Date: 12-10-2018

IRB #: IRB-2018-247
Title: Pop Up and Grow: Designing Interactive Sound Toys That Develop with a Child
Creation Date: 3-26-2018
End Date: 5-13-2019
Status: Approved
Principal Investigator: Kristin Carlson
Review Board: Illinois State University IRB
Sponsor:

Study History

Submission Type Initial	Review Type Expedited	Decision Approved
Submission Type Modification	Review Type Expedited	Decision Approved

Key Study Contacts

Member Kristin Carlson	Role Principal Investigator	Contact kacarl1@IllinoisState.edu
Member Kristin Carlson	Role Primary Contact	Contact kacarl1@IllinoisState.edu
Member Greg Corness	Role Investigator	Contact gcorness@colum.edu

Initial Submission

Submission Routing : Initial Submission : Version 1.14 : 3/8/18

Is this the first time a submission has been sent to ISU's IRB for this study?

- Contact the *Research Ethics and Compliance office* if this study was previously submitted in IRBNet

✓ Yes

No

Collaborative Research

Is this a multi-institutional collaboration?

✓ Yes

No

Is ISU leading this research project?

✓ Yes

Before any research involving other collaborating institutions occur, collaborating researchers should consult with their institutions to determine if there are any additional permissions required from their institutuions. If research will be conducted at that site, site permission must be included in this study.

No

Human Subject Research

Does this study meet the definition of Human Subjects Research?

✓ Yes

No

I am not sure

Review Level Requested

Exempt

******Research with prisoners cannot be exempt******

✓ Expedited or Full

Funding

Will this study be funded?

Select "Yes" if you plan on seeking out external and/or internal (university) funding.

Yes

✓ No

The principal investigator (PI) **must be an ISU faculty or staff member**. The PI **is responsible** for ensuring that the research is conducted in a manner that is consistent with federal regulations, ISU Policy, and any submissions approved by the ISU IRB. There can **only be one** PI.

Principal Investigator

If the name that appears here is not the name of the Pi click on the "x" on the far right and then search for and select the name of the principal investigator.

Important

- *If you are changing the PI and want **to make sure that you will still have access to the form**, use the "F**ind People"** function to list yourself within this section (as the PC) or within the "Research Team" section before you change the PI. Not doing this may cause you to lose access to the submission.*

Name: Kristin Carlson
Organization: Theatre
Address: School of Theatre Campus Box 5700, Normal, IL 61790-5700
Phone: 309-438-8783
Email: kacarl1@IllinoisState.edu

Unable to find the PI's name in the database.

Other Members

Is there anyone else on the research team (besides the PI)?

✓ Yes

No

Questions about the other members will be asked in a new section (Research Team) that will automatically open.

Departmental Requirements

Select the box if it applies.

The PI is faculty within the Department of Psychology

Primary Contact

Search for and select the name of the PI.

- *If not the PI, the primary contact **must** be a research team member listed on this submission and be CITI trained*

Name: Kristin Carlson
Organization: Theatre
Address: School of Theatre Campus Box 5700, Normal, IL 61790-5700
Phone: 309-438-8783
Email: kacarl1@IllinoisState.edu

PI Training

Attach the PI's CITI completion report here.

- Link to CITI's website

- *Click on the link provided (or the "?") for information on what courses are accepted by the IRB*

Completion Report

PI's Additional Experience

Describe any additional experience **the PI** might have that could help protect the welfare of the participants.

I have completed research and ethics training at my PhD institution, Simon Fraser University in Canada, and managed ethics for a large scale research project.

Research Team

For Expedited and Full Board studies:
Anyone who will be consenting participants or who will have access to identifiable data must be listed on the protocol and CITI trained. Prior to filling out this section, review the IRB Training Requirements to determine what training is appropriate for the team member listed.

PIs are responsible for ensuring that each team member is properly trained and that the training is current and documented. Additional requirements apply.

Thesis/Dissertation

Is this study for a thesis or dissertation?

- [ ] Yes
- [x] No

Co-Principal Investigators

A Co-PI is a research team member that plays a key leadership role and makes research design-related decisions.

Are there any research team members that are CO-PIs?

- [x] Yes
- [ ] No

Search for and select the names of any Co-PIs.

If there is more than one co-PI, search for both within the window that opens up when you click on "find people".

- *Once added this person will be able to edit this form*

Name: Greg Corness
Organization: Theatre
Address: School of Theatre Campus Box 5700, Normal, IL 61790-5700
Phone:
Email: gcorness@colum.edu

A co-PI is not affiliated with Illinois State University.

I am unable to find this person.

Access to Form

To give someone the ability to access and edit this study they must be listed in a submission using the "Find People" function.

- Use the "Find People" button below to give access to any research team members **not already selected in the form**.
- Anyone listed here is interpreted as a research team member and must be CITI trained.

I am unable to find this person.

Investigators

Are there any other research team members that were not identified above or within the "Principal Investigator" section?

Yes

✓ No

CITI Training

Attach the CITI Completion Reports for all of the research team members identified above (except the PI).

- Link to CITI's website
- *ISU CITI training requirements*

citiprogram.org/verify/?k5f908875-0c56-4e58-bef9-224c75cd8768-26705392

Additional Training or Experiences

Besides CITI training, have any of the research team members completed any training or have any experiences that could help protect the welfare of the participants?

Yes

✓ No

Purpose

Briefly describe this study in layperson's terms.

- *Include information regarding the research goals or hypotheses examined in this study and describe why this research may be beneficial.*
- *Do not cut and paste from grant proposals, thesis/dissertation proposals, or similar documents.*

This research explores how to design sound for toys that consider a child's developmental experiences including their physical, perceptual, and cognitive changes. In previous studies we have observed how, as the child develops and explores new ways of engaging in their world, they reassess the objects around them, the noise their toys make, and find new way of employing them to engage the world. In this way the sound a toy makes and how it continues to be relevant in the child's expanding world is a large part of their engagement with the toy.

To investigate this, we created a set of prototypes with 5 developmental sound stages from newborn to 4 years old. These prototypes consider a wide variety of factors, such as the physical, kinetic, and sound elements of the design in order to address our developmental milestones. Our research questions fall into two categories:
1. How can children develop new forms of engagement with a single toy over multiple developmental milestones?
2. How can the affordances of the toy shift over time to create new forms of play?

