

OFFICIAL USE ONLY	
Doc Name :	Informed Consent Form Template
Doc Number :	207-001
Doc Version :	13
	Date : 31 Jan 2022

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

You/your child is invited to participate in a research study. Please read the information provided, it is important that you/your child understand the information provided in this sheet. You/your child are welcome to ask any questions before you/your child consent to participate in this study. Should you/your child agree to participate in this study, please complete the online consent form together with your parent/child.

1. Study Information

Protocol Title:

Integrative Adolescence Research Programme (IARP) – iAdoRe Sub-study (Saliva)

Principal Investigator & Contact Details:

Professor Johan Eriksson

Institute of Human Development and Potential (IHDP)

Brenner Center, 30 Medical Drive, Singapore 117609

Email: Johan_ericsson@sics.a-star.edu.sg

Tel: 8854 6302

2. Purpose of the Research Study

The purpose of this sub-study is to study potential association of genetic factors and biomarkers which may influence health and overall well-being in adolescents.

You/your child are invited to participate in this sub-study because you/your child are enrolled in the iAdoRe study. This sub-study targets to recruit about 1000 – 1200 adolescents, aged 13 – 17 years old, from the main iAdoRe study over a period of 12 months.

3. Study Procedures

If you/your child agree to take part in this study, you/your child will be required to provide a one-off saliva sample. The collection will take no more than 5 minutes, without eating/drinking 30 minutes prior to collection. Saliva collection kits will be issued in school by the study team and collected saliva samples will be returned onsite in school or posted back (in self-addressed envelope) to the study team.

The saliva sample obtained during the course of this study will be analyzed only for the purpose of this study for a period not exceeding 5 years and will be destroyed after the completion of this study. The saliva samples will not be used for restricted human biomedical research involving human-animal combinations.

Any individually-identifiable data obtained during the course of this sub-study will be stored and analysed for the purposes of this study and will not be used for future biomedical research. However, data collected from the main study may be stored, analyzed, and used for future research purposes.

“Incidental findings” are findings that have potential health or reproductive importance to research participants like you/your child and are discovered in the course of conducting the

study, but are unrelated to the purposes, objectives or variables of the study. There will not be any incidental findings arising in this research.

4. Your Responsibilities in This Study

If you/your child agree to participate in this study, you/your child should follow the instructions for saliva collection by the study team. You/your child should be prepared to undergo one-off saliva collection procedure.

5. What Is Not Standard Care or is Experimental in This Study

This study is not part of your/your child's clinical care and is only meant for research purposes. The saliva sample collected will be used strictly for research purposes only.

6. Possible Risks and Side Effects

Collecting saliva is a simple, painless and non-invasive process. There are no known risks or significant side effects associated with this procedure.

There is a minimal risk of breach of privacy and confidentiality in the study. All personal identifiers (e.g. name, email address) and data collected from this study will be securely stored and protected. Identifiable personal data will only be accessible by delegated study team members.

7. Possible Benefits from Participating in the Study

There is no direct benefit from participating in this study. However, your/your child's participation may contribute to advancing our knowledge of adolescent health and well-being in Singapore.

8. Alternatives to Participation

If you choose not to take part in this study, you will not need to undergo the research procedure outlined above.

9. Costs & Payments if Participating in the Study

There are no costs involved for your child to take part in the study. After confirmation of saliva sample receipt, you/your child will be reimbursed with \$50 worth of gift vouchers for your/your child's participation.

10. Voluntary Participation and Compensation for Injury

Your/your child's participation in this study is entirely voluntary, and you/your child has the right to withdraw from the study at any time without any penalty.

If you/your child decide to stop taking part in this study, you/your child should inform the study team via email / phone. However, the data that has been collected until the time of your/your child's withdrawal will be kept and analysed. This is to enable a complete and comprehensive evaluation of the study.

The saliva samples collected for the study will be deemed to be gifted to IHDP which will not be returned to you/your child. You/your child will also not have any right or claim to any share in the commercial gain derived from the research (if any). However, you/your child retain the right to ask the Principal Investigator to discard or destroy any remaining samples if the biological sample(s) is individually-identifiable and has not been used for the research or it has been used for research but it is practicable to discontinue further use of the biological sample(s) for the research.

