

# ଟ-ଏଡ଼ା

Consortium on Vulnerability to Externalizing Disorders and Addictions

Standard Operating Procedure

**Follow Up Manual**

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# PART 1: FOLLOW UP DESIGN

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## 1. Introduction

cVEDA employs an accelerated longitudinal design with planned missingness for follow ups i.e. different groups of participants will be followed up at different time points. All participants get randomized into 2 groups. First group enters the 1-year follow-up and the other will be followed up at 2 years. Randomization is stratified by a) age band, b) gender, c) month of recruitment.

Follow-up assessments are done in same month that the participant was recruited in, this simplifies the process and reduces burden on sites. Phone-based follow-up assessments are carried out in most sites. However, a combination of phone and in-person assessments can be used depending upon participant availability. All neuroimaging participants are invited for an in-person assessment.

# Part 2: INSTRUMENTS

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## 2.1 PSYTOOLS Computer battery

1. The instruments selected pick up a measure that is likely to change over the follow-up duration of one year
  - a. Developmental change
  - b. Environmental change
  - c. Occurrence of medical/psychiatric illness
  - d. Changes in socio-demographic details
2. The instruments are amenable for a phone assessment
3. For the C1 age band, the data is collected from parents

## 2.2 Instruments

### Core assessments

1. Socio-demographic information
  - a. Marital status
  - b. Education
  - c. Housing details
  - d. Migration (urbanization)
  - e. Occupation
  - f. Household possessions
2. Environment exposures questionnaires (focused on the past one year)
3. Strengths & Difficulties questionnaire
4. ASSIST-Plus
5. Questions to enquire about medical & psychiatric illnesses in subjects
6. Questions to enquire about psychiatric illnesses in first- & second-degree relatives

### Additional assessments (For neuroimaging participants)

1. Anthropometry
2. Physical developmental scale
3. ACE-IQ
4. MINI/MINI KID

### Assessments for Follow-up at 2 years

1. Temperament (Childhood behaviour questionnaire, Early adolescent temperament questionnaire, Adult temperament questionnaire)
2. Neuropsychological assessments

## 2.3. Conducting follow up assessments

A list of PSC1 codes to be followed up is sent to each site. These are randomly generated list of half the PSC1 codes from subjects recruited at a site. The month for follow-up is mentioned next to the PSC1 code. This is calculated as one/two years from the time of baseline ‘assessment’. As far as possible, participants should undergo follow-up assessments in the same month as baseline assessment. So, if someone completed baseline assessment in November 2016, the follow-up assessment will be done in November 2017, and so on.

Participants/parents/guardians are contacted over phone for inviting them to participate in the follow-up assessments. An appointment (about 30-45 MIN) is fixed for the assessment with the parent and participant in C1 & C2, and only participant in C3, as per the assessments in table below. In-person or phone-based assessment can be conducted. The choice is noted in Psytools.

Questionnaire	C1	C2	C3	Time estimate
SDIM	Parent	Parent	Participant	5 min
EEQ	Parent	Parent	Participant	5 min
SDQ	Parent	Parent + Participant	Participant	10 min 20min for C2
FHQ	Parent	Parent	Participant	2-3 min
MPQ	Parent	Parent	Participant	2-3 min
ASSIST-Plus	Participant/Parent	Participant	Participant	5 min
<b><i>Parental assessments – Information on this has to be collected ‘about the parent’</i></b>				
ASSIST Plus	Parent	Parent	Parent	5 min
SDQ-Adult	Parent	Parent	Parent	5 min

### Sample calling script for phone-based assessments

*“I am ...(name of interviewer)... I am calling from ...(name of institute)... Last year you/your child have/has participated in a research study at ...(name of institute)... Just to remind you, you/your child had at that time answered many questions about health and your child had also done some tests on the computer and undergone a blood/urine/MRI test. We want to thank you for being a part of this study. We want to tell you that information given by you is being used by scientific researchers and is helping answer important questions about how psychological illnesses develop. We also want to share with you that we now have information on more than 3000 individuals across the country, and we are continuing to include more and more people in this work. So, you/your child are/is part of an important scientific journey that could help us understand how to keep our children and the future generations healthy.*