This study will observe and interview how children play with and experience sound in tangible toys. The three toy prototypes have different functions that address different developmental sound stages depending on how you use them, which we hope would promote extended exploration of affordances to different age groups. This research will be beneficial to better understand how children incorporate their developmental experience of sound into their play, which is often overlooked or minimized in current toy design.

Biomedical Procedures

Will this research involve any biomedical procedures?

- These procedures include the taking or withholding of medication, ingestion of any food or other substances, injections, blood drawing, or any other procedure which would normally be done under medical supervision.

Yes

✓ No

Participants

Number of participants

What is the maximum number of participants that you will recruit?

- *A modification request will need to be submitted and approved before more participants are recruited.*

30

Minors

What age will the participants be?

- *Select both if applicable.*

✓ Below the age of 18

✓ 18 or older

Vulnerable Populations

Additional safeguards for vulnerable populations are required by federal regulations.

Prisoners

Will this study aim to recruit prisoners?

Yes

✓ No

Other Vulnerable Populations

Will this study aim to recruit participants from any of the groups below?

- *Select any of the options that apply.*

  Students enrolled in a course that one of the research team members are teaching

  People with an impaired decision making ability

  Other

  - Examples: People with an economic or educational disadvantage, pregnant women, human fetuses, and neonates

Type of Participant

Describe the participants that you will be collecting data from.

- Make sure to describe any characteristics that would make someone ineligible to participate and any characteristics that would make someone eligible to participate
- Example: This study will be seeking ISU college students who are over the age of 18 and live on campus

This study will be seeking children between the ages of 2-7 years as well as their parents who live in the Bloomington/ Normal, IL area. The researcher's own child, age 2.5, will be included in the study.

How will participants be recruited?

Include the following information if applicable:

1. How the potential participants will be reached
2. Where the recruiting will occur
3. Who will be doing the recruiting

*** You should not include information about how informed consent will be obtained here. ***

- *Recruitment is focused on how potential participants will be notified of the study and consent focuses on how permission to be researched is obtained. Information about obtaining consent will be asked for later.*

This study will recruit potential participants through emailing College of Fine Arts faculty that are known to have young children. Kristin Carlson, the PI and a faculty in CFA, will be sending the email and asking faculty if they are interested in participating in the study along with their children. The researcher's own child will be included in the study.

Coercion or undue influence

Describe how you will minimize the potential for coercion or undue influence.

- ***This must be included in the consent form.***
- *It would be helpful to Indicate whether or not the voluntary nature of the study will be emphasized when the potential participant is approached.*

Risks and Discomforts: The risks associated with this research are no greater than those encountered in everyday life, though include perceived coercion to participate from the PIs' colleagues, their children, and her own child. Participants will be ensured that any risk of coercion will be mitigated. Participants will be given multiple reminders that participation for them or their children is voluntary and may end at any time, we will not contact them a second time if they have not responded to the initial invitation, and children will be told regularly that no one will be upset it they do not participant, or if they decide to stop participating at any time.

Will a mass communication be sent out to ISU students, faculty, and/or staff?

Per ISU policy, "Any electronic communication of the same message, in multiple or single distribution, to 100 or more individuals" is considered mass communication.

Yes

✓ No

Is access to the information needed to contact potential participants restricted?

- Examples of restricted information include probation records, private health information, and/or text messsages
- If the participants will identify themselves select "No"

Yes

✓ No

Recruitment Materials

Attach any recruitment scripts and materials (e.g. fliers, emails, posters, etc...) that will be used.
Recruitment.docx

Some or all of these materials cannot be attached.

No recruitment materials will be used.

Compensation

Will compensation (e.g. money, extra credit, food, etc.) be offered to the participants?

Yes

✓ No

Describe the locations where the data collection will occur.

- Provide information about how private the location(s) are.

Data collection will occur at Illinois State University in the old university gallery space. This space will be used to provide ample room to run, play, and explore and will be free from additional traffic on the weekends.

Permission where permission is required*** *** Permission must be documented for all sites

If applicable, attach documentation of permission to access data, recruit, and/or conduct research at any of the locations/organizations.

- *Permission must be from someone with the authority to grant permission*
- *If participants are being recruited from district 87, unit 5, Olympia or an ISU lab school, click here for specific site permission requirements .*

Permission has been obtained for some but not all of the locations where it is required.

Required site permission has not been acquired.

✓ I do not need site permission

International Research

Will any of the research team members travel outside of the US to conduct this research or specifically seek out participants outside of the US?

- Yes
- ✓ No

Study Design and Methodology

Describe what the participants will do in this study and how the study is designed

- *Specific details about how the participants will be recruited and how consent will be obtain should be provided in other questions and do not need to be described here.*

Study Protocol: Children and their parents will be asked to interact with a variety of physical toys in an open, unguided environment in order to play and describe their experience with the toys. The study will take place in a 30 minute session with 10 participants. Participants will be recruited through an open email call and will be given ample opportunity to accept or decline. Participants will be informed of the procedure verbally and through a written document describing the procedure and any risks, including the ability to quit or leave the procedure at any time.

Throughout the session, participants will be observed and interviewed using an open interview procedure. Each session and interview will be videotaped. Tapes will be marked only with the session number and will be kept in a locked cabinet. Transcriptions of the interview will be used for the analysis of the data. The transcriptions will be marked only by the session number. Participants' names will not be used in association with any of the collected data.

Pre-Study Protocol:
0. At the beginning of the session, the researcher will describe the basic structure of the study and the data that will be collected during the study.
1. The parent participant will be given the two consent forms and will receive a verbal description of the consent form's contents.
2. The parent participant will need to agree to and sign the consent form for their own participation, and a second consent form for their child's participation.
3. The study will begin after the child participant has given positive assent.

Study Protocol: The parent and child participants will be asked to explore a variety of toys in an unguided play session. The participants will then be asked to describe their experience of play, and what aspects were fun, not fun, challenging, intriguing, or mysterious.

