IRB #: NUS-IRB-2023-859 Title: Exploring the Role of Parental Emotion Regulation and Outcomes of Parental Emotional Coaching on Child and Adolescent Psychosocial Outcomes Creation Date: 10-16-2023 Status: Awaiting Org Approval Principal Investigator: Jiehan Ong

Getting Started

Initial Submission Application, V9, 1 Mar 2021

About Cayuse IRB

Cayuse IRB is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted may appear. You do not have to finish the application in one sitting. All information can be saved.

For more information about the IRB submission Process, IRB Tracking, and Cayuse IRB Tasks, please refer to the <u>Cayuse IRB Support website</u> or by clicking the orange question mark at the bottom right hand corner.

Getting Started

Throughout the submission, you may be required to provide the following information:

- Detailed Study Information
- Study Recruitment
- Data Storage Information
- Details on Reimbursement
- Details if a waiver of Informed Consent is requested

Other Important Information

- You cannot begin your study until a **formal approval letter** from the chair of the IRB has been received.
- The IRB meets as needed during the regular academic year. Please submit the application as soon as possible.

Guidelines

- Please go to the NUS-IRB website to download the relevant guidelines.
- Please note that guidelines are accessible to NUS researchers only.
- For non-NUS researchers, please contact irb@nus.edu.sg.

*required

Confirmation

✓ I have read the information above and I am ready to begin my submission.

Simplified Title

For use in recruitment documents, e.g. Participant Information Sheet & Consent Form, advertisements.

Please leave blank if main protocol title will be used in study documents.

Second Simplified Title

Is there a second Simplified Title for this project?

🖌 No

Yes

Key Personnel

Please list the key personnel on this project.

Principal Investigator

*required

Please find the Principal Investigator in the people finder, below.

Name: Jiehan Ong Organization: Dept of Psychology Address: 21 Lower Kent Ridge Road , Singapore, 119077 Phone: 65161143 Email: psyoj@nus.edu.sg

Principal Investigator's Alternate Email Address

e0776001@u.nus.edu

Student Principal Investigator

Is the PI a student at NUS?

No

✓ Yes

*Please provide the name of your Faculty Supervisor, below.

Faculty Supervisor

*required

Please find the Faculty Supervisor in the people finder below.

Name: Yee Shiun Hong Organization: Dept of Psychology Address: 21 Lower Kent Ridge Road , Singapore, 119077 Phone: 65166120 Email: psyhysr@nus.edu.sg ryan.hong@nus.edu.sg

Primary Contact

*required

Please find the Primary Contact in the people finder, below.

Name: Jiehan Ong Organization: Dept of Psychology Address: 21 Lower Kent Ridge Road , Singapore, 119077 Phone: 65161143 Email: psyoj@nus.edu.sg

Primary Contact's Alternate Email Address

e0776001@u.nus.edu

Co-Investigator(s)

Please find the Co-Investigator(s) in the people finder, below, if applicable.

More than one Co-Investigator may be selected. **Please do not include** collaborators if they are not co-investigators in this study.

Name: Tji Tjian Chee Organization: Dept of Psychological Medicine Address: 21 Lower Kent Ridge Road , Singapore, 119077 Phone: 65166666 Email: pcmctt@nus.edu.sg

Name: Poh Lin Tan Organization: Dept of Paediatrics Address: 21 Lower Kent Ridge Road , Singapore, 119077 Phone: 65166666 Email: paetpl@nus.edu.sg

Co-Investigator(s)'s Alternate Email Address(es)

External Co-Investigator(s)

If applicable.

Please do not include collaborators if they are not co-investigators in this study.

Will there be external co-investigators on this study?



External Co-investigator(s)' Details

Please provide their information below.

If there are more than 5 external Co-Is in this study, please use the List of PI and Co-I Form <u>here</u> and attach the document below.

