















STUDY PROTOCOL

Exploring attitudes to research involving human subjects among Vietnamese university students: establishing a prospective longitudinal mixed-methods student cohort at the University of Medicine and Pharmacy at Ho Chi Minh City [version 1; peer review: 2 approved with reservations]

Vy Pham -Tram ¹, Nguyet Minh Nguyen ¹, Susan Heatherley¹, Kien Vu Duy¹, Bao Hung Vu¹, Giang Pham Thi Huong¹, Hang Nguyen Thi Thu ¹, Hong Huynh Thuy Phuong², Truong Thi Tuyet Thanh², Chi Le Phuong ¹, Thuy Nguyen Thi Van ¹, Trung Dinh The¹, Dong Thi Hoai Tam¹, Mary Chambers ^{1,3}, Katrina Lawson ^{1,3}, Jennifer Ilo Van Nuil ^{1,3}, Dung Do Van ², Tuan Diep Tran ², Evelyne Kestelyn ^{1,3}, Bridget Wills ^{1,3}

¹Oxford University Clinical Research Unit, Hospital for Tropical Diseases, Ho Chi Minh City, Vietnam

²University of Medicine and Pharmacy at Ho Chi Minh City, Ho Chi Minh City, Vietnam

³Centre for Tropical Medicine and Global Health, University of Oxford, Oxford, UK

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Abstract



Research capacity is increasing in low- and middle-income countries (LMICs), with progressive development in the range and complexity of studies being undertaken, often in collaboration with high-income country partners. Although senior local stakeholders are typically involved in ensuring that research is conducted according to accepted standards for ethical and scientific quality, to date there has been little exploration of the views of younger generations around the ethics of research involving human subjects.

We present our protocol to establish a longitudinal mixed-methods student cohort at the University of Medicine and Pharmacy at Ho Chi Minh City, Vietnam, that is investigating students' views around the ethics of clinical and public-health oriented research. We use a synergistic approach involving initial deliberative engagement activities (*e.g.* science cafes, debates) to inform participants about complex concepts, prior to formal quantitative and qualitative methods (surveys, focus group discussions and in-depth interviews) that are designed to explore the students' views in detail. We focus in

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2. **Suryane S Susanti** , Universitas Indonesia, Depok, Indonesia

Any reports and responses or comments on the

particular on dengue, as an example of a locally relevant disease, and probe students' thoughts on such themes as appropriate remuneration for research participants, involvement of vulnerable groups, use of human challenge trials in LMICs *etc.*

A snapshot of the cohort and its activities after one year is also presented; among 429 active students, primarily from the Faculty of Medicine, the proportions of male and female students were similar, the majority were from southern or central Vietnam where dengue is endemic, and available data indicates the cohort to be representative of the expected spectrum of socioeconomic groups.

The cohort provides a unique resource to investigate the views of young people on medical ethics, an important but hitherto underrepresented group in such discussions. Feedback indicates a clear interest in contributing thoughts and ideas to the development of clinical research in Vietnam.

Keywords

Vietnam, university students, attitudes, human subjects' research, mixed methods

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article can be found at the end of the article.



This article is included in the [Oxford University Clinical Research Unit \(OUCRU\) gateway](#).

Corresponding authors: Vy Pham -Tram (vyptk@oucru.org), Bridget Wills (bwills@oucru.org)

Author roles: **Pham -Tram V:** Data Curation, Formal Analysis, Investigation, Methodology, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Nguyen NM:** Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Resources, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Heatherley S:** Formal Analysis, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; **Vu Duy K:** Investigation, Methodology, Writing – Review & Editing; **Vu BH:** Investigation, Methodology, Project Administration, Software, Writing – Review & Editing; **Pham Thi Huong G:** Data Curation, Investigation, Writing – Review & Editing; **Nguyen Thi Thu H:** Data Curation, Investigation, Writing – Review & Editing; **Huynh Thuy Phuong H:** Conceptualization, Data Curation, Investigation, Methodology, Resources, Writing – Review & Editing; **Thi Tuyet Thanh T:** Project Administration, Resources, Writing – Review & Editing; **Le Phuong C:** Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Project Administration, Resources, Writing – Review & Editing; **Nguyen Thi Van T:** Conceptualization, Data Curation, Investigation, Methodology, Project Administration, Resources, Supervision, Writing – Review & Editing; **Dinh The T:** Conceptualization, Investigation, Methodology, Resources, Writing – Review & Editing; **Thi Hoai Tam D:** Conceptualization, Investigation, Methodology, Resources, Writing – Review & Editing; **Chambers M:** Conceptualization, Supervision, Writing – Review & Editing; **Lawson K:** Conceptualization, Supervision, Writing – Review & Editing; **Ilo Van Nui J:** Conceptualization, Supervision, Writing – Review & Editing; **Do Van D:** Conceptualization, Supervision, Writing – Review & Editing; **Diep Tran T:** Conceptualization, Supervision, Writing – Review & Editing; **Kestelyn E:** Conceptualization, Supervision, Writing – Review & Editing; **Wills B:** Conceptualization, Funding Acquisition, Investigation, Methodology, Resources, Supervision, Validation, Writing – Original Draft Preparation, Writing – Review & Editing