Methodology: This study will use a mixed-methods approach to data collection. The open play session will be videotaped and used for observation data to explore the types of actions the child and parent participants performed, for how long, and in what order. This data will provide quantitative data that can help guide information from the interviews. Open interviews will also be performed with the participants after their open play session, which will focus on remembering sensory-based cues from play to help them recall moments of interaction. The participants will also be asked questions around what aspects of play were fun, not fun, challenging, intriguing, or mysterious. This data will provide qualitative information to complement the quantitative data.

I am using Qualtrics

Data

Describe the data that will be collected and how you will obtain that data.

- *Include information about identifiers*
- *If online software/systems will be used, please identify the system to be used and describe the system's confidentiality protections.*

Collected data will include consent forms, notes from interviews, and video capture. Parent participants and their children will be aware that their participation will be recorded. Participant data confidentiality will be maintained in digital documents by encoding data numerically before it is stored on a secure laptop.

Instruments

Will any instruments be used in this study?
Examples of instruments include surveys, tests, PROPS, interview items, and vignettes.

✓ Yes

No

Attach the instruments here.

Any instruments that will be used must be attached.
PopUp Interview Questions.docx

This instrument cannot be attached.

Select any of the options below if it applies to this study

✓ Audio recordings will be collected

✓ Video recordings will be collected

Images will be collected

Bio-specimens will be collected (e.g. blood, saliva, stool, etc)

Level of Identifiability

Risk to participants is often based on the identifiability of data.
If multiple types of data will be collected, select the option that is most identifiable

- Example: If there will be some data that is recorded anonymously and other data that will collected in an identifiable manner, select identifiable.

Anonymous

- *Participants cannot be ascertained directly or through identifiers tied to the data.*

Confidential

- *Participants could be identified but this information will not be disclosed*

✓ Identified

- *The data will be collected in a manner that identifies the participants and identifying information will be disclosed (such as presenting a video or an audio clip without blurring the image or scrambling the voice)*

Data Security

Data Storage

Where will the data be stored?

On the PI's personal laptop or a password-protected USB locked in the PI's office.

Will the data be kept separate from any signed consent forms?

✓ Yes

No

Where will the signed consent forms be stored?

In a separate locked cabinet in the PI's office.

Will the data ever be stripped of its identifiers?

✓ Yes

No

Describe when and how the data will be deidentified.

Transcripts of the videos will be deidentified by using numbers to separate participant comments and observations. However, videos may be shown in public conferences where facial features may be seen.

Besides stripping the data of identifiers and storing the data securely, will anything else be done to protect the confidentiality of the participants?

Yes

✓ No

Will any of the data be destroyed?

Destroying the data is not required by the IRB.
****Signed consent forms must be kept three years after the study was closed. [45 CFR 46.117(a) & 45 CFR 46.115(b)]****

Click the "?" icon for additional details.

Yes

✓ No

Dissemination of Data

In what ways will the results of this study be disseminated?

Examples: The results of this research may be presented at public symposiums, published in journals, and placed on ISU's research website.

The results of this research may be presented at public conferences, published in conference proceedings and journals, and placed on ISU's research website. Recordings from the study will be used for analysis by the research team and potentially as media support in a future conference presentation.

Identifiable Information

Will any individually identifiable information, including images/recordings of subjects or direct quotes, be published, shared, or otherwise disseminated?

- ✓ Yes
- No

What individually identifiable information will be shared?

This must be described in the consent form as well.

Video may be shown at conferences and has been included in the consent form.

Recordings (Audio/Visual/Images)

Identifiers

What identifiers will be recorded, e.g., partial facial features, full facial features, subject's name?

In this study full facial features will be recorded, and the subject's name may be captured on video as well. These identifiers will not be used in transcriptions or written documentation of the study.

Purpose

Describe how the recordings will be used.

- *e.g. educational or commercial purposes, analysis by the research team, future unspecified use*

Recordings from the study will be used for analysis by the research team and potentially as media support in a future conference presentation.

Can someone still participate in the study if they do not consent to be recorded?

✓ Yes

No

If the recording is an optional procedure the consent form must include a signature line to indicate that they consent to be recorded which must be separate from the signature line used to indicate the participant's consent to participate.

Risks

What additional risks to the subject may arise from the recording?

Additional risks in this study may be perceived coercion to participate from the PIs' colleagues, their children, and her own child.

Storage

Where will the recordings be stored?

Recordings will be stored in a password protected folder on the PI's laptop.

Access

Include who will have access to the recordings?

- *This information should be in the consent form*

In addition to Dr. Carlson, the PI, one other researcher will have access to the data: Dr. Corness at Columbia College Chicago . Data will be shared in person and will not leave the PI's personal laptop.

Transcribing

Will the recordings be transcribed?

✓ Yes

No

Transcription Process

Describe how the data will be transcribed and who will transcribe the recordings.

- If a company or service, state the name of the company/service and check the box below.

Data will be transcribed by Dr. Carlson and Dr. Corness, and only shared and discussed between them.

This study will use an external service to transcribe the data

Data Removal

Will the recordings be kept indefinitely?

- *The data does not need to be destroyed*

✓ Yes

No

Study Risk

Level of Risk

Is it expected that this study will place the participants at more risk than they would normally encounter in everyday life?

Yes

✓ No

Risks

Describe any foreseeable risks that the participants could potentially be subjected to if they participate in this study.

- Please ensure that any potential physical, psychological, or social risks are listed

******These risks must be indicated in the consent form.******

The risks associated with this research are no greater than those encountered in everyday life, though include perceived coercion to participate from the PIs' colleagues, their children, and her own child.

Risk Mitigation

Describe how any of the risks indicated above will be minimized.

- If nothing will be done, please describe why.

*****This must also be indicated in the consent form.*****

Participants will be ensured that any risk of coercion will be mitigated. Participants will be given multiple

reminders that participation for them or their children is voluntary and may end at any time, we will not contact them a second time if they have not responded to the initial invitation, and children will be told regularly that no one will be upset it they do not participant, or if they decide to stop participating at any time.

Resources

Will any resources be provided if the participant experiences any of the expected risks?

Yes

✓ No

Deception

Will this study include any deception?

Yes

✓ No

Direct Benefit

Will there be any direct benefit to the participant?

- *Compensation is not considered a direct benefit*

✓ Yes

No

Describe how this study will benefit the participant directly.

