the larger project is to analyze costs, benefits, and quality of existing early care and education services to develop a model early childhood care and education plan that provides maximum benefits to all children at a minimum cost. The goal of the

pilot study is to examine the feasibility of implementation of the model early childhood care and education plan, while refining it through implementation. Additionally, researchers will gather initial data about the cost-effectiveness of specific services delivered during the pilot study.

- 15.) **Describe the study design, research methods and procedures. (Please append copies of the consent form and all measures, including interview questions and self-report questionnaires, to this form.) What are the qualifications of the individual(s) who will be collecting the data?**

The pilot study will be a quasi-experimental quantitative design using the regression-discontinuity model. The experimental group will be services for children ages 3-5 who reside in one district-specified elementary school zone. The control group will be the services for children ages 3-5 who live in the school district outside of the district specified elementary school zone. Data will be collected about the cost, quality, and characteristics of services provided during the school year in the identified district. Teacher satisfaction, parent satisfaction, and administrator satisfactions will also be measured. Detailed descriptive information about the development of the Model Early Childhood Care and Education Services Plan and its implementation will be collected.

The data will be collected by graduate students enrolled in an Early Childhood or Early Childhood Special Educaiton program and a Project Manager who has at least a master's degree in a related field. All researchers involved in this study have expereince working in schools and/or childcare centers, gathering educational data and completing educational assessments. Additionally, they will receive thorough training on the environmental assessments that will be used.

Part III: Research Participants

- 16.) **Briefly describe the characteristics of your population(s). Describe the ethnic background, sex, age, state of health, and the criteria for inclusion or exclusion of participants. (Include rationale for use of special classes of participants such as pregnant women, children, institutionalized mentally disabled, prisoners, or those whose ability to give voluntary informed consent may be in question.) If your population is all one gender or ethnic group, please explain.**

Participants will be children ages 3-5 years and their teachers and/or childcare providers. All children who reside in one public school elementary zone, determined by the school district, will be invited to participate. Location of perminant residence and children's age will be the only inclusion/exclusion criteria. Ethnic background, state of health, and sex will not be used to determine eligibility to participate.

- 17.) **Indicate the anticipated sample size.**

The anticipated sample size is 150-200 children and 30-50 teachers and/or caregivers.

- 18.) **Explain the recruitment process. State how potential participants will be identified and who will make the initial contact. Explain how you will ensure that recruitment and selection of participants is equitable. (Please include all recruitment materials, including scripts, flyers, and advertisements as attachments to this form.)**

The public school district will determine which elementary zone to implement the experimental service delivery model. In June, a letter will be sent from the school district to all households in the district explaining the change of services and offering parents of children 3-5 years of age the ability to opt-in or -out of their neighborhood program during the experimental school year. At the same time, a the school distrctit and research team will send a letter to all preschools and childcare centers in the experimental elementary school zone, explaining the research project and inviting participation of teachers and administrators. In August, parents of children 3-5 years of age in the experimental elementary school, will receive a letter from the school district and the researchers inviting them to participate in the research project. Finally, children whose parents give permission to the inclusion of their participation will be asked to give their assent to participate.

Part IV: Risks/Benefits

- 19.) **Identify any expected or potential risks or discomforts (including physical, psychological, social, or legal) to which participants may be exposed as a result of participation in the research project (beyond those encountered in everyday life).**

The proposed project involves no potential risks to participants beyond those encountered in everyday life.

- a.) **What safeguards will you use to protect the participants from these risks, as well as to protect their rights, welfare, and privacy? (Must provide a response; never answer "N/A".)**

Each participant will be assigned an ID number for tracking data, so their information will be anomomous beyond their consent forms. Consent forms, and all paper data collection forms will be kept in a locked file cabinet in 220 White Hall. Electronic data will be stored in password-protected files on the two password-protected laptops which will be used exclusively for this study.