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Introduction

At the turn of the millennium the Global Forum for Health Research highlighted the uncomfortable truth that, while low/middle-income countries (LMICs) accounted for 85% of the world's population and 92% of the global disease burden, less than 10% of global spending on health research was dedicated to overcoming the health challenges prevalent in these countries^{1,2}. Subsequently the 2013 World Health Report emphasized the need for research evidence to be generated by all nations to achieve the goal of universal health coverage³. There has also been a conscious commitment to improve health in LMICs via the establishment of the United Nations Sustainable Development Goals (SDGs); in particular SDG3 endeavours to "Ensure healthy lives and promote well-being for all at all ages"⁴. An integral part of this commitment involves the promotion of partnerships between high-income countries (HICs) and LMICs to improve health inequalities by developing health research capacity in LMICs. In recent years there has been a marked increase in the range and complexity of studies undertaken in partnerships involving HIC and LMIC actors, most dramatically following the onset of the coronavirus disease 2019 (COVID-19) pandemic in early 2020^{5,6}.

Given the financial and structural inequalities that exist between LMICs and HICs, it is crucial that such partnerships are mutually beneficial and provide long-term health benefits for all partners and communities involved⁷⁻⁹. Although ethical and regulatory systems to support oversight of such research efforts are regularly reviewed, intermittent reports of unethical or inappropriate practices, together with a general lack of knowledge about clinical research among LMIC populations, can increase public anxiety^{10,11}. In turn this may contribute to development of anti-science views, potentially exacerbating the vaccine hesitancy that is becoming increasingly apparent globally¹²⁻¹⁴.

The Oxford University Clinical Research Unit (OUCRU) is a large-scale Wellcome funded clinical and public health research facility with sites in Vietnam, Indonesia and Nepal. For over 30 years, OUCRU has worked closely with local partners to coordinate a comprehensive programme of research focused on infectious diseases and other locally relevant health issues. One disease of particular importance for Vietnam is dengue, a mosquito-borne viral infection that results in major disease and economic burdens for the country^{15,16}. Disease pathogenesis, virology and immunology are complex and poorly understood¹⁷. No specific therapeutics are available and development of safe and effective vaccines is proving difficult¹⁸. Many types of dengue research are undertaken by OUCRU and its partners, including observational studies, cohort studies, therapeutic intervention trials and human-to-mosquito transmission studies, some of which involve vulnerable populations such as children and/or very sick patients in intensive care units. In addition, novel research approaches, including the potential use of human challenge models, are under consideration.

All research must be performed in accordance with internationally recognized standards for ethical and scientific quality, but

it is also crucially important that attention is paid to the views and principles of local stakeholders and research collaborators. Senior local stakeholders are always involved in discussions and decision-making about research performed by OUCRU and its partners, but as the breadth and range of activities expands there is increasing need for engagement with stakeholders at all levels of society to ensure that an equitable and balanced approach is adopted. The unique perspective of adolescents and young adults is increasingly being recognised, with the importance of listening to these views and involving them in advocacy roles and policy development highlighted in a recent Lancet editorial¹⁹. Although studies have been undertaken in various other countries to explore young people's views about research ethics²⁰⁻²², until recently no such research had been carried out to understand the opinions of younger generations of Vietnamese society about clinical and/or scientific issues related to research. Notably however an on-line survey was conducted during the pandemic to look at predictors of COVID-19 vaccine acceptability among Vietnamese health profession students²³.