✓ Add Co-Investigator
*required
Full Name

Chin Zhen Hui

*required Title / Salutation Dr

*required

Position

Principal Clinical Psychologist

*required

Department

Psychological Medicine

*required

Institution

National University Hospital

*required

Email

zhen_hui_chin@nuhs.edu.sg

*required

Office No. / HP No.

NA

Add Co-Investigator

*required

Full Name

Ng Min Geng

*required

Title / Salutation

Ms

*required

Position

Student

*required

Department

Psychology

*required

Institution

National University of Singapore

*required

Email

mingeng@u.nus.edu

*required

Office No. / HP No.

NA

Add Co-Investigator

Add Co-Investigator

Add Co-Investigator

Please attach the List of Pl and Co-I Form here, if applicable.

Funding

Is this project funded? No Yes

*required

External IRB(s)

Has the protocol for this project been submitted to or approved by other local/overseas IRBs?

No

✓ Yes

*required

Select the IRB(s) to which this protocol has been submitted.

✓ NHG Domain Specific Review Board (DSRB)

SingHealth Centralized IRB (CIRB)

Other local institution(s)

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Overseas IRB(s)
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*required

External IRB Supporting Documents

Please provide supporting documents (e.g. Approval letter, application form, consent form, etc.).

DSRB Submission 231023.pdf

Social, behavioral, and education research (SBER) encompasses a range of methodologies and tackles questions that seek to improve our understanding of human behavior, attitudes, beliefs, and interactions as well as social and economic systems, organizations, and institutions.

Human Tissue Framework: Please refer <u>here</u> for more information and the <u>HTF</u> Self-Checklist for PI.

Human Biomedical Research: Please refer to the link to the <u>Act</u> for the definition and the HBR Self-Checklist for Pl.

Review Classification

*required

Social, Behavioral, Educational Research (SBER) Category

Does this project fall under the Social, Behavioral, Educational Research (SBER) category?

✓ Yes

No

*required

SBER Exemption

Is the PI requesting an exemption for this study?

Yes No TYPE OF STUDY: SBER Expedited or Full Board

Abstract

Please provide an abstract of this study in no more than 300 words.

The abstract must be self-contained so that it can serve as a succinct and accurate description of the application when separated from it.

Emotional regulation has been found to play a crucial role in an individual's mental well-being and emotional dysregulation is implicated in most of psychiatric disorders listed in the Diagnostic and Statistical Manual, Fifth Edition (DSM-5) (APA, 2013; Gross & Levenson, 1997; Thoits, 1985). Specifically in children, poor emotional regulation skills and parental emotional dysregulation contribute significantly to childhood psychopathology (Han & Shaffer, 2014). This study has two parts - Part 1 aims to explore and identify the parental emotion socialization factors that contributes to a child's emotion regulation abilities and examine how parental emotion dysregulation contribute to the profile of a child's emotional and behavioral difficulties; Part 2 attempts to determine the effectiveness of parental emotional coaching in developing a child's emotion regulation abilities and reducing a child's symptoms of psychopathology. Participants will include both nonclinical and clinical samples, consisting of children and adolescents, aged 7 to 17 years old (middle childhood to adolescence) and their parents. Participants will be invited to complete a set of questionnaires (Part 1) and to participate in a randomized controlled trial that provides parents with a workshop on emotion coaching skills (Part 2). Data will be analysed using correlation, regression analyses and Analysis of Co-variance (ANCOVA). Clinical implications from this study includes, informing of improvements to the clinical services provided in the healthcare setting, as well as contribute to the transdiagnostic formulation of children and adolescent mental health conditions.

*required

Specific Aims

This research aims to (1) explore and identify the parental emotion socialization factors that contributes to a child's emotion regulation (ER) abilities, (2) examine how parental emotion dysregulation contribute to the profile of a child's emotional and behavioral difficulties, and (3) determine the effectiveness of parental emotional coaching in developing a child's emotion regulation abilities and reducing a child's symptoms of psychopathology.

Hypothesis 1: Poor parent ER is associated to poor child ER, and high child internalizing and externalizing problems.

