**IMPORTANT: DO NOT CHANGE THE FORMAT OF THE FORM. ANY CHANGE OR MODIFICATION OF THE FORM WILL RESULT IN REJECTION OF THE APPLICATION BY THE CANDIDATE.**

**Please Fill in the Places Highlighted in Grey. Delete all examples when submitting.**

**PROTOCOL TITLE:**  Title should match protocol and grant

**PRINCIPAL INVESTIGATOR/SUPERVISOR:**   Name, Degree, Department

**CO-INVESTIGATOR/STUDENT INVESTIGATOR:**  Name, if applicable

**What is the Purpose of this Study?**

Your child is being asked to take part in a research study. This form has important information about the reason for the study, what your child will do, and the way we would like to use information about your child if you choose to allow them to be in the study.

* Open with a statement that briefly explains what the study is about/the purpose of the research.
* State why the prospective subject is being asked to participate.

**Examples:**

Your child is being asked to participate in a research study…

* about how children respond to messages that hurt their feelings.
* about how children process information.
* of negotiation skills and behavior.

The purpose of this study is...

Examples listed below:

* is to determine how people collectively remember an event...
* is to observe how children…
* is to better understand how children think about…

Your child is being asked to participate in this study because describe why the child is being asked to participate .

**What will my child do in this Study?**

* Provide a clear, concise but complete description of what subjects will do or experience.
* Include the total time commitment, the number of visits/sessions involved, the length of each visit/session.
* Describe all activities in chronological order.
* Indicate whether procedures are experimental.
* If there are many procedures, use a table, lists, or subheadings to organize this information.

If consenting will occur prior to the initial study visit, include the following: As a participant in this study, your child will be asked to come to  insert location .

As a participant in the study your child will be asked to  describe procedures .

Your child’s participation in this study will last for  insert number of hours, days, months  and will involve  number of  visits/sessions.

**Examples:**

* Your child will be asked to come to the Psychology Lab at (room number) for two sessions lasting 30 minutes each. use this example only if subjects will be consented prior to the lab visit
* Your child’s participation in this study will last one hour.
* Your child’s participation in this study will include three visits to the lab. Each visit will last about 45 minutes. The three visits will take place over a month. We will schedule them at a time that is convenient for you and your child.
* We would like to video record your child as he/she performs insert the study task that will be recorded. We will do so only with you and your child’s permission.
* We would like to audio tape the interview with your child and take detailed notes afterward. We will do so only with you and your child’s permission. You and your child have the right to review and edit the tape to delete any material you and your child do not want recorded. Your child may also ask us to turn off the tape at any point in the conversation.

 If taping is optional, insert “I agree...” and “I do not agree...” options at the end of the form.

* After the interview, the tape will be transcribed and a written copy will be sent to you for review. You and your child may delete anything you do not want included in the interview.

If audio and/or video recording is not optional, use the following:

* Audio / Video recording is required for participation. If you or your child do not wish to be recorded, it is not possible for your child to be in this study.

Describe the procedures for discontinuation of a subject's participation, including the right to withdraw data already collected, if applicable.

At any time in the study, you and your child may decide to withdraw from the study. If your child withdraws, no more information will be collected from your child. When you or your child indicate he/she wishes to withdraw, the investigator will ask if the information/specimens/materials already collected from your child can be used.

**What are the Possible Risks or Discomforts to my Child?**

 Open this section with one of the following statements:

Your child’s participation in this study does not involve any physical or emotional risk to him/her beyond that of everyday life.

 Or

Your child’s participation does not involve any risks other than what your child would encounter in daily life.

 Or

Your child’s participation in this study may involve the following risks…

* Include anticipated risks of discomfort and harm (to psyche, reputation, employability, insurability, social status, criminal or civil liability) that may occur as a result of participation.
* Note, risks are not always immediate; anger, emotional upset, or stress may appear later. If this is a possibility, explain and provide an appropriate person’s name and contact information.
* Address emotional and psychological risks, including risks of emotional discomfort from being asked about or discussing sensitive issues.