*“Would you like to ask me anything about the study?”*

*“I am contacting you now, after one year, because we are interested in seeing how children are growing/developing year after year. To study this we are conducting some assessments*

*on phone that will not take more than half an hour of your time. I can understand if you are busy now. We can fix a time when you will be free. I will need to speak with you/your child.*

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BEFORE PROCEEDING WITH THE INTERVIEW – CHECK THE NAME OF THE CHILD/PARENT AND DATE OF BIRTH AS PER YOUR RECORDS.(ALL CARE MUST BE TAKEN TO ASCERTAIN THE IDENTITY OF THE PERSON BEING INTERVIEWED AND TO MAKE SURE THAT THE SAME CHILD FROM A FAMILY IS FOLLOWED-UP)

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*“For the interview, I would like to request you to please sit down in a quieter part of your home, so that you can carefully listen to the question asked and answer after giving it adequate thought. I would also like to request you to complete the entire interview in one setting. We wouldn’t want to disturb you again for a phone interview.*

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*Thank you very much for devoting your time to this research again. I can assure you that all the information that you have shared with me will be coded and kept confidential. If at any point you want to contact me or anyone on the team, please do not hesitate to call us on this same number.”*

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If the participant/parent are willing for the assessment. Go ahead for the full battery of assessment.

If they are not willing/hesitant to cooperate, as them if they can just give you 10-15 min on the current call. Proceed with the following questions.

- 1) In the last one year, has there been any change regarding the following:
  - a. Marital status
  - b. Education
  - c. Have they changed their house – another place in same district? Different district? Different state? Different country?
  - d. Current residence in urban or rural area?
  - e. How many years of their life have they lived in an urban area?
- 2) Have they had any mental or other health problems in the last one year?
- 3) Have any of their family members (parents, children, aunts, uncles, nephews, nieces, grandparents) had any mental or other health problems in the last one year?

If after these initial few questions the person becomes more amenable to continue with the interview, ask them if you can take 10 more minutes of their time. If they say yes, proceed with the SDQ – parent version for C1 and C2 and adult version for C3.

*“I am going to be reading out to you 25 statements about different types of behaviors. Please listen to each statement carefully and let me know if the statement is true for you or*

*not, i.e. if the statement describes your/your child's behaviour or not. If a statement is true, please tell me if it is sometimes true or always true."*

Proceed with the SDQ...

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If the participant is coming for an in-person follow-up, the following additional instruments have to be done.

1. ACE-IQ
2. Physical development scale
3. Anthropometry
4. MINI/MINI-KID – tailored for assessment of last one year

### **Assessments on both parents**

Our current assessments do not have any information about parental personality or substance uses, which can be important players in the 'vulnerability' to externalizing disorders and addictions. It is with this premise that the ASSIST-Plus and the SDQ-Adult have been added to the follow-up battery. These have been labelled for each parent (appended with 'mother'/'father'), in addition to those for the child.

The recruitment teams are required to pilot these as well. These assessments have to be done on the mother and father separately. The following script could be used.

*"It has been seen in research, and you might have also noted in your experience, that parental behaviours are a big influence on child development. Children often tend to learn from/copy their parents. So, we believe that to really understand child development from our study, we should understand behaviors and attitudes of parents as well.*

*"I have two questionnaires, each of which will take about 5 minutes. I would like to ask both parents to respond to these, one by one.*

*"Could we proceed with this? Do you have any questions for me at this point?"*

PROCEED WITH THE SDQ AND ASSIST FOR PARENTS.

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*Thank you very much for devoting your time to this research again. I can assure you that all the information that you have shared with me will be coded and kept confidential. If at any point you want to contact me or anyone on the team, please do not hesitate to call us on this same number."*

### **3 Neuroimaging Follow Ups**

ALL subjects scanned at baseline undergo follow up scan. The neuroimaging PSC1 codes is identified from the follow-up list sent to the site. All individuals are invited for an in-person follow-up.

Post 2 years of baseline assessments, all MRI participants will be contacted again with focus on those who did not come for first round of follow up, while individuals who had consented for repeat scan after one year, will also be approached again. FU2 therefore will include participants who undergo first follow up scan, after two years and participants who undergo second follow up scan.