We hope the participant will be interested in exploring the affordances of toys in new ways that might extend to their normal play at home.

Minors

Children are considered a protected population because of their inability to provide legal consent. Instead, the typical process involves permission from the parent or guardian and assent from the child.

Protection of Minors Committee

This research activity must be registered with the Protection of Minors Committee if minors are included.

- *Link to the registration page.*

Necessity

Why is it necessary to engage children in this research?

The research is about exploring the design of sound in toys for young children (0-7 years old) in interaction with their parents. It is not possible to evaluate this experience of play with only older children or adults, however we will include the interactions between both children and their parents in our data. The researcher's own child will be included in the research.

Research in Schools

Will this research occur while the students are in school?

Yes

✓ No

Consent

Click here to view the Research Ethics and Compliance Office's tips on how to write a consent form.

Consent Waivers

Select any of the options below that apply to your study.

- *In some studies, multiple waivers may be requested*

✓ I am seeking consent without requesting any waivers

Waiver of documentation of consent

- *A request to not obtain a signed consent form*

Alteration of consent

- *A request to include some but not all of the required consent content*

Waiver of informed consent

- *A request to not obtain consent*

Consent Procedures

Describe the procedure that will be used to obtain consent.

Parents will be given a consent form for their own participation, and a second form for the participation of their child. Children will be asked to give assent as verbal or non-verbal and will be reminded throughout the session that they may stop participating at any time. Parents will also be reminded that they can stop participating or stop their child participating at any time.

Who will be obtaining consent from participants?

The parent.

Consent Form

Attach the consent form that will be used.

Link to tips on informed consent
PopUp Consent Form Parents.docx
PopUp Permission Form Child.docx

Consent Content Checklist

This checklist is an easy way to help researchers check to see whether or not they have included all of the required consent content in their study.

*** Your responses on this checklist will not be reviewed by the IRB and you do not need to fill out this checklist***

Click here if you would like to review/use the consent form checklist

Click here to view the Research Ethics and Compliance Office's tips on how to write a consent form.

Assent

Assent is the equivalent of consent for minors or those unable to provide consent on their own behalf

Assent Waivers

Select any of the options below that apply to your study.

- *In some studies, multiple waivers may be requested*

✓ I am seeking the participant's assent without requesting any waivers

Waiver of documentation of assent

A request to not obtain a signed assent form

Alteration of informed Assent

A request to include some but not all of the required consent content

Waiver of informed assent

A request to not obtain assent

Select the age group that will be researched.

Select both if your study includes minors from both groups

- ✓ Children below the age of 8 can participate
- Children 8 and above can participate

Children under 8 years of age,

What non-verbal cues will you watch for to indicate the child is ready to end or pause participation?

We will watch for non-verbal cues such as children avoiding eye contact or interaction with the toy or researcher, a disinterest in the toy, making themselves small, enclosing their arms, or turning away from the toy and or researcher. Participation may pause or completed end at this time.

How will minor assent be obtained?

We will ask the minor if they are interested in playing with a new toy. They may affirm their assent through a gesture, action, expression, or verbal confirmation that includes reaching for the toy, looking at the toy, or stating they are interested.

Assent Script (Below 8 years)

Attach a copy of the assent script for children under 8 years.
Minor Assent Script.docx

Parental Permission

The obtainment of parental permission is required if a minor is being researched. Permission from an alternative legally authorized representative can be sought if a parent is unavailable

Permission Waivers

Select any of the options below that apply to your study.

- *In some studies, multiple waivers may be requested*

✓ I am seeking parental permission without requesting any waivers

Waiver of documentation of permission

A request to not obtain a signed permission form

Alteration of permission

A request to include some but not all of the required consent content

Waiver of informed permission

A request to not obtain permission

How will parental permission be obtained?

Parental permission will be obtained through written consent form. The researcher will provide a consent form for their own child, who will be included in the research, as well.

Parental Permission form

Attach the permission form that will be used

Link to tips on informed consent
PopUp Consent Form Child.docx

Assent/Permission Content Checklist

This checklist is an easy way to help researchers check to see whether or not they have included all of the required consent content in their study.

*** Your responses on this checklist will not be reviewed by the IRB and you do not need to fill out this checklist***

Click here if you would like to review/use the checklist

Description

While this template is designed to ensure that only the required information is asked for, there may be unanticipated study designs or situations where additional information may help the IRB conduct their review. This section is here in case there is a need to attach any additional documents or provide any additional information that may help the IRB conduct their review.

You may also use this section as a spot to store additional research-relevant documents. Just keep in mind that anything in this section will be reviewed by the IRB.

***** It is reccomended that you wait to fill out this section until all the other items have been addressed*****

Additional Documents

Attach any additional non-required documents here.

Additional Comments

Provide any additional information here.

Attachments

This section is here to show what attachments have been attached to the study within a single section. If preferred, required attachments can be attached to this section.

PI Training

Completion Report

Research Team Training

citiprogram.org/verify/?k5f908875-0c56-4e58-bef9-224c75cd8768-26705392

Consent Form

PopUp Consent Form Parents.docx
PopUp Permission Form Child.docx

Parental Permission Form

PopUp Consent Form Child.docx

Assent Script

Minor Assent Script.docx

Recruitment materials

Recruitment.docx

Instruments

Surveys, Interviews items, questionnaires, etc
PopUp Interview Questions.docx

Site Permission

Modification Submission

Modification Request(s)

Version 1.05: 5/7/18

Information on this Form

This system automatically uploads what you put into the initial submission document (you should see the sections below). To fill out this form you are not required to change anything within those sections (except if you are changing the PI or if your modification moves the study up to expedited or full). Instead, based upon what you indicate in this section below, a new section will open up for each change. These new sections should not have a check mark indicating that they are complete.

Please contact the REC office if you have any questions.

Level of Review

What level was this study reviewed at?

- *Click on the "?" icon for tips on how to identify the review level.*

Exempt

✓ *Expedited*

Full Board

Type of Modification

Select the modification that will be requested.

- *Multiple requests may be made.*

Change in PI

Give a research team member the ability to edit/access this submission in CayuseIRB
If this is a new research team member, check the "Add a research team member" box below

Add a research team member

Remove research team members

Change in Instruments

Adjust the recruitment procedure.