Hypothesis 2: Poor parent ER might be associated with high parental mood and stress levels (such as depressive, anxiety and stress symptoms), low parent sense of competency and poor parent-child relationship.

Hypothesis 3: Results from Hypothesis 1 and 2 will be significantly more salient in the clinical sample versus the non-clinical sample.

Hypothesis 4: In both samples, parents who received emotion coaching will report reduced internalizing and externalizing behaviours in their child, as compared to those who did not receive the training. Hypothesis 5: Parent emotion coaching will reduce parental negative mood and stress levels, increase parent sense of competency, and enhance parent-child relationship, for all parents from both samples. Hypothesis 6: Parent emotion coaching will improve parent ER skills and therefore, contribute to improvement of child ER skills.

*required

Preliminary Studies

State those studies relevant to this project.

Bariola, E., Gullone, E., & Hughes, E. K. (2011). Child and Adolescent Emotion Regulation: The Role of Parental Emotion Regulation and Expression. Clin Child Fam Psychol Rev, 14, 198-212. Bradley S. (2000). Affect Regulation and the Development of Psychopathology. New York: The Guilford Press. Breinholst, S., Esbjørn, B. H., Reinholdt-Dunne, M. L., & Stallard, P. (2012). CBT for the treatment of child anxiety disorders: A review of why parental involvement has not enhanced outcomes. Journal of Anxiety Disorders, 26(3), 416–424. http://doi.org/10.1016/j.janxdis.2011.12.014 . Brent, D. A., Emslie, G. J., Clarke, G. N. et al. (2009). Predictors of spontaneous and systematically assessed suicidal adverse events in the treatment of SSRI-resistant depression in adolescents (TORDIA) study. American Journal of Psychiatry, 166, 418–426. Bridges, L. J., Denham, S. A., & Ganiban, J. M. (2004). Definitional issues in emotion regulation research. Child Development, 75, 340-345. Buckholdt, K. E., Kitzmann, K. M., & Cohen, R. (2016). Parent emotion coaching buffers the psychological effects of poor peer relations in the classroom. Journal of Social and Personal Relationships, 33(1), 23-41. Cicchetti, D, Ackerman B.P., & Izard, C. (1995) Emotions and emotion regulation in developmental psychopathology. Dev Psychopathol.; 7, 1-10. Cunningham, J.N, Kliewer, W. & Garner, P.W. (2009). Emotion socialisation, child emotion understanding and regulation, and adjustment in urban African American families: Differential associations across child gender. Development and Psychopathology, 21, 261–283. Denham, S. A. (1998). Emotional development in young children. New York: The Guilford Press. Dix, T. (1991). The affective organization of parenting: Adaptive and maladaptive processes. Psychological Bulletin, 110, 3-25. Dunsmore, J. C., Booker, J. A., & Ollendick, T. H. (2013). Parental Emotion Coaching and Child Emotion Regulation as Protective Factors for Children with Oppositional Defiant Disorder. Social Development, 22(3), 444-466. Dunsmore, J. C., Booker, J. A., Ollendick, T. H., & Greene, R. W. (2016). Emotion socialization in the context of risk and psychopathology. Maternal emotion coaching predicts better treatment outcomes for emotionally labile children with oppositional defiant disorder. Social Development, 25(1), 8-26.Gilmore, L.

