| CREA COMMUNITY OF RESEARCH ON EXCELLENCE FOR ALL | **Research Protocol –** for use by CREA researchers |
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## RESEARCHER INFORMATION

| | |
|---|---|
| Name of the principal investigator | |
| Name of the researcher sending this form | |

## STUDY INFORMATION

| | |
|---|---|
| Study Title | |

## 1. FUNDING INFORMATION

**1.1 Is your study funded?**

☐Yes
☐No

If "yes", please indicate the name of the research Project and of the funding agency:

## 2. RESEARCH COLLABORATIONS AND LOCATIONS

### LOCATIONS

**2.1 Where will this study take place?**

☐University
☐Schools
☐Hospitals, clinical units and other health sites
☐Other context (specify below)
☐Internationally (please, specify the country/countries below)

**2.2 Thinking about the locations where this study will take place, are there any permissions that must be obtained from cooperating institutions, community leaders, government officials?** ***This may include a review by a local ethics board, school district, Ministry of Health, or other institutional approval process, whether domestic or international. A statement that formal review is not required along with your source of information that the proposed research is in accordance with local laws, regulations, and customs is also acceptable.***

☐Yes ***(see below)***
☐No

*If "Yes" describe and if available, upload it.*

## COLLABORATIONS/SITES

**2.3 Will you be collaborating with any researchers not affiliated with CREA to carry out this study?**

☐Yes
☐No ***(skip to next section)***

**2.4 Will the actions of these collaborators include any of the following: Have contact with human subjects; Have access to data that is identifiable; OR Are responsible for the design, conduct, or reporting of the research?**

☐Yes
☐No ***(skip to next section)***

**2.5 Will these collaborators receive their own ethics review?**

☐Yes, all will receive their own IRB review (skip to next section)
☐No, none will receive their own IRB review
☐Some will receive their own IRB review and some will not

## 3. RESEARCH PURPOSE

**3.1 Provide the research questions that you hope to answer.**

**3.2. Describe the importance of this research in adding to existing knowledge.**

## 4. STUDY PROCEDURES

**4.1. Provide a brief overview of the study:**

- **Describe the procedures participants will be asked to complete or undergo.**
- **Include how long the procedures will take, and where.**

## 5. RISK AND BENEFIT ASSESSMENT

**5.1. Describe the foreseeable risks associated with your study. Please include discussion of any physical risks and non-physical risks, such as economic, psychological, social, and legal harms.**

**5.2. Describe the steps that you will take to minimize risks to your participants (for example, using pseudonyms or a coding system, etc.)**

**5.3. If applicable, what steps will you take if a participant becomes distressed during your study?**

**5.4. Describe any potential direct benefits to participants in the study and to society**

## 6. CHARACTERISTICS OF THE STUDY POPULATION

**6.1. Indicate the estimated number of participants, by subgroup if applicable.**

**6.2. Describe the criteria for enrollment –Please also describe any criteria that will exclude people from enrollment.**

**6.3. Are there any potential vulnerable populations or individuals proposed for involvement in the research? (check all that apply)**

- ☐Children
- ☐Prisoners/Detainees
- ☐Adults not Competent to Consent
- ☐Non-Spanish or none other regional language Speaking

☐Undergraduate Students (as a focus of the study)
☐Disabled
☐ Cultural and ethnic minorities
☐ Other – ***(see below):***

*If "Other" please specify:*

### *CHILDREN*

**6.4. What is the age range of children participating in your study?**

**6.5. Are there any special considerations that need to be taken into account? For example, do the children have a learning disability?**

## 7. INFORMED CONSENT PROCESS

### ADULT PARTICIPANTS

**7.1. Will you be obtaining informed consent or an agreement to participate (for Exempt studies) from participants that take part in your study?**

☐ Yes, I will be obtaining informed consent or an agreement to participate.
☐ No, I will not be obtaining consent or an agreement to participate **(skip to next section after answering below)**

**7.2. Where will the consent or an agreement to participate process take place?**

☐In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

***If other, please describe:***

***7.3.*** **Who will obtain consent or an agreement to participate from participants*?***

**7.4. Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.**

*Please attach the information sheet and the consent form to this protocol

## CHILDREN PARTICIPANTS

**7.5. Will you be obtaining assent or an agreement to participate (for Exempt studies) from child participants that take part in your study?**

☐ Yes, I will be obtaining assent or an agreement to participate.
☐ No, I will not be obtaining assent or an agreement to participate ***(skip to next section after answering below)***

**7.6. Will the assenting or an agreement to participate process involve obtaining a signature?**

☐ Yes
☐ No ***(see below)***

**7.7. Where will the assent or an agreement to participate process take place?**

☐In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

*If other, please describe:*

***7.8.*** **Who will obtain assent or an agreement to participate from child participants?**

**7.9. Describe the process that will be used to obtain assent or an agreement to participate from children.**

**7.10. Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.**

*Please attach the information sheet and the assent form to this protocol

## PARENT PERMISSION

**7.11. Will you be obtaining parent permission or an agreement to participate (for Exempt studies) from parents whose child takes part in your study?**

☐ Yes, I will be obtaining parent permission or an agreement to participate.
☐ No, I will not be obtaining parent permission or an agreement to participate

**7.12. Will the parent permission or an agreement to participate process involve obtaining a signature?**

☐ Yes
☐ No (see below)

*If a signature is not obtained, explain why:*

**7.13. Where will the parent permission or an agreement to participate process take place?**

☐In-person
☐Online
☐Over the telephone
☐Other ***(see below)***

*If other, please describe:*

***7.14.* Who will obtain parent permission or an agreement to participate from the parents?**

**7.15. Describe the process that will be used to obtain parent permission or an agreement to participate from parents.**

**7.16. Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.**

*Please attach the information sheet and the consent form to this protocol

## OTHER TYPES OF PARTICIPANTS

**7.17. If you will be obtaining consent from other vulnerable populations, such as non-English speaking participants, illiterate participants, or adults not competent to consent, please explain how you will obtain consent from those individuals.**

**7.18. Describe how you will assess comprehension of the research and what it means to participate, including understanding of the voluntary nature of participating.**

# 8. DATA SECURITY AND MANAGEMENT

## INITIAL COLLECTION

**8.1. Describe the identifiability of the data when first obtained/collected:**

☐Will not contain any direct or indirect identifiers (Anonymous)

☐Will not be directly identifiable but there will be a code held by the data source that links to the identities (Coded) – *i.e., if receiving data from another site*

☐Will contain direct identifiers (Identifiable)

**8.2. Will the study require the use of Mobile Apps?**

☐ Yes,

☐ No

**8.3. If you will be using a Mobile App, please list the names:**

## DATA MANAGEMENT / STORAGE

**8.4. In what format will the research data be stored?**

☐Paper

☐Electronic

☐Other – ***(see below)***

*If "Other" please specify:.*

**8.5. How will the consent forms be collected and stored?**

☐ Paper- *Keep under lock and key away from collected data and samples. Shred when no longer needed.*

☐ Electronic - *Keep in separate systems from collected data and samples. Delete when no longer needed. Recommended Example: Use Qualtrics for consent forms and REDCap for survey data.*

***8.6.*** **Explain where the research data will be stored while the study is active (e.g., personal laptop, thumb drive, departmental computer server, office file cabinet, etc.).**