**PARTICIPANT INFORMATION SHEET**

**Exploring cross-cultural differences in perceptions and attitudes to research involving human subjects, with a focus on human challenge studies, among university students from different countries.**

**Short title: Cross-cultural Attitudes to Human Challenge Studies (BRANCH Project)**

We are inviting groups of medical students from different institutions around the world to participate in a mixed methods social science research study aiming to explore perceptions of and attitudes towards clinical research in human subjects, with a particular focus on human challenge studies. The execution of the study is a joint effort between the Oxford University Clinical Research Unit (OUCRU) and the University of Medicine and Pharmacy at Ho Chi Minh City (UMP) in Vietnam, (and XXX institution/country).The study is being conducted and coordinated by OUCRU-VN.

Please take your time to read this information sheet carefully. If you have any questions, please ask one of the study investigators to discuss it with you. If you are happy to participate in this study, you are requested to sign this document electronically on the last page.

**What is the reason for the study?**

Establishing a clear understanding of public perceptions and attitudes toward clinical research in any given context is an essential step to guide development of appropriate research study procedures and processes. Senior local stakeholders are usually involved in discussions and decision-making with respect to clinical research studies, but typically in the past there has been little focus on exploring the understanding and opinions of younger generations of society, who may hold a different range of views from older generations. A longitudinal cohort study (the SEED project) is currently underway, involving more than 500 medical and public health students undertaking their studies at UMP in Ho Chi Minh City (HCMC), Vietnam, aiming to explore the students’ perceptions and views of clinical and public health orientated research focused on dengue, and to examine factors that influence these views. Although the focus of the SEED project has been on dengue, a mosquito-borne viral infection of major global significance that exerts huge public health and economic burdens in Vietnam, the study platform is also being used to explore students’ attitudes to a variety of important themes relating to clinical research in general. In the current phase of the project we are beginning to explore the students’ views on use of human challenge studies in low-income and middle-income (LMIC) countries / endemic settings.

One area of particular interest relates to the potential for cross-cultural differences in perceptions and attitudes to research involving human subjects. Thus, in this extension to the Vietnam study, we wish to explore cross-cultural differences in views around research involving human subjects among comparable student groups from different countries. Following the same format we have established in HCMC we plan to hold a series of on-line science cafes/debates, focus groups discussions (FGDs) and in-depth interviews (IDIs) at intervals during the next year, but now involving mixed groups of students from different countries attending the same on-line events. We will explore attitudes and perceptions towards the main themes already probed with the HCMC student group, but given the increasing focus on human challenge studies for SARS-CoV-2 (and other pathogens) at the present time we will take particular interest in issues relating to human challenge studies for this comparative work. Specifically, we will explore how ideas around risk perception, consent, and appropriate remuneration for challenge studies may differ according to the context. The study findings will be used to improve our understanding of public perceptions and possible barriers to acceptance of clinical research in different countries.

**What will happen if I take part in the study?**

If you agree to participate, you will be asked to register your details with a member of the SEED project staff so that we can contact you about upcoming on-line activities to arrange participation, and you will be allocated a unique identification code. We aim to have balanced representation from different insitutions and groups at these events, so the final selection of attendees will be coordinated by the study staff; we hope that all interested inviduals will be able to attend at least one event in 2022. We will also invite you to join a closed Facebook group to facilitate frequent communication and keep you updated about the various activities that are organized. These activities will include but are not limited to:

* Completing a general questionnaire about yourself, your family, and your background
* Completing an on-line survey relating to clinical research in human subjects
* Science café and/or debating sessions, which typically involve 40-50 people discussing particular topics related to research involving human subjects. During these sessions (total duration up to 3 hours), you may be asked to form smaller groups to discuss particular issues in detail. You will also be asked to complete questionnaires and/or feedback forms before and after the different sessions
* In-depth interviews, which last for 60 – 90 minutes
* Focus group discussions, typically involving 8-10 people and lasting for 60 – 90 minutes.

All of the above activities will be organized on-line by the OUCRU study team. The IDIs and FGDs will be audio/video-recorded and transcribed verbatim for analysis. Study staff will also observe all activities and note down information in an observation form. If you prefer your comments not to be audio/video-recorded, we will arrange to take written notes of your opinions instead.

**What are the potential risks and benefits of the study?**

There are no immediate risks should you decide to take part in this study. You would need around 10 minutes to complete a survey or questionnaire, around 60 – 90 minutes for an interview or discussion, and around 2-3 hours to attend a science café or debate. We will try to organize it so that all activities occur at times that do not conflict with or prevent your attendance at regular curricular commitments at your institution. There is no financial compensation for taking part, and you should not incur any costs. Should you wish it we can provide a certificate confirming your voluntary participation in the research programme.