and Cuskelly, M. (2008). Factor structure of the parenting sense of competence scale using a normative sample. Child: Care, Health, and Development, 35 (1), 48-55. Gottman, J. M. (1998). Raising an Emotionally Intelligent Child. New York: Simon and Schuster. Gottman, J. M., Katz, L. F., & Hooven, C. (1997). Meta-emotion: How families communicate emotionally. Mahwah, NJ: Lawrence Erlbaum Associates. Gratz, K. L. & Roemer, L. (2004). Multidimensional assessment of emotion regulation and dysregulation: Development, factor structure, and initial validation of the Difficulties in Emotion Regulation Scale. Journal of Psychopathology and Behavioral Assessment, 26, 41-54. Gross, J. J. (1998). The Emerging Field of Emotional Regulation: An Integrative Review. Review of General Psychology, 2(3), 271-299. Gross, J.J., & John, O.P. (2003). Individual differences in two emotion regulation processes: Implications for affect, relationships, and well-being. Journal of Personality and Social Psychology, 85, 348-362. Gross, J. J., & Levenson, R. W. (1997). Hiding feelings: The acute effects of inhibiting positive and negative emotions. Journal of Abnormal Psychology, 106, 95-103. Gullone, E., & Taffe, J. (2011, October 24). The Emotion Regulation Questionnaire for Children and Adolescents (ERQ-CA): A Psychometric Evaluation. Psychological Assessment. Gus, L., Rose, J. & Gilbert, L. (2015). Emotion Coaching: A universal strategy for supporting and promoting sustainable emotional and behavioural well-being. Educational & Child Psychology, 32(1), 31-41. Han, Z.R., & Shaffer, A. (2014). Maternal expressed emotion in relation to child behaviour problems: Differential and mediating effects. Journal of Child and Family Studies, 23, 1491-1500. Havighurst, S. S., Duncombe, M., Frankling, E., Holland, K., Kehoe, C., & Stargatt, R. (2015). An emotion-focused early intervention for children with emerging conduct problems. Journal of abnormal child psychology, 43(4), 749-760. Hunter, E.C., Katz, L.F., Shortt, J.W., Davis, B., Leve, C., Allen, N.B. & Sheeber, L.B. (2011). How do I feel about feelings? Emotion socialisation in families of depressed and healthy adolescents. Journal of Youth and Adolescence, 40(4), 428-441. Morris, A. S., Silk, J. S., Steinberg, L., Myers, S. S., & Robinson, L. R. (2007). The role of the family context in the development of emotion regulation. Social Development, 16, 361-388. Peris, T. S., & Miklowitz, D. J. (2015). Parental Expressed Emotion and Youth Psychopathology: New Directions for an Old Construct, Child Psychiatry Hum Dev., 46(6), 863-873, Peris, T. S., & Piacentini, J. (2013), Optimizing treatment outcome for complex cases of pediatric obsessive compulsive disorder. J Clin Child Adolesc Psychol, 42, 1-8. Ramsden, S. R., & Hubbard, J. A. (2002). Family Expressiveness and Parental Emotion Coaching: Their Role in Children's Emotion Regulation and Aggression. Journal of Abnormal Child Psychology, 30(6), 657-667. Restifo, K. & B€ogels, S. (2009). Family processes in the development of youth depression: Translating the evidence to treatment. Clinical Psychology Review, 29, 294–316. Rose, J., Gilbert, L., & McGuire-Snieckus, R. (2015). Emotion Coaching-a strategy for promoting behavioural self-regulation in children/young people in schools: A pilot study. The European Journal of Social & Behavioural Sciences, 13, 1766-1790. Sander, J. B. & McCarty, C. A. (2005). Youth depression in the family context: Familial risk factors and models of treatment. Clinical Child and Family Psychology Review, 8, 203-219. Sheeber, L. B., Davis, B., Leve, C., Hops, H. & Tildesley, E. (2007). Adolescents' relationships with their mothers and fathers: Associations with depressive disorder and subdiagnostic symptomatology. Journal of Abnormal Psychology, 116, 144–154. Suveg, C., Zeman, J., Flannery-Schroeder, E., & Cassano, M. (2005). Emotion socialization in families of children with an anxiety disorder. Journal of Abnormal Child Psychology, 33, 145-155. Thoits, P. A. (1985). Self-labeling processes in mental illness: The role of emotional deviance. American Journal of Sociology, 91, 221-249. Thompson, R. A. (1994). Emotion Regulation: A theme in search of definition. Monographs of Society for Research in Child Development, 59, 25-52. Zeman, J., Cassano, M., Perry-Parrish, C., & Stegall, S. (2006). Emotion Regulation in Children and Adolescents. Developmental and Behavioural Pediatrics, 27(2), 155-168.