✓
- or recruit a new group of participants

Include a new research location

✓
- or submit site permission from a location listed already

Increase the number of participants

Change a research procedure

✓ Modify the consent, assent or parent permission forms

Change in funding

Other

Risk

Describe how these changes will influence the risks that the participants may be subjected to.

- Indicate that "No change in risk is expected" if the changes will not add or remove risk.
- Include any information about what will be done to minimize any new risks

No change in risk is expected.

Details on Change

Describe how the recruitment will change.

This study will also recruit potential participants through Cadence Academy Preschool. Parents will be informed through school's email communication system to ask if children and their teachers may partake in this study. I have spoken briefly to the Director of the school, Kadi Juris.

Reason for Change

Why is the modification to the recruitment procedure necessary?

This modification is necessary in order to recruit additional participants.

New Recruitment Materials

Attach any new or revised recruitment materials here

- If revised, highlight any changes that were made

Recruitment.docx

Research Location

New Location Name

List the new sites below

Cadence Academy Preschool on Main Street

New Site Permission

Attach site permission. here

- Can be email correspondence

Gmail - Potential Sound Toy Study.pdf

Justification

Justify the addition of the new site(s).

This site will enable us to study children's play with their parents/ teachers in a comfortable environment.

Consent

Description

Describe what changes to the consent process you are proposing.

I will include teachers as well as parents in the consent form, in order to expand the adult options in play.

Reason

Describe the reason for the change(s).

This change is to broaden the options for adult/ child engagement with toys in the school context.

Waiver

Is a waiver of informed consent being requested?

- Yes
- ✓ No

New forms

Attach the revised consent forms.

- Highlight any changes

PopUp Consent Form Parents.docx

Is this the first time a submission has been sent to ISU's IRB for this study?

- Contact the *Research Ethics and Compliance office* if this study was previously submitted in IRBNet

✓ Yes

No

Collaborative Research

Is this a multi-institutional collaboration?

✓ Yes

No

Is ISU leading this research project?

✓ Yes

Before any research involving other collaborating institutions occur, collaborating researchers should consult with their institutions to determine if there are any additional permissions required from their institutuions. If research will be conducted at that site, site permission must be included in this study.

No

Human Subject Research

Does this study meet the definition of Human Subjects Research?

- ✓ Yes
- No
- I am not sure

Review Level Requested

Exempt

******Research with prisoners cannot be exempt******

- ✓ Expedited or Full

Funding

Will this study be funded?

Select "Yes" if you plan on seeking out external and/or internal (university) funding.

- Yes
- ✓ No

The principal investigator (PI) **must be an ISU faculty or staff member**. The PI **is responsible** for ensuring that the research is conducted in a manner that is consistent with federal regulations, ISU Policy, and any submissions approved by the ISU IRB. There can **only be one** PI.

Principal Investigator

If the name that appears here is not the name of the Pi click on the "x" on the far right and then search for and select the name of the principal investigator.

Important

- *If you are changing the PI and want **to make sure that you will still have access to the form**, use the "F**ind People"** function to list yourself within this section (as the PC) or within the "Research Team" section before you change the PI. Not doing this may cause you to lose access to the submission.*

Name: Kristin Carlson
Organization: Theatre
Address: School of Theatre Campus Box 5700, Normal, IL 61790-5700
Phone: 309-438-8783
Email: kacarl1@IllinoisState.edu

Unable to find the PI's name in the database.

Other Members

Is there anyone else on the research team (besides the PI)?

✓ Yes

No

Questions about the other members will be asked in a new section (Research Team) that will automatically open.

Departmental Requirements

Select the box if it applies.

The PI is faculty within the Department of Psychology

Primary Contact

Search for and select the name of the PI.

- *If not the PI, the primary contact **must** be a research team member listed on this submission and be CITI trained*

Name: Kristin Carlson
Organization: Theatre
Address: School of Theatre Campus Box 5700, Normal, IL 61790-5700
Phone: 309-438-8783
Email: kacarl1@IllinoisState.edu

PI Training

Attach the PI's CITI completion report here.

- Link to CITI's website

- *Click on the link provided (or the "?") for information on what courses are accepted by the IRB*

Completion Report

PI's Additional Experience

Describe any additional experience **the PI** might have that could help protect the welfare of the participants.

I have completed research and ethics training at my PhD institution, Simon Fraser University in Canada, and managed ethics for a large scale research project.

Research Team

For Expedited and Full Board studies:
Anyone who will be consenting participants or who will have access to identifiable data must be listed on the protocol and CITI trained. Prior to filling out this section, review the IRB Training Requirements to determine what training is appropriate for the team member listed.

PIs are responsible for ensuring that each team member is properly trained and that the training is current and documented. Additional requirements apply.

Thesis/Dissertation

Is this study for a thesis or dissertation?

- [ ] Yes
- [x] No

Co-Principal Investigators

A Co-PI is a research team member that plays a key leadership role and makes research design-related decisions.

Are there any research team members that are CO-PIs?

- [x] Yes
- [ ] No

Search for and select the names of any Co-PIs.

If there is more than one co-PI, search for both within the window that opens up when you click on "find people".

- *Once added this person will be able to edit this form*

Name: Greg Corness
Organization: Theatre
Address: School of Theatre Campus Box 5700, Normal, IL 61790-5700
Phone:
Email: gcorness@colum.edu

A co-PI is not affiliated with Illinois State University.

I am unable to find this person.

Access to Form

To give someone the ability to access and edit this study they must be listed in a submission using the "Find People" function.

- Use the "Find People" button below to give access to any research team members **not already selected in the form**.
- Anyone listed here is interpreted as a research team member and must be CITI trained.

I am unable to find this person.

Investigators

Are there any other research team members that were not identified above or within the "Principal Investigator" section?

Yes

✓ No

CITI Training

Attach the CITI Completion Reports for all of the research team members identified above (except the PI).

- Link to CITI's website
- *ISU CITI training requirements*

citiprogram.org/verify/?k5f908875-0c56-4e58-bef9-224c75cd8768-26705392

Additional Training or Experiences

Besides CITI training, have any of the research team members completed any training or have any experiences that could help protect the welfare of the participants?

Yes

✓ No

Purpose

Briefly describe this study in layperson's terms.