Your contribution to the study will help researchers understand public perceptions and possible barriers to acceptance of clinical research in humans and to explore whether these differ (or not) in different settings; this knowledge will help to ensure that future research studies pay due attention to these views.

**Is your participation voluntary?**

You are free to decide whether to join this study. XXX Institution supports the general concept of this programme, but university staff will not be involved in organizing the different activities or have access to the participant list. Whatever your decision, there will be no impact on your studies at your institution. During any of the activities you can refuse to answer any questions and we will move on with other questions. We understand that your contribution to the IDIs and FGDs will only represent your personal opinions, not those of anyone else.

You can withdraw from the study at any time without a reason or a consequence. Should you choose to withdraw from a particular activity, you will be asked if you wish your data to be deleted from the record; if so, all relevant data collected (identified using your unique code) will be deleted. However, if your data is part of a collaborative piece of work it may be used but your identity will be protected.

**Has the study been approved by an Ethics Committee?**

This study has been approved by the Ethics Committee of the University of Medicine and Pharmacy at Ho Chi Minh City, Vietnam, by the Oxford Tropical Research Ethics Committee, and by the Ethics Committee of XXX Institution.

**Confidentiality of personal information**

All personal information will be kept in strict confidence by those who are working on this study. Each student who joins the cohort will be given a unique identifying code to distinguish them in all subsequent activities, so all of your answers will be stored and analyzed anonymously. Your name will not be used on any of the study documents or in any reports or publications about this study.

All data generated during the course of this study will be treated confidentially and stored in a ring-fenced fashion in the OUCRU-VN secure database for a minimum period of 10 years in accordance with OUCRU policy. The notes, audio recordings and video files generated during the discussion activities will be deleted after being transcribed into electronic word documents using only your unique identifying code. Only persons who have completed good research practice and data protection training and are authorized will have access to the stored data. Participants’ personal identifying information will be kept strictly confidential.

We recognize that participants in the cohort might disclose information about other participants. The Facebook group will be a closed group and everyone in the cohort will be given information about participant confidentiality and the importance of upholding the rights of others. We strongly urge you to commit to respect each other’s confidentiality by not discussing group members’ comments outside the study activities.

**What if I have more questions?**

You are encouraged to ask any questions related to this study at the time of enrolment and during the time of participation. If you have any other questions about the study, please contact the study principal investigator Prof. Bridget Wills (+44 7763798396) or the main study coordinator Ms Nguyen Thi Van Thuy (+84 919088058) or the local contact for your institution (XXX, XXXX)

If you have general questions, please contact the OUCRU Clinical Trials Unit at +84 28 3924 1983.

**Data protection and data sharing**

All data collected will be used solely for research purposes. The University of Oxford is responsible for ensuring the safe and proper use of any personal information you provide. Information collected on you during the study may be made available to others in the future for research purposes only, provided no one can identify you from the details provided.

**Thank you for your time and your consideration to participate in this study.**

**INFORMED CONSENT FORM – ELECTRONIC VERSION**

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**For research participant:**

* I have read the information sheet and freely agree to participate in this study.
* I have been provided with information about the risks and benefits if I participate in the study. I have had the opportunity to ask questions and these questions have been answered and explained to my satisfaction. I know who to contact if I need more information.
* I have understood that data collected from me could be shared with other researchers in the future (open access) as long as no one could identify me from these data.
* I understand that I have the right to withdraw from participation at any time and it will not affect my studies at the university.
* I have understood that my opinions will be audio/video-recorded and/or noted in writing if I agree to participate in this study, and that measures will be taken to ensure that no one can identify me from the data recorded.
* I will respect the confidentiality of all participants in the study. I commit not to disclose personal information about other participants or discuss their views with anyone else outside the group activities.

***Please check one option for each of the the following statements:***

**🞏 YES or 🞏 NO I AGREE** to participate in the study.

**🞏 YES or 🞏 NO I ALLOW** the team to audio/video-record and/or make notes on my opinions.

**🞏 YES or 🞏 NO I AGREE** that the data collected from me during the study or up to the point of withdrawal can be used for further analysis. I understand that if I choose to withdraw from an activity I will be given an opportunity at that time to ask for any relevant data to be deleted from the record.

By signing this document electronically I confirm what is written above.

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| Participant’s Full Name | Participant’s Email Address | Date |

**Participant’s ID: 55DXb - [\_\_|\_\_|\_\_] - [\_\_|\_\_|\_\_|\_\_]** *(filled by study team after the e-ICF is signed)*