**Examples:**

* Your child may get tired during the tasks. He/she can rest at any time.
* Your child may feel emotional or upset when answering some of the questions. Your child will be instructed to tell the interviewer at any time if he/she wishes to take a break or stop the interview.
* Your child may be uncomfortable with some of the questions and topics we will ask about. If your child is uncomfortable, he/she will be told they are free to not answer or to skip to the next question.

Include a statement about withdrawing from the study.

Your child may withdraw from the study at any time.

**What are the Possible Benefits for My Child or Others?**

Your child is not likely to have any direct benefit from being in this research study.

 Or

The possible benefits to your child from this study include…

 Or

Taking part in this study may help scientists to better understand...

* State any benefits that can be reasonably expected in a way that is not potentially coercive. If this study focuses on persons with a condition (e.g., a learning disability) avoid stating that the subject may benefit from closer monitoring of their condition.
* Do not include information on payment or reimbursement for participation.

**What Alternatives are Available?**

 Open this section with the following statement

Your child may choose to not participate in this research study.

 and, if applicable

If you do not wish for your child to participate in this study, the following alternatives are available:

* List any and all currently available alternative procedure(s). (If there is no alternative to participation, the opening statement is sufficient.)

**Financial Information**

Participation in this study will involve no cost to you or your child. Your child will not be paid for participating in this study.

 or

* Provide specific information about payment and reimbursement (e.g., INR per visit, payment for testing, evaluation, transportation).
* Specify when payment will be made and in what form (cash, check, gift card).
* Indicate whether you will prorate payment for partial participation, and explain exactly how this will be done.
* For lottery drawings, include the following: when the drawing(s) will occur, who will conduct the drawing(s), how payment will be made, the value of the prize(s), the number of prizes, the chances of winning.
* Do Not use the term “compensation.” Acceptable terms include “payment,” “remuneration,” “reimbursement,” “gift,” “prize,” “token of appreciation,” etc.

Examples:

* You will receive reimbursement for the cost of traveling by public transportation to the research lab. You will be paid in cash at the time of the each visit.
* Your child will receive (dollar amount) for his/her participation in this research study. Your child will be paid (method of payment, timing). If your child withdraws from the study, he/she will be paid (for the portions that you completed, half the total amount, etc.)
* In appreciation for your participation in the study, your child will receive … (specify what will be given to the child.

**What are my Child’s Rights as a Research Participant?**

 The first 3 paragraphs are required.

If you choose to allow your child to be in this study, your child has the right to be treated with respect, including respect for their decision whether or not they wish to continue or stop being in the study. Your child is free to stop being in the study at any time.

Choosing not to be in this study or to stop being in this study will not result in any penalty to your child or loss of benefits to which your child is otherwise entitled. Then add one or more of the following, combining parts of sentences as applicable: If you and your child decide to not be in this study, this will not affect your child’s right to any present or future medical treatment.   if subjects are seeking any kind of medical or mental health treatment  **OR** If you and your child decide to not be in this study, this will not affect your child’s class standing.  if subjects are students in a classroom

If you or your child want to speak with someone *who is not directly involved* in this research, or if you or your child have questions about your child’s rights as a research subject, contact Chitkara University Office for the Institutional Ethics Review Board at +91-\_\_\_\_\_\_\_\_\_or send e-mail cu.ierb@chitkara.edu.in

 Use the clauses below as applicable:

Any new findings developed during the course of this research that may affect your willingness to have your child continue will be provided to you.

Your child’s participation in this study may be discontinued by the investigator without your consent if (specify conditions, such as if sponsor discontinues study, findings indicate participation should end).

**Examples:**

* Your child’s participation in this study is voluntary and they are free to withdraw at any time.
* Your child may choose not to answer particular questions if they do not want to.
* Your child may ask that the tape/video recorder be turned off at any point during the (interview, observation) if there is something that they do not want to have recorded.