- *Include information regarding the research goals or hypotheses examined in this study and describe why this research may be beneficial.*
- *Do not cut and paste from grant proposals, thesis/dissertation proposals, or similar documents.*

This research explores how to design sound for toys that consider a child's developmental experiences including their physical, perceptual, and cognitive changes. In previous studies we have observed how, as the child develops and explores new ways of engaging in their world, they reassess the objects around them, the noise their toys make, and find new way of employing them to engage the world. In this way the sound a toy makes and how it continues to be relevant in the child's expanding world is a large part of their engagement with the toy.

To investigate this, we created a set of prototypes with 5 developmental sound stages from newborn to 4 years old. These prototypes consider a wide variety of factors, such as the physical, kinetic, and sound elements of the design in order to address our developmental milestones. Our research questions fall into two categories:
1. How can children develop new forms of engagement with a single toy over multiple developmental milestones?
2. How can the affordances of the toy shift over time to create new forms of play?

This study will observe and interview how children play with and experience sound in tangible toys. The three toy prototypes have different functions that address different developmental sound stages depending on how you use them, which we hope would promote extended exploration of affordances to different age groups. This research will be beneficial to better understand how children incorporate their developmental experience of sound into their play, which is often overlooked or minimized in current toy design.

Biomedical Procedures

Will this research involve any biomedical procedures?

- These procedures include the taking or withholding of medication, ingestion of any food or other substances, injections, blood drawing, or any other procedure which would normally be done under medical supervision.

Yes

✓ No

Participants

Number of participants

What is the maximum number of participants that you will recruit?

- *A modification request will need to be submitted and approved before more participants are recruited.*

30

Minors

What age will the participants be?

- *Select both if applicable.*

✓ Below the age of 18

✓ 18 or older

Vulnerable Populations

Additional safeguards for vulnerable populations are required by federal regulations.

Prisoners

Will this study aim to recruit prisoners?

Yes

✓ No

Other Vulnerable Populations

Will this study aim to recruit participants from any of the groups below?

- *Select any of the options that apply.*

  Students enrolled in a course that one of the research team members are teaching

  People with an impaired decision making ability

  Other

  - Examples: People with an economic or educational disadvantage, pregnant women, human fetuses, and neonates

Type of Participant

Describe the participants that you will be collecting data from.

- Make sure to describe any characteristics that would make someone ineligible to participate and any characteristics that would make someone eligible to participate
- Example: This study will be seeking ISU college students who are over the age of 18 and live on campus

This study will be seeking children between the ages of 2-7 years as well as their parents who live in the Bloomington/ Normal, IL area. The researcher's own child, age 2.5, will be included in the study.

How will participants be recruited?

Include the following information if applicable:

1. How the potential participants will be reached
2. Where the recruiting will occur
3. Who will be doing the recruiting

*** You should not include information about how informed consent will be obtained here. ***

- *Recruitment is focused on how potential participants will be notified of the study and consent focuses on how permission to be researched is obtained. Information about obtaining consent will be asked for later.*

This study will recruit potential participants through emailing College of Fine Arts faculty that are known to have young children. Kristin Carlson, the PI and a faculty in CFA, will be sending the email and asking faculty if they are interested in participating in the study along with their children. The researcher's own child will be included in the study.

Coercion or undue influence

Describe how you will minimize the potential for coercion or undue influence.

- ***This must be included in the consent form.***
- *It would be helpful to Indicate whether or not the voluntary nature of the study will be emphasized when the potential participant is approached.*

Risks and Discomforts: The risks associated with this research are no greater than those encountered in everyday life, though include perceived coercion to participate from the PIs' colleagues, their children, and her own child. Participants will be ensured that any risk of coercion will be mitigated. Participants will be given multiple reminders that participation for them or their children is voluntary and may end at any time, we will not contact them a second time if they have not responded to the initial invitation, and children will be told regularly that no one will be upset it they do not participant, or if they decide to stop participating at any time.

Will a mass communication be sent out to ISU students, faculty, and/or staff?

Per ISU policy, "Any electronic communication of the same message, in multiple or single distribution, to 100 or more individuals" is considered mass communication.

Yes

✓ No

Is access to the information needed to contact potential participants restricted?

- Examples of restricted information include probation records, private health information, and/or text messsages
- If the participants will identify themselves select "No"

Yes

✓ No

Recruitment Materials

Attach any recruitment scripts and materials (e.g. fliers, emails, posters, etc...) that will be used.
Recruitment (1).docx

Some or all of these materials cannot be attached.

No recruitment materials will be used.

Compensation

Will compensation (e.g. money, extra credit, food, etc.) be offered to the participants?

Yes

✓ No

Describe the locations where the data collection will occur.

- Provide information about how private the location(s) are.

Data collection will occur at Illinois State University in the old university gallery space. The gallery space will be used to provide ample room to run, play, and explore and will be free from additional traffic on the weekends.

Permission where permission is required***

*** Permission must be documented for all sites

If applicable, attach documentation of permission to access data, recruit, and/or conduct research at any of the locations/organizations.

- *Permission must be from someone with the authority to grant permission*
- *If participants are being recruited from district 87, unit 5, Olympia or an ISU lab school, click here for specific site permission requirements .*

Permission has been obtained for some but not all of the locations where it is required.

Required site permission has not been acquired.

✓ I do not need site permission

International Research

Will any of the research team members travel outside of the US to conduct this research or specifically seek out participants outside of the US?

- Yes
- ✓ No

Study Design and Methodology

Describe what the participants will do in this study and how the study is designed

- *Specific details about how the participants will be recruited and how consent will be obtain should be provided in other questions and do not need to be described here.*

Study Protocol: Children and their parents will be asked to interact with a variety of physical toys in an open, unguided environment in order to play and describe their experience with the toys. The study will take place in a 30 minute session with 10 participants. Participants will be recruited through an open email call and will be given ample opportunity to accept or decline. Participants will be informed of the procedure verbally and through a written document describing the procedure and any risks, including the ability to quit or leave the procedure at any time.

Throughout the session, participants will be observed and interviewed using an open interview procedure. Each session and interview will be videotaped. Tapes will be marked only with the session number and will be kept in a locked cabinet. Transcriptions of the interview will be used for the analysis of the data. The transcriptions will be marked only by the session number. Participants' names will not be used in association with any of the collected data.