Please submit a copy of all investigators' CVs.

CV_Jamie_Ong_Jiehan (Official).pdf

Dr Chee Tji Tjian CV 3p Dec 2021.docx

Ng Min Geng-CV(2023).docx

Tan PL CV (Full Oct 2023 Eduport).pdf

Zhen Hui CV_2023.pdf

*required

Study Participants [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

Will this project involve the recruitment of human participants?

✓ Yes

No

Type of Study [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

Interventions includes <u>educational</u> such as implementing new peer-marking scheme or using virtual reality to conduct lessons, <u>physical</u> such as temperature / taste / smell sensory evaluation or exercise, <u>physiological</u> such as memory recall, or <u>psychological</u> such as decision-making tasks.

Archived / Existing Data

Questionnaire / Survey / Interview / Focus Group Discussion

Copy of questionnaire / survey / interview guide / focus group discussion guide

Please submit a copy of questionnaire /survey/interview guide/ focus group discussion guide, if available. ER Study Child Qnnaire V1.doc

ER Study Parent Qnnaire V1.doc

Observations

, Interventions / Experiments

Educational Research

Use of non-Medical Devices

Deception

Human Biological Materials

Use of Medical Device(s)

Testing of Device(s)

Animal Procedures

Other(s)

*required

Procedures

Describe research procedures, including research visits (frequency and duration of procedures involved).

Proposed Methodology

This research proposes 2 studies to investigate the above stated questions. Study 1 will utilize a cross-sectional design with children and adolescents, as well as their parents (from clinical and non-clinical populations), completing questionnaires provided, while Study 2 will involve inviting participants from Study 1 to participate in a randomized clinical trial.

Participants & Procedure

Participants include children and adolescents aged 7 to 17 years old, and one of their parents. Both clinical and nonclinical samples will be recruited for this study. Clinical samples will be recruited from the outpatient clinic at the Paediatrics Department and Department of Psychological Medicine, at National University Hospital. Patients that are experiencing emotional and behavioural difficulties will be recruited. Patients that report psychotic symptoms, neurodevelopmental disorders and severe mood or anxiety disorders are excluded. In addition, to reduce possibility of confounding variable, patients on the waitlist for treatment will be approached. Non-clinical samples will be recruited from the community. Both parents and children will be required to be fluent in the English language.

In terms of procedure, suitable participants (parent-child dyads) will be invited to participate. Consent will be collected from the child and their parents. After consent is taken, participants will be asked to complete a set of questionnaires and indicate their interest to participate in Study 2.

In Study 2, a randomized controlled trial is designed to test the effects of parent emotion coaching on parental factors (such as ER skills, sense of competency, and mood and stress levels), child factors (such as ER skills, internalizing and externalizing problems, and treatment outcomes), as well as parent-child relationship. Participants will be a subset of Study 1's participants.

If participants indicate interest to participate in Study 2, the parents will be randomly assigned to the following experimental groups: 1. Emotion Coaching Training, or 2. Waitlist Control condition. Parents in the emotion coaching workshop will be invited to attend an online training on emotion coaching strategies, while parents in the control condition will not be receiving any training workshops during the study. They will be invited to join the online workshops when the study is completed. The training module consists of a three-hour workshop, followed by 2 bi-weekly 30-minute phone/online consultations, and 5 weekly push

notifications (e.g., in the form of reminders of the specific strategies taught in the workshop). Parents and children will be required to complete the set of outcome measures at pre-, post-treatment and at a 1-month follow-up.

*required

Study Sites [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

Will research procedures be conducted in non-NUS premise(s)?

✓ Yes

*required

Please state the premise(s).