In the event of any new information becoming available that may be relevant to your/your child's willingness to continue in this study, you/your child will be informed in a timely manner by the Principal Investigator or his representative, and further consent may be required.

While no injuries are anticipated in this study, IHDP without legal commitment will compensate you/your child for the injuries arising from your/your child's participation in the study without you/your child having to prove IHDP is at fault. There are however conditions and limitations to the extent of compensation provided. You/your child may wish to discuss this with the Principal Investigator.

By signing the consent form, you/your child will not waive any of your/your child's legal rights or release the parties involved in this study from liability for negligence.

11. Confidentiality of Study and Medical Records

Your/your child's participation in this study will involve the collection of "Personal Data". "Personal Data" means data about you (your child) which makes you (your child) identifiable (i) from such data, or (ii) from that data and other information which an organization has or likely to have access. Examples of personal data can include your name, nationality, date of birth and telephone number.

Information and "Personal Data" collected for this study will be kept confidential. Your/your child's records, to the extent of the applicable laws and regulations, will not be made publicly available.

To protect your/your child's confidentiality, research data collected will be coded and identifying information will be removed. Your/your child's personal data will never be used in publications, presentations, or future research. The link between your/your child's own identifiable information and the code number will be locked and may only be accessed by the study team and trusted third parties.

However, the Regulatory Agencies, Institutional Review Board and auditors will be granted direct access to your/your child's study records to verify study procedures and data, without making any of your/your child's information public.

Research arising in the future, based on your/your child's "Personal Data" will be subject to review by the relevant institutional review board.

By signing the Informed Consent Form, you/your child are authorizing (i) the collection, access to, use and storage of your/your child's "Personal Data", and (ii) the disclosure to authorized service providers and relevant third parties. Any biological samples and/or information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will not be transferred out of Singapore.

By participating in this research study, you are confirming that you/your child have read, understood and consent to the A*STAR Personal Data Protection Notification available at <https://www.a-star.edu.sg/privacy-statement>

12. Who To Contact if You Have Questions

If you/your child have any questions about this research study, please contact the Principal Investigator or research team at iadore@sics.a-star.edu.sg / +65 8854 6302

The study has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you/your child want an independent opinion to discuss problems and questions, obtain information and offer inputs on your (your child's) rights as a research subject, you/your child may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You/your child can also find more information about participating in clinical research, the NHG Domain Specific Review Board and its review processes at www.research.nhg.com.sg.

PARTICIPANT CONSENT FORM

Protocol Title:

Integrative Adolescence Research Programme (IARP) – iAdoRe Sub-study (Saliva)

Principal Investigator & Contact Details:

Professor Johan Eriksson
Institute of Human Development and Potential (IHDP)
Brenner Centre, 30 medical Drive, Singapore 117609
Email : Johan_ekriksson@sics.a-star.edu.sg
Tel: 8854 6302

I voluntarily consent to take part in the **iAdoRe** Sub-study (Saliva). I have fully understood the purpose and procedures of this study and its possible benefits and risks.

By electronically signing this consent form, I agree to participate in the study and consent to the following:

- (1) Collection, access to, use and storage of my Personal Data by IHDP, NIE and Ministry of Education (MOE), other Ministry organizations [e.g Health Promotion Board (HPB)]
- (2) Data to be combined with other relevant datasets for additional analysis
- (3) To be contacted and invited to participate in other studies related to iAdoRe study

Full Name of Child Participant:

Child Mobile number (if any):

School Email Address:

Name of School:

Class:

Date of Consent:

eSignature

PARENTAL CONSENT SECTION:

By electronically signing this consent form, I am consenting for my child to participate in the study:

Full name of Parent / Legal Guardian:
Parent's / Legal Guardian Email address:
Date of Consent:

eSignature

NOTE : The Parties (Participant and Parent/Legal Guardian) may execute this Informed Consent Form using electronic signature process and agree that signatures obtained or transmitted through electronic means, shall be binding and effective for all purposes as if the signatures were executed in-person.