- 20.) **Describe the anticipated benefits to individual subjects and to society expected to be gained from this project.** (This should include any direct benefits to the participants as well as any generalized gain in knowledge. If there are not direct benefits to individual subjects, state that.)

Children who participate in the study may benefit from increased quality of educational and childcare experiences. Teachers and caregivers who participate in the study may benefit from free professional development services offered at their program sites. Indirect benefits from this study could include improving quality of early childhood education and care services as well as improving access to those services.

- 21.) **Describe the qualifications of the person administering drugs, alcohol, or nutritional supplements, or drawing blood, taking tissue samples, or giving injections.**

Please note:

- i. Persons doing venipuncture must provide a copy of their certification to draw blood and proof that they completed a blood-borne pathogens training course.
- ii. Indwelling venous catheters and lines can only be inserted and accessed by licensed/registered/certified medical personnel such as physicians, RNs, and EMTs. Proof of certification is required.
- iii. Arterial blood sampling can only be carried out in an appropriate medical facility such as a hospital, clinic, or the KSU Health Center. The procedure can only be carried out by qualified personnel under the direct supervision of a licensed physician.

The proposed project does not include any medical procedures nor the administration of drugs, alcohol or nutritional supplements.

- 22.) **Describe any form of compensation to participants. (i.e., money, extra credit, etc. If money, extra credit, or grade is given to students who participate in the project, what opportunity for extra credit or grade is provided to students who choose not to participate?)**

Please note:

- a. If the research participation affects the course grade (e.g., extra credit), then alternative opportunity for course credit is needed.
- b. For multi-phase projects, compensation should not be contingent upon completion of the whole project. Rather, some compensation should be given for each phase of the project. The nature of the compensation should be stated in the consent form.

Teacher/Caregiver participants who participate in the development of the model service delivery plan and/or co-teach with an ECIS as part of the model service delivery plan will receive a \$500 stipend for their participation. No other participants will receive compensation.

- 23.) **Research participants will be informed of the risks and benefits through:**

- Consent form (Include with application)
- Verbal Script (Include with application)
- Parental Consent form for parents/guardians (required for children 18 of age and younger)
- Assent form (in addition to Parental Consent form for children 12 years of age and younger)

Part V: Informed Consent (You *must* include a copy of the informed consent document with application materials.

Visit the IRB website for more information about informed consent documents)

- 24.) **Describe the consent process. Explain when and where consent will be obtained and identify who will be obtaining informed consent.**

The Project Manager will first gain permission from school program administrators as necessary for the research team to invite participants from their schools/programs. Members of the research team will then send letters to teachers, caregivers, and parents of children ages 3-5 who live (or work) within the designated geographical boundary inviting them to participate in the study along with necessary consent forms.

- 25.) **If you will be using children under 18, explain in detail how you will obtain parental consent and assent (for children under 12) or consent (for children 12 to 18). If assent/consent will be obtained orally, supply a script of what you will say and how you will give the children the opportunity to agree to participate or decline.**

Children will not be directly involved in any research activities. Researchers will obtain parent consent to access school records of children, but the only child-level data that will be collected will be information normally collected by the school or center.

- 35.) Describe the type of deception being used. Consider in your answer both deception by omission (an important aspect of the research is withheld from the subject) and deception by commission (the subject is misled about the true purpose of the research).
NA
- 36.) Why is deception a necessary and unavoidable component of the experimental design? (Does the deception improve the internal or external validity of the study?)
NA
- 37.) Has this research protocol (involving deception) been previously used? If "Yes," please provide information on any actual harms to the participants and reactions of the participants to the use of deception in this research.
NA
- 38.) What alternative procedures were considered that did not involve deception and why were these alternatives rejected?
NA
- 39.) Since deception precludes informed consent by the subject prior to participation:
- a.) How will participants be debriefed?
NA
 - b.) Who will debrief them?
NA
 - c.) Will the debriefing of participants be:
 - Immediate (immediately following the experimental session in which deception occurs)
 - Delayed
 - Full (all deceptive aspects of the study will be revealed)
 - Partial (some deceptive aspects of the study will remain unexplained)
- 40.) If debriefing is delayed, why is delayed debriefing necessary and when will debriefing occur?
NA
- 41.) If debriefing is partial, why is the partial debriefing necessary? Why is unexplained deception necessary? Would the subject be harmed in any way by full debriefing?
NA
- 41.) Even if the subject is partially debriefed during the study, will full debriefing occur later?
NA
- 42.) Does the presence of deception increase the risk of harm to the subject?
NA
- 43.) Is the respondent free to withdraw his/her data after being fully debriefed? (e.g., form like audio/video taping).
NA