National University Hospital

No

*required

Anticipated Study End Date

12-30-2025

Participant Groups [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

This project involves the following group(s):

Healthy Adults

NUS Students

Minors who are not NUS Students

*Please check the age of majority at the site of recruitment.

*required

 \checkmark

Target Number

150

*required

Lower Age Limit

7

*required Upper Age Limit

17

Elderly with mental capacity

Individuals who lack mental capacity

Vulnerable Population(s)

 ✓ (excluding minors who are <u>not</u> NUS students, elderly with mental capacity and individuals who lack mental capacity)

Vulnerable Populations [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

*required

Please state who the vulnerable population(s) to be recruited are *(e.g. pregnant women, prisoners, etc)*.

Children who are seeking clinical services at NUH

*required

Target Number

150

*required

Lower Age Limit

7

*required

Upper Age Limit

17

*required

Total Number of Study Participants

300

Please identify which criterion is applicable for specific group(s) of research subjects.

Participants include children and adolescents aged 7 to 17 years old, and one of their parents. Paediatric patients that are experiencing emotional and behavioural difficulties will be recruited, together with one of their parent. Non-clinical samples will be collected from the community. Parents and children have to be fluent in English.

*required

Exclusion Criteria

Please identify which criterion is applicable for specific group(s) of research subjects. Paediatric patients that report psychotic symptoms, neurodevelopmental disorders and severe mood or anxiety disorders are excluded.

Relationship with Researchers [SBER and Biomedical Research (Non-HBRA) Studies only]

*required

Are there any participants in a dependent relationship with the researchers?

🖌 No

Yes

*required

PI's Confirmation

Researchers will prevent cases where participants agree to participate while under duress.

✓ Confirmed

Recruitment Locations [SBER and Biomedical Research (Non-HBRA) Studies only]

Where will participants be recruited from?

Select all that apply.

✓ General Public

NUS

Organisations / Agencies / Companies / Institutions / Schools

*required

List of Organisations / Agencies / Companies / Institutions / Schools

National University Hospital

*required

PI's Confirmation

Permission will be obtained from relevant authorities for recruitment of their staff / clients / students or on their premises, if necessary.



Correspondence of willingness from participating Organisations / Agencies / Companies / Institutions / Schools **Overseas Recruitment**

Will participants be recruited from overseas?

🖌 No

Yes

*required

How will participants be recruited? [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

Select all that apply.

NUS Research Pool Program

Online survey platform

Word of mouth / Snowballing / Referral / Personal contacts

Phone calls

Email invitation / Letters

Advertisements / Flyers / Posters

*required

1

Permission will be obtained from the relevant authorities for the posting/distribution of recruitment materials, if necessary.

✓ Confirmed

Poster V1.pdf

Social media

*required PI's Confirmation

Permission will be obtained from the relevant platform administrators for recruitment on their social media, if necessary.

✓ Confirmed

Door-to-door recruitment

Other method(s)

*required

PI's Confirmation

PI confirms that permission, where applicable, will be/has been obtained from potential subjects for the use for their personal data (e.g. name and contact information) for recruitment purposes.

✓ Confirmed

Recording the Procedure(s)

Will the procedure(s) be recorded?

🖌 No

Yes

Assessment of risk involved

Minimal risk means the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests.

*required

Anticipated Benefits and Risks [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

What are the anticipated benefits and risks to the participants in this study?

If applicable, please state the mitigating factors.