Pre-Study Protocol:
0. At the beginning of the session, the researcher will describe the basic structure of the study and the data that will be collected during the study.
1. The parent/teacher participant will be given the two consent forms and will receive a verbal description of the consent form's contents.
2. The parent/ teacher participant will need to agree to and sign the consent form for their own participation, and a second consent form for their child's participation.
3. The study will begin after the child participant has given positive assent.

Study Protocol: The parent/ teacher and child participants will be asked to explore a variety of toys in an unguided play session. The participants will then be asked to describe their experience of play, and what aspects were fun, not fun, challenging, intriguing, or mysterious.

Methodology: This study will use a mixed-methods approach to data collection. The open play session will be videotaped and used for observation data to explore the types of actions the child and parent participants performed, for how long, and in what order. This data will provide quantitative data that can help guide information from the interviews. Open interviews will also be performed with the participants after their open play session, which will focus on remembering sensory-based cues from play to help them recall moments of interaction. The participants will also be asked questions around what aspects of play were fun, not fun, challenging, intriguing, or mysterious. This data will provide qualitative information to complement the quantitative data.

I am using Qualtrics

Data

Describe the data that will be collected and how you will obtain that data.

- *Include information about identifiers*
- *If online software/systems will be used, please identify the system to be used and describe the system's confidentiality protections.*

Collected data will include consent forms, notes from interviews, and video capture. Parent participants and their children will be aware that their participation will be recorded. Participant data confidentiality will be maintained in digital documents by encoding data numerically before it is stored on a secure laptop.

Instruments

Will any instruments be used in this study?
Examples of instruments include surveys, tests, PROPS, interview items, and vignettes.

✓ Yes

No

Attach the instruments here.

Any instruments that will be used must be attached.
PopUp Interview Questions.docx

This instrument cannot be attached.

Select any of the options below if it applies to this study

✓ Audio recordings will be collected

✓ Video recordings will be collected

Images will be collected

Bio-specimens will be collected (e.g. blood, saliva, stool, etc)

Level of Identifiability

Risk to participants is often based on the identifiability of data.
If multiple types of data will be collected, select the option that is most identifiable

- Example: If there will be some data that is recorded anonymously and other data that will collected in an identifiable manner, select identifiable.

Anonymous

- *Participants cannot be ascertained directly or through identifiers tied to the data.*

Confidential

- *Participants could be identified but this information will not be disclosed*

✓ Identified

- *The data will be collected in a manner that identifies the participants and identifying information will be disclosed (such as presenting a video or an audio clip without blurring the image or scrambling the voice)*

Data Security

Data Storage

Where will the data be stored?

On the PI's personal laptop or a password-protected USB locked in the PI's office.

Will the data be kept separate from any signed consent forms?

✓ Yes

No

Where will the signed consent forms be stored?

In a separate locked cabinet in the PI's office.

Will the data ever be stripped of its identifiers?

✓ Yes

No

Describe when and how the data will be deidentified.

Transcripts of the videos will be deidentified by using numbers to separate participant comments and observations. However, videos may be shown in public conferences where facial features may be seen.

Besides stripping the data of identifiers and storing the data securely, will anything else be done to protect the confidentiality of the participants?

Yes

✓ No

Will any of the data be destroyed?

Destroying the data is not required by the IRB.
****Signed consent forms must be kept three years after the study was closed. [45 CFR 46.117(a) & 45 CFR 46.115(b)]****

Click the "?" icon for additional details.

Yes

✓ No

Dissemination of Data

In what ways will the results of this study be disseminated?

Examples: The results of this research may be presented at public symposiums, published in journals, and placed on ISU's research website.

The results of this research may be presented at public conferences, published in conference proceedings and journals, and placed on ISU's research website. Recordings from the study will be used for analysis by the research team and potentially as media support in a future conference presentation.

Identifiable Information

Will any individually identifiable information, including images/recordings of subjects or direct quotes, be published, shared, or otherwise disseminated?

- ✓ Yes
- No

What individually identifiable information will be shared?

This must be described in the consent form as well.

Video may be shown at conferences and has been included in the consent form.

Recordings (Audio/Visual/Images)

Identifiers

What identifiers will be recorded, e.g., partial facial features, full facial features, subject's name?

In this study full facial features will be recorded, and the subject's name may be captured on video as well. These identifiers will not be used in transcriptions or written documentation of the study.

Purpose

Describe how the recordings will be used.

- *e.g. educational or commercial purposes, analysis by the research team, future unspecified use*

Recordings from the study will be used for analysis by the research team and potentially as media support in a future conference presentation.

Can someone still participate in the study if they do not consent to be recorded?

✓ Yes

No

If the recording is an optional procedure the consent form must include a signature line to indicate that they consent to be recorded which must be separate from the signature line used to indicate the participant's consent to participate.

Risks

What additional risks to the subject may arise from the recording?

Additional risks in this study may be perceived coercion to participate from the PIs' colleagues, their children, and her own child.

Storage

Where will the recordings be stored?

Recordings will be stored in a password protected folder on the PI's laptop.

Access

Include who will have access to the recordings?

- *This information should be in the consent form*

In addition to Dr. Carlson, the PI, one other researcher will have access to the data: Dr. Corness at Columbia College Chicago . Data will be shared in person and will not leave the PI's personal laptop.

Transcribing

Will the recordings be transcribed?

✓ Yes

No

Transcription Process

Describe how the data will be transcribed and who will transcribe the recordings.

- If a company or service, state the name of the company/service and check the box below.

Data will be transcribed by Dr. Carlson and Dr. Corness, and only shared and discussed between them.

This study will use an external service to transcribe the data

Data Removal

Will the recordings be kept indefinitely?

- *The data does not need to be destroyed*

✓ Yes

No

Study Risk

Level of Risk

Is it expected that this study will place the participants at more risk than they would normally encounter in everyday life?

Yes

✓ No

Risks

Describe any foreseeable risks that the participants could potentially be subjected to if they participate in this study.

- Please ensure that any potential physical, psychological, or social risks are listed

******These risks must be indicated in the consent form.******

The risks associated with this research are no greater than those encountered in everyday life, though include perceived coercion to participate from the PIs' colleagues, their children, and her own child.