**What about my Child’s Confidentiality and Privacy Rights?**

 This section must open with the following statement:

We will use all reasonable efforts to keep your child’s personal information confidential, but we cannot guarantee absolute confidentiality. When this research is discussed or published, no one will know that your child was in the study. But, when required by law or university policy, identifying information (including yours or your child’s signed consent form) may be seen or copied by:

* The Institutional Ethics Review Board Office that approves research studies;
* University and state auditors responsible for oversight of research; and

Include all of the following that are appropriate or applicable to the research study

* The financial sponsor of the research, [Insert sponsor name, if externally funded];
* CDSCO [for drug or device studies];
* Indian Council of Medical Research [for research funded or supported by NIH];
* Hospital name [for research funded or supported by hospitals]

If actual or suspected abuse, neglect, or exploitation of a child or a disabled or elderly adult is disclosed, the researcher or members of the study staff will report the information to the law enforcement agency.

* Use the clauses below as applicable.
* As a rule, do not replace “confidential” with synonyms such as “secret.”
* If it is necessary to show faces or use voices in order to understand the research, indicate this in the following paragraph and provide explicit “I agree...” “I do not agree...” to the use of my audio or video recordings in professional meetings options at the end of the form.

Results of this study may be used for teaching, research, publications, presentations at professional meetings **.** If your child’s individual results are discussed, your child’s identity will be protected by using a code number rather than your child’s name or other identifying information.

Centralized Data Collection or Registries  include only if applicable. NOTE: this does not apply to the use of a secure computer.

The results of your child’s examinations will be collected in a centralized computer or data registry at   name the facility and give the location—city and state. Indicate whether results will be stored by name, identifier, or other code, and describe protections in place for maintaining security of records.

Certificate of Confidentiality Please read below the definition of a CoC and include only if applicable

A Certificate of Confidentiality helps protect the privacy of human research participants enrolled in biomedical, behavioral, and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant.

In this study, your child will be asked about specify, e.g., illegal activities, sensitive information . We will keep information about your child as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, courts have subpoenaed research records.

Audio/Video Recordings  include only if applicable

At the end of this consent form, you will be given the option of allowing us to take photographs and/or make audio or video recordings of your child. If you agree, these may be used in analyzing the research data only. Permission to use audio or video recordings of your child in presentations in the classroom, at professional meetings or in publications will only be requested if it is relevant to understanding the results.

With the clause above, include check-boxes in the Consent section, stating “I [do][do not] give permission for photographs or videotapes of me to be used (as described in this section)”

 OR

All audio, video, and recorded records will be destroyed at the end of the study.

  If recordings will not be destroyed, justify this in the protocol and specify this in the consent form.

**Whom should I Call if I have Questions or Concerns about this Research Study?**

If you or your child have any questions delete the following if minimal risk: problems, illness, or injury during your child’s time on this study, call us promptly.  PI's name  is the person in charge of this research study. You can call him/her at  phone #  on  insert when the person can be called, e.g., Monday through Friday, from 9 a.m. to 5 p.m. . You can also call  insert research personnel name, phone #, and times available with questions about this research. For problems arising evenings or weekends, you may call  insert phone # .

* Contact information for evenings and weekends is not necessary for minimal risk research.
* For more than minimal risk research, information for reporting injuries is required.
* If study is International, include International Calling Codes for all phone #’s.

**Consent** ensure this section is on one page

I have read this form and the research study has been explained to me. I have been given the opportunity to ask questions and my questions have been answered. If I have additional questions, I have been told whom to contact.

**Optional Study Elements**

This section should include other explicit consents for optional elements of the research, such as audiotaping, videotaping, storing photographs for future use, or using the subject’s actual name in research publications.

Initial one of the following to indicate your choice:

\_\_\_\_\_ (initial) I agree to…

\_\_\_\_\_ (initial) I do not agree to…

I agree to let my child \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (print name) be in the research study described above. A copy of this consent form will be provided to me after I sign it.

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

Parent/Legal Guardian’s Name (printed) and Signature Date

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

Name (printed) and Signature of Person Obtaining Consent Date