- Direct benefits include Parents receiving complimentary parent workshop (and psychological consultation) and learning skills and strategies to manage their children's emotions and behaviours. This will directly help them build a more conducive relationship with their child and thus contribute to the improvement of the mental health outcomes of both the parent and child.
- Indirect benefits include The data obtained in this research will inform important questions relating to understanding the various family and parental factors that might contribute to children and adolescent mental health. The study outcomes will provide valuable directions in tailoring familiar and parental support available in the community and clinical setting, for example how to encourage better parent-child relationship and creating a conducive family emotional climate. The findings can also be used to inform practical policy decisions in Singapore. For instance, if parent ER skills was found to significantly contribute to child's ER and risk for psychopathology, then emotion coaching strategies can be included in intervention programmes. In addition, if specific parental and child characteristics have been found to be risk or protective factors for a child developing psychopathology, then prevention programmes aimed at targeting these factors can be developed or included in current programmes. Potentially, findings from this study will provide a stepping stone to further develop research and services in the area of children and adolescent with emotional and behaviour disorders. It will contribute to the professional development of clinicians and professionals working with this population.
- Anticipated Risks: During the parent workshop, parents might get emotional when sharing about their difficulties. The workshop facilitators are either trained psychologists or psychologist trainees, and all are/will be equipped to manage such situations. Probability and magnitude of this risk is low.

Will participants be reimbursed for their participation? [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]



*required

Type of Reimbursement [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

What type of reimbursement will be provided?

✓ Cash / Voucher

*required

Please elaborate.

SGD10 will be given for each participant for completion of each set of questionnaire.

Course credit(s)

Lucky draw

Other(s)

*required Withdrawal after participation Will participants be entitled to reimbursement if they withdraw after their participation?

```
Yes
✓
```

*required Please explain.

> If the participants completed the questionnaires before withdrawal, then yes they will be entitled. But if they withdrew without completing the questionnaires, then will not be entitled to it.

*required

Withdrawal mid-way

Will reimbursement be pro-rated if participants withdraw from the study mid-way?

✓ Yes

No

Healthy adults/ Elderly with mental capacity/ Vulnerable population/ NUS students / Minors who are not NUS students

[SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

Will documented informed consent be taken?

✓ Yes

*required

Participant Information Sheet & Consent Form (PIS&CF)

Please upload the PIS&CF. <u>Consent and Assent Form DSRB appln V1.doc</u>Sample documents: <u>SBER and Non-HBRA</u> <u>PIS&CF Template</u> Child Assent Form 6 to 12 DSRB appln V1.doc

No

N.A. (for studies conducted anonymously only)

*required

Minors who are not NUS students [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

Please confirm documented parental consent will be obtained.

✓ Yes

*required

Consent and Assent Form DSRB appln V1.doc

No

*required

Consent Procedure [SBER Studies only]

Summarize the consent procedure. Please specify how informed consent will be obtained and who will obtain consent.

After the potential participants verbally agree for the study team to contact them, a member of the team will reach out to them to provide more information on the study and get formal consent signed (from both parents and the child). When formal written consent has been received, then we will proceed to provide the participants with the questionnaires and assign them to an experimental group.

Request for Waiver [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

*required

I require a waiver of:

Documentation of Informed Consent

Documentation of Parental Consent

Informed Consent

Parental Consent

Informed Consent as my research involves Deception

Not Applicable

[SBER / Biomedical Research (Non-HBRA) Studies only]

*required

Will personal data be collected in this research? [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

✓ Yes

No

*required

Type(s) of personal data collected

What type of personal data will be collected, e.g. name, contact number, etc.? Name, contact details and some other demographic info, such as education and monthly income.

*required

Linkage of personal data to research data [SBER Expedited / Full Board or Biomedical Research (Non-HBRA) Studies only]

Will personal data be linked to research data?

✓ Yes

No

*required PI's confirmation

PI confirms personal data and research data will be coded at the earliest possible stage of the research study.

*required

Code Key Holder

Who will be holding onto the key to the code? PI - Ong Jiehan Jamie

*required

Code Key Location

At which secure / password-protected platform will the key to the code be kept? Password protected document, saved on the organisation's (i.e. NUS) shared drive, which is ONLY accessible by the PI.

*required

Code Key Destruction

When will the key to the code be discarded? When the study expires.

Location of Personal Data [SBER / Biomedical Research (Non-HBRA) Studies]

Where will personal data be kept?

Please see <u>NUS Research Data Management Policy Guidelines</u> and <u>NUS Data Management</u> Policy.