In late 2019, with funding from Wellcome, we started a programme of work to explore attitudes towards research in humans across a range of different Vietnamese stakeholders, with a project entitled RESHAPE (RESearch in Humans: Attitudes and PERceptions). Under this umbrella we have developed a prospective longitudinal cohort of university students (the SEED cohort) enrolled at the Faculties of Medicine and Public Health at the University of Medicine and Pharmacy (UMP) at Ho Chi Minh City (HCMC), with the aim of exploring Vietnamese students' perceptions and views of clinical and public health orientated research. We plan to use the information generated to improve our understanding of public perceptions and possible barriers to acceptance of clinical research in Vietnam, in order to better design informational material and public engagement activities for future research, especially for novel or complex studies.

Here we present the protocol for the study, describing the approach we used to establish the cohort and the various techniques employed to explore the students' views. We also present an overview of the structure of the cohort after the first year of activity.

Methods

In setting up this prospective mixed-methods social science research platform our main goal has been to establish a cohort of university students undertaking their studies in Ho Chi Minh City who are willing to explore attitudes towards clinical and public health orientated research in Vietnam from the youth perspective.

We elected to focus our recruitment among medical and public health students, since it is possible that these individuals may become involved in the execution of clinical research studies in the future, either as junior clinicians or scientists contributing to data collection or laboratory studies, or potentially as future research participants. Secondly, we wished to recruit cohort members early in their university

careers and to follow them over several years, to assess how their advancing medical and scientific knowledge and awareness might influence their attitudes over time.

We are interested to assess socio-cultural factors that may contribute to these views, but rather than targeting students from particular geographical or socioeconomic backgrounds, we aim for broad recruitment across the student body. Although our overall approach is general, where appropriate we focus on dengue-related research, as an example of a specific disease that is of considerable relevance to this population.

Recruitment of participants to the SEED cohort

With formal agreement from the university governing body, each year promotional flyers are posted on relevant social media sites prior to a series of introductory talks given separately to 1st and 3rd students immediately after lectures/activities that the student body are expected to attend. The sessions are presented by members of the OUCRU RESHAPE team (comprising clinicians, social scientists, and public engagement and communication personnel), who use a variety of methods including formal presentations, short debates, question and answer sessions, icebreaker activities, and quizzes to increase interaction with students to present information about dengue and different types of clinical research, and also to highlight some of the important ethical and practical considerations involved in such research studies. These talks are intended to raise awareness of the rationale for developing the student cohort and to encourage students to volunteer if they find the ideas interesting but are not part of the standard curriculum.

After each talk, the students are given an information sheet or a link with an OUCRU contact point, offering an opportunity to formally join the student cohort. Those who express interest are invited to attend small group (10–20 individuals) meetings where more detailed information is presented about the planned activities within the cohort, and those who choose to proceed are invited to sign an Informed Consent Form (ICF). OUCRU has no official standing within the Vietnamese university hierarchy and the information sheet makes it clear that involvement is entirely voluntary.

Each student who joins the cohort is given a unique code which is used to identify them in all subsequent activities. Additionally, each student is asked to complete a demographic questionnaire (see extended data²⁴) describing their background, family structure and socioeconomic status.

Ensuring effective communication with cohort members

For informational purposes we use the project website (<https://www.reshape.oucru.org>) and [Zalo](#), a widely popular texting application in Vietnam. The website serves as the official communication channel, where cohort participants can browse general information about the project, view team member profiles, and learn about our activities. Zalo is utilised for quicker and more direct communication, with

different chat groups created for the different academic years; notifications are sent directly to every member in the chat group, so this platform is most suited to send logistic updates and important practical information to the students.

For engagement and general conversation, we created a private [Facebook](#) group, operated under the umbrella of OUCRU's official Facebook page. Only cohort participants may join, so the students can feel comfortable initiating and engaging in discussions with other members as well as the project team.

Finally, the SEED Ambassadors group helps the project team to connect with the students in a more intimate and friendly way. These ambassadors facilitate active two-way communication between the team and the student body, providing suggestions on how to engage with the students more creatively and effectively, while also acting as representatives of the cohort to raise opinions and give feedback.

Cohort activities

The first activity for all newly recruited students is a kick-off half-day seminar designed to introduce the students to each other, OUCRU and the study team, and to briefly review the material presented during the introductory talks. Subsequently a variety of important themes relating to clinical research in human subjects are approached sequentially, combining in-depth qualitative methods with synergistic engagement activities. We start with deliberative engagement activities designed to introduce the often-complex ideas related to a particular theme at interactive events (science cafes, science debates); at these events participants are encouraged to explore their thoughts and opinions in a non-threatening space where all ideas are welcomed. Subsequently, selected students are invited to participate in focus group discussions (FGDs) or in-depth interviews (IDIs) that examine that particular theme in more detail. Individuals who participate in any event receive a small sum (<10 USD) to compensate them for their time and effort.