Risk Mitigation

Describe how any of the risks indicated above will be minimized.

- If nothing will be done, please describe why.

*****This must also be indicated in the consent form.*****

Participants will be ensured that any risk of coercion will be mitigated. Participants will be given multiple

reminders that participation for them or their children is voluntary and may end at any time, we will not contact them a second time if they have not responded to the initial invitation, and children will be told regularly that no one will be upset it they do not participant, or if they decide to stop participating at any time.

Resources

Will any resources be provided if the participant experiences any of the expected risks?

Yes

✓ No

Deception

Will this study include any deception?

Yes

✓ No

Direct Benefit

Will there be any direct benefit to the participant?

- *Compensation is not considered a direct benefit*

✓ Yes

No

Describe how this study will benefit the participant directly.

We hope the participant will be interested in exploring the affordances of toys in new ways that might extend to their normal play at home.

Minors

Children are considered a protected population because of their inability to provide legal consent. Instead, the typical process involves permission from the parent or guardian and assent from the child.

Protection of Minors Committee

This research activity must be registered with the Protection of Minors Committee if minors are included.

- *Link to the registration page.*

Necessity

Why is it necessary to engage children in this research?

The research is about exploring the design of sound in toys for young children (0-7 years old) in interaction with their parent/ teachers. It is not possible to evaluate this experience of play with only older children or adults, however we will include the interactions between both children and their parents in our data. The researcher's own child will be included in the research.

Research in Schools

Will this research occur while the students are in school?

Yes

✓ No

Consent

Click here to view the Research Ethics and Compliance Office's tips on how to write a consent form.

Consent Waivers

Select any of the options below that apply to your study.

- *In some studies, multiple waivers may be requested*

✓ I am seeking consent without requesting any waivers

Waiver of documentation of consent

- *A request to not obtain a signed consent form*

Alteration of consent

- *A request to include some but not all of the required consent content*

Waiver of informed consent

- *A request to not obtain consent*

Consent Procedures

Describe the procedure that will be used to obtain consent.

Parents will be given a consent form for their own participation, and a second form for the participation of their child. Children will be asked to give assent as verbal or non-verbal and will be reminded throughout the session that they may stop participating at any time. Parents will also be reminded that they can stop participating or stop their child participating at any time.

Who will be obtaining consent from participants?

The parent.

Consent Form

Attach the consent form that will be used.

Link to tips on informed consent
PopUp Consent Form Parents.docx
PopUp Permission Form Child.docx

Consent Content Checklist

This checklist is an easy way to help researchers check to see whether or not they have included all of the required consent content in their study.

*** Your responses on this checklist will not be reviewed by the IRB and you do not need to fill out this checklist***

Click here if you would like to review/use the consent form checklist

Click here to view the Research Ethics and Compliance Office's tips on how to write a consent form.

Assent

Assent is the equivalent of consent for minors or those unable to provide consent on their own behalf

Assent Waivers

Select any of the options below that apply to your study.

- *In some studies, multiple waivers may be requested*

✓ I am seeking the participant's assent without requesting any waivers

Waiver of documentation of assent

A request to not obtain a signed assent form

Alteration of informed Assent

A request to include some but not all of the required consent content

Waiver of informed assent

A request to not obtain assent

Select the age group that will be researched.

Select both if your study includes minors from both groups

- ✓ Children below the age of 8 can participate
- Children 8 and above can participate

Children under 8 years of age,

What non-verbal cues will you watch for to indicate the child is ready to end or pause participation?

We will watch for non-verbal cues such as children avoiding eye contact or interaction with the toy or researcher, a disinterest in the toy, making themselves small, enclosing their arms, or turning away from the toy and or researcher. Participation may pause or completed end at this time.

How will minor assent be obtained?

We will ask the minor if they are interested in playing with a new toy. They may affirm their assent through a gesture, action, expression, or verbal confirmation that includes reaching for the toy, looking at the toy, or stating they are interested.

Assent Script (Below 8 years)

Attach a copy of the assent script for children under 8 years.
Minor Assent Script.docx

Parental Permission

The obtainment of parental permission is required if a minor is being researched. Permission from an alternative legally authorized representative can be sought if a parent is unavailable

Permission Waivers

Select any of the options below that apply to your study.

- *In some studies, multiple waivers may be requested*

✓ I am seeking parental permission without requesting any waivers

Waiver of documentation of permission

A request to not obtain a signed permission form

Alteration of permission

A request to include some but not all of the required consent content

Waiver of informed permission

A request to not obtain permission

How will parental permission be obtained?

Parental permission will be obtained through written consent form. The researcher will provide a consent form for their own child, who will be included in the research, as well.

Parental Permission form

Attach the permission form that will be used

Link to tips on informed consent
PopUp Consent Form Child.docx

Assent/Permission Content Checklist

This checklist is an easy way to help researchers check to see whether or not they have included all of the required consent content in their study.

*** Your responses on this checklist will not be reviewed by the IRB and you do not need to fill out this checklist***

Click here if you would like to review/use the checklist

Description

While this template is designed to ensure that only the required information is asked for, there may be unanticipated study designs or situations where additional information may help the IRB conduct their review. This section is here in case there is a need to attach any additional documents or provide any additional information that may help the IRB conduct their review.

You may also use this section as a spot to store additional research-relevant documents. Just keep in mind that anything in this section will be reviewed by the IRB.

***** It is reccomended that you wait to fill out this section until all the other items have been addressed*****

Additional Documents

Attach any additional non-required documents here.

Additional Comments

Provide any additional information here.

Attachments

This section is here to show what attachments have been attached to the study within a single section. If preferred, required attachments can be attached to this section.

PI Training

Completion Report

Research Team Training

citiprogram.org/verify/?k5f908875-0c56-4e58-bef9-224c75cd8768-26705392

Consent Form

PopUp Consent Form Parents.docx
PopUp Permission Form Child.docx

Parental Permission Form

PopUp Consent Form Child.docx

Assent Script

Minor Assent Script.docx

Recruitment materials

Recruitment (1).docx

Instruments

Surveys, Interviews items, questionnaires, etc
PopUp Interview Questions.docx

Site Permission