✓ <u>nBox</u>

Encrypted thumbdrive and/or device(s)

✓ Other(s)

*required

Please describe.

If nBox is discontinued, it will be kept on another secure document platform.

*required

Access

Who will have access to the personal data?

✓ NUS research team

Other(s)

*required

Discarding Personal Data

When will personal data be discarded?

✓ Before / Upon completion of study

Kept beyond research period

*required

What will happen to the personal data if subjects withdraw from research?

✓ All of their personal data will be discarded at the earliest possible time

Other(s)

*required

Location of Research Data [SBER / Biomedical Research (Non-HBRA) Studies]

Where will research material / research data be kept?

Please see <u>NUS Research Data Management Policy Guidelines</u>and <u>NUS Data Management</u> <u>Policy</u>.

✓ <u>nBox</u>

Encrypted thumbdrive and/or device(s)

✓ Other(s)

*required

Please describe.

If nBox is discontinued, it will be kept on another secure document platform.

 Research data will be kept for at least 10 years in accordance with NUS Research Data Management Policy.

Other(s)

*required

Who will have access to the research material / research data?

✓ NUS research team only

Other(s)

*required

What will happen to the research data if subjects withdraw from research?

✓ All of their research data will be discarded at the earliest possible time

Only research data which are individually-identifiable will be discarded

Other

As the Principal Investigator of this research study, I hereby declare that:

- The information provided in this form is correct.
- I will not initiate this research until I receive notification of NUS-IRB's approval and any other approval from relevant authorities (local/overseas).
- I will not initiate any change in protocol without prior written approval from NUS-IRB except when it is necessary to reduce or eliminate risk to the subject.
- I will promptly report any unexpected or serious adverse events, unanticipated problems and incidents that may occur in the course of this research.
- I will maintain all relevant study documents and recognize that the NUS-IRB staff and regulatory authorities may inspect these records.
- I understand that failure to comply with all applicable regulations, institutional and NUS-IRB policies and requirements may result in the suspension or termination of this research, and other actions as stated in the NUS Code & Procedures on Research Integrity.
- I declare that there is no existing or potential conflict of interest (financial or otherwise) for any of the investigators participating in this research and/or their immediate family members. If there are conflicts of interest, I have declared them accordingly.
- I will promptly report any change in the conduct of the research study that deviates from the IRB application form.

✓ Confirmed

Please read:

- 1. Confirm all sections are complete with a **white check** (tick) next to the section name in the left column.
- 2. Attach any and all relevant documents in the Attachments section.
- 3. Leave any comments relevant to this study in the Comments section. (Optional)
- 4. Click Complete Submission at the bottom of the left column.
- 5. Please check that the **"Organisation" unit** in the **Study Details page** is correct **<u>BEFORE</u>** the PI certifies the application.

List of PI and Co-I Form

*required

External IRB Supporting Documents

DSRB Submission 231023.pdf

*required

CVs

CV_Jamie_Ong_Jiehan (Official).pdf

Dr Chee Tji Tjian CV 3p Dec 2021.docx

Ng Min Geng-CV(2023).docx

Tan PL CV (Full Oct 2023 Eduport).pdf

Zhen Hui CV_2023.pdf

Correspondence of willingness from participating Organisations / Agencies / Companies / Institutions / Schools

Copy of Questionnaire / Survey / Interview guide / FGD guide

ER Study Child Qnnaire V1.doc

ER Study Parent Qnnaire V1.doc

*required

Copies of Advertisements / Flyers / Posters

Poster V1.pdf

*required

PIS&CF

Consent and Assent Form DSRB appln V1.docSample documents: SBER and Non-HBRA PIS&CF
Template
Child Assent Form 6 to 12 DSRB appln V1.doc

*required

Parental IS&CF

Consent and Assent Form DSRB appln V1.doc

Please attach any other relevant documents for this Research Protocol submission that may be important to reviewers and that were not included in the application.

Currently, PI has applied for funding but awaiting results.