For the first theme we focused on the broad question, "What is clinical research and how is it relevant to Vietnam?", to encourage students to become familiar with the general approach. A new theme is now introduced every 3–4 months, focusing on more complex ethical issues such as inclusion of vulnerable groups in clinical studies, how to set appropriate standards for remuneration of research participants, recruiting healthy volunteers for vaccine trials, use of human challenge studies in LMIC settings particularly on dengue. All students who are cohort members at the time a particular theme is explored are eligible to participate, but preference is given to students who have not previously contributed. We aim to provide each student at least one opportunity for active involvement each year they remain in the cohort.

Science cafés. We employ a modified science café format adapted from the general principles of the world café design (<https://theworldcafe.com>)^{25,26}. Groups of 30–40 students are

invited to attend a meeting during which general information on the topic of interest is first presented, incorporating visual aids and/or short games to explain complex concepts, following which groups of 6–8 students are asked to consider a series of questions related to the particular theme. Over about an hour, research team members observe and support, but do not direct, the ensuing conversations, following which student representatives summarise the main points discussed; the students' points, as well as any field notes recorded by the team, are then used to feed into the discussion guides used during related activities. Small gifts are presented to the student representatives who coordinate these group discussions, as well as prizes for other students considered by the project team to have been particularly proactive.

Science debates. Formal debates are commonly used as pedagogical tools in HICs but remain unfamiliar to students in Vietnam²⁷. The technique can be effective in encouraging individuals to consider different aspects of a problem in order to establish a position and express a viewpoint using supporting arguments and evidence^{28–31}. Groups of 40–60 interested students are informed in advance of the debate question, receive information on the basic principles and structure of a debate, and are given pointers to relevant on-line resources to explore the available evidence. At a preliminary meeting the students are asked to vote for or against the motion and are then separated into two approximately equal teams, in line with their choice where possible. The students are informed that each team's overall performance will be assessed in terms of style, strategy and content, and particular study staff make themselves available to the opposing groups to support them with background research. Subsequently, during the actual event, an experienced external speaker reiterates a summary of the general structure and rules for the activity, and the two sides are given 50 minutes to prepare together before nominating four representatives for the formal debate. The speakers from each team alternate their arguments for or against the proposition, with the final speakers summarising their team's overall position, after which a general discussion takes place before the student body votes again on the motion.

An adjudication committee, comprised of the external speaker and two senior SEED project staff, rates the overall performance of the opposing teams and provides feedback to the students on their efforts before awarding the committee prize to the winning team. In addition, a "people's choice award" is presented to the team favoured by the student body.

Focus group discussions and in-depth interviews. Following on from the engagement activities centred around a particular theme, students are purposefully selected to cover a range of socioeconomic backgrounds and are invited to attend either an FGD or an IDI. The FGDs are suited to gathering rich and diverse perspectives, stimulated by interactions between the students present, while the IDIs are employed later to cover more sensitive information or intricate themes in detail. Family FGDs are also arranged, involving small groups of students each accompanied by a chosen family member.

At these events we investigate the role of parents in students' decision-making.

Guides for the FGDs and IDIs are developed after reviewing the published literature around that theme and taking into account issues raised by the students themselves during the relevant engagement activities. The guides concentrate on questions related to perceptions of and assumptions around important concepts related to the theme, as well as practical aspects of different types of research. Additional topics and probes are included as necessary during the events, depending on the nature of the evolving discussion.

Student-led participatory initiatives. In addition to the events listed above, we also incorporate student-led approaches in our engagement agenda. As an example, cohort members are intermittently offered opportunities to conduct their own fieldwork, by interviewing their peers or family members to explore perceptions and attitudes related to SEED project topics of personal interest to themselves. Following appropriate training the students are encouraged to take the lead in developing ideas for these conversations, and then to use their mobile phones to record interviews and upload a copy of the unedited material to the OUCRU secure server for review and assessment by project staff. Subsequently, some students are selected from among those submitting video interviews (based on the length, technical quality and content of their submission), and trained to make more complex short films that are designed to be shown publicly.