Part VIII: Request for Waiver of Elements of Informed Consent

- 43.) Are you requesting a waiver of the documented (signed) informed consent form for each participant?
 Yes No

Please indicate the justification for requesting this waiver:

- The only record linking the subject to the research would be the signed consent document and the principal risk of the research would be breach of confidentiality.
- The research involves only minimal risk to the subjects and involves no procedures for which written consent is normally required outside of the research context (e.g. anonymous surveys of adults).

Note: Participants must still be provided with a written statement regarding the research that contains the required elements of informed consent. Refer to the [Informed Consent Template](#) on our website for more information.

- 44.) Are you requesting a waiver or alteration of any of the other required elements of informed consent? No
 Yes (An IRB may, on occasion, approve a consent process that alters some or all of the required elements of informed consent or waive the requirement for informed consent. The following criteria must be met: 1) the research involves no more than minimal risk, 2) waiver or alteration will not adversely affect the rights and welfare of subjects, 3) the research could not practicably be carried out without waiver or alteration, and 4) when appropriate, the subjects will be provided with additional pertinent information after participation.)

- a.) Provide justification for the waiver.
- b.) Indicate why the proposed research presents no more than minimal risk to participants.
- c.) Explain whether or not a waiver of written informed consent would adversely affect the rights and welfare of participants.
- d.) Explain why it would be impracticable to carry out the research without a waiver or alteration of informed consent.
- e.) How will pertinent information be provided to participants, if appropriate, at a later date?

Part IX: Conflict of Interest

- 45.) Do the researchers conducting this protocol have any potential conflicts of interest? *Conflicts of interest may include financial or personal interest, or any condition in which the investigator's judgment regarding a primary interest may be biased by a secondary interest. Examples include speaking and consultation fees, travel expenses, stock options, royalties, company ownership or equity, etc.)*

- No Yes (If yes, conflict of interest must be disclosed)

**Kent State University Institutional Review Board
Application for Approval to Use Human Research Subjects**

CHECKLIST- THE FOLLOWING MATERIALS MUST BE SUBMITTED WITH THE APPLICATION FOR APPROPRIATE REVIEW (Note: all items may not be necessary for the specific application)

Double click on the box, a window will appear asking if it should be checked or unchecked

CHECK IF NECESSARY:	FORMS SUBMITTED:	APPENDIX LETTER OR NUMBER (IF NOT NECESSARY, MARK "N/A"):
<input checked="" type="checkbox"/>	Completed Application (including signatures)	
<input checked="" type="checkbox"/>	Recruitment script and materials	A, B
<input checked="" type="checkbox"/>	Surveys, questionnaires, interview questions	C, D
<input type="checkbox"/>	Data collection materials	N/A
<input checked="" type="checkbox"/>	<u>Informed Consent Documents</u>	E, F
<input type="checkbox"/>	Audio/Visual Consent Forms	N/A
<input type="checkbox"/>	Assent Statement/Script (for children ≤ 12; will also need parental consent form)	N/A
<input type="checkbox"/>	Debriefing Script	N/A
<input type="checkbox"/>	Approval from other institutions	N/A
<input checked="" type="checkbox"/>	Signed Investigator Assurance	
<input checked="" type="checkbox"/>	Training Verification/CITI certificate	G