Another opportunity involves creation of scientific posters or short (2–3 minute) informational videos that focus on topics relevant to the project. Interested students are invited to attend a training workshop where they receive guidance on how to develop informative content and select creative and effective communication methods. The students are then encouraged to develop their own material, working either as individuals or together in small groups, with SEED team members providing advice and support as necessary. The resulting posters and videos are then showcased at an exhibition held at UMP, that aims to raise awareness of the SEED cohort within the wider student population. A panel of judges selects winning entries in different categories and prizes are presented during the event; subsequently, the posters and videos are also exhibited in a public space within the university, thereby encouraging wider dissemination of the students' ideas.

The experience of taking the lead in the research cycle, from developing an initial idea through to execution of all the necessary activities required to deliver an output suitable for public display, has proved very popular with the students³². These initiatives also encourage the bi-directional flow of thoughts and ideas between SEED project staff and cohort members, ensuring the study team's input is responsive and supportive rather than unidirectional and reinforcing our efforts to ensure the students understand that their knowledge and capabilities are respected and valued, all of which are important principles of participatory research³³.

Ethical approvals and informed consent

The research programme follows international standards for the ethical conduct of research involving human subjects, and all staff involved have up-to-date training in Good Research Practice (GRP)³⁴. The protocol and related documents have been reviewed and approved by the Ethics Committee at UMP (Reference number: 351/UMP-BOARD approved on 26 May 2020) and the Oxford Tropical Research Ethics Committee (OxTREC Reference: 540-20 approved on 02 July 2020).

All participants, who must be aged 18 years or more, are provided with a detailed Participant Information Sheet (PIS) before signing the ICF. Cohort members are asked at intervals if they would consider inviting their parents/adult family members to certain activities; if so, the students discuss the study with their relatives and provide them with a copy of the PIS/ICF to read. Relatives who wish to participate contact the study coordinator to register their interest, who then invites them to attend relevant family FGDs or IDIs as they occur. Staff review the PIS/ICF with family members before an activity commences, and all present are asked to sign a consent form.

Specifically with respect to video or filmmaking activities, verbal consent is recorded on camera at the start of the video/film, in accordance with the protocol approved by the Ethics Committees at UMP and OxTREC. Since visual data collected by the students could reveal the identity of individuals involved, students receive training in GRP before participating in any collaborative data collection. The initial verbal consent is an agreement to be interviewed and filmed by the students, with the understanding that any resulting material is intended only for internal use among the study participants and researchers. However, possible wider uses of the data are discussed with all participants prior to filming, and they are asked specifically if they would permit their data to be used for public activities. Subsequently if any material is selected to be made public, a draft of the final product is sent to all individuals involved in that particular video/film, so that they may decide if they wish their contribution to be included; at this time they are asked to provide written informed consent.

Data collection and analysis

Both quantitative and qualitative data collection methods are employed. As well as the demographic questionnaire, all students are asked to complete a Comprehensive Survey (see extended data²⁴) designed to explore their general perceptions of and attitudes towards clinical research, when they attend their first event and again at serial time points during the life of the project to explore changes over time. To develop this tool, we carried out translation and back translation, as well as pilot testing and cognitive interviews with representative students to check content validity and ensure the final Vietnamese wording was appropriate.

We use standard statistical methodology to describe the general characteristics of the cohort population. We aim to

engage widely with students and their families, to ensure broad representation across the spectrum of socio-economic backgrounds. The approaches used to classify the socio-economic status of each family, and the occupational categories of the parents/guardians, using information provided in the demographic questionnaire are described in the extended data²⁴.

Information from field notes, audio recordings and video files are transcribed into electronic word documents, using only the unique identifying code assigned to each participant at recruitment. Information from the FGDs and IDIs of cohort participants and their family members is then translated as necessary, and the data uploaded into [Nvivo 12](#) for management and coding. Alternatively, the free Coding Analysis Toolkit (CAT) is another option that can be utilized for performing comparable tasks. For the qualitative research component, we use a grounded theory approach³⁵ employing alternating cycles of data collection, interpretation and analysis^{36,37}. First, we identify recurring ideas and concepts from the initial coding of data and generate a preliminary codebook. This is then used to pose emergent enquiries that require further exploration; following adaptation of the interview discussion guides, additional data is gathered through a second round of in-depth interviews with more students. Finally, we adjust and combine all the coding with more field data and further review of the literature and discuss the emerging themes until the final codebook is established.

Confidentiality and data protection

Participants are assured that all information generated, including all audio and visual digital media, will remain confidential and be securely stored in accordance with OUCRU policies.

Quantitative information is collected primarily via on-line questionnaires and surveys using the [JISC Online Survey](#) platform. Upon completion of any survey the data are exported promptly to the OUCRU secure server. The qualitative data takes the form of written field notes and audio/video files used for recording the various activities. All data for which there is no clear consent are destroyed, while audio and video files obtained with appropriate consent are transferred to the OUCRU secure server. Ownership of all images and videos collected by the cohort participants on their own devices remains with the students themselves; their responsibilities with respect to confidentiality are highlighted on the PIS/ICF that each student signs at the start of the study. All material recorded on project equipment belongs to the project and the students may not keep copies themselves unless the material is in the public domain.

Original essential documents and any audio/video files that include informed consent are maintained for a minimum of three years after the last interaction with any of the cohort participants. Subsequently these documents, together with all other materials generated from project activities, will be stored in an electronic archive on the secure OUCRU server for an additional period of 10 years.

Adaptations to study procedures related to COVID-19

As a result of the COVID-19 pandemic, all activities were transferred from in-person to on-line formats from June 2021 until March 2022. Activities are carried out in compliance with local government regulations, UMPs planned teaching schedule (*i.e.* in-person *versus* on-line lectures), and the OUCRU policies for health and safety in place at any particular time.

The format for the on-line activities remains very similar to the in-person events but conducted via a web platform making use of break-out rooms and digital notice boards and supported by an active social media presence. To minimise social anxiety and encourage a collegiate atmosphere, participating students are sent a colourful project backdrop beforehand. Support staff are also on hand to deal with any technical issues and to encourage participants to feel comfortable in the on-line space so that they are empowered to express their opinions.

Timelines and study status

From May to July 2020, we obtained the necessary ethical approvals to set up the cohort and developed relevant materials for the initial engagement activities. The first introductory talks and enrolment events took place in July 2020, resulting in recruitment of some 200 students. Subsequent recruitment waves have occurred at intervals up to December 2021, typically in conjunction with the annual new student intakes at UMP.

Cohort activities started in October 2020 and take place intermittently throughout the university calendar year, with novel themes introduced every few months. The engagement activities and in-depth social science qualitative methods are synergistic with each other; events related to a particular theme are scheduled to occur in parallel so that findings from the engagement work can inform the social science data collection and vice versa. The themes previously highlighted in the Methods section were covered sequentially during the first 2 years of the project, culminating with a major theme focusing on use of human challenge methodology in LMICs during the latter half of 2022. For the current work (2023), we are exploring cross-cultural differences in perceptions and attitudes to human challenge studies among comparable groups of students recruited from different countries.

In this manuscript, we present a detailed summary of the study design and methodology used to recruit and maintain the Vietnamese cohort, alongside a comprehensive description of the practical aspects of the various engagement and social science activities undertaken. We are presently analysing the qualitative and quantitative data generated around particular themes of interest and are using the findings to explore several important research questions. By providing a clear methodological description of the cohort and its complex activities, we hope to facilitate understanding and interpretation of our findings as they are published. An overview of the general structure of the cohort at one year is presented in the next section.

Overview of the cohort structure at one year

Although the cohort continues to evolve, for the purposes of this manuscript we concentrate on describing the general structure as of 31st July 2021. At this time, 1360 students had attended at least one introductory talk and a total of 439 students had consented to join the cohort (Figure 1). Among the 439 students enrolled, 10 had neither completed a questionnaire nor attended any events (inactive students). An additional six students had formally withdrawn citing “time pressure”, but all six consented for their data to the point of withdrawal to be retained for analysis. A total of 52 activities (either offline or online) were organised during the first year, with 370/429 (86%) active students attending at least one event.

Summary demographic information for 427/429 (99%) of these active students is presented in Table 1. Most participants were from the Medical (71%) rather than the Public Health (29%) Faculty. The majority were representative in age of their university year-group (18–22), with only two students being older than 23, (25 and 29). The overall proportion of male and female students who enrolled was similar, in line with the demographics for UMP admissions in the relevant years. Subsequent involvement in the various cohort activities was also reasonably balanced between male and female students. Most students (379/424, 90%) were ethnic Kinh, the most common ethnicity in Vietnam, with only a few other Vietnamese ethnic minority groups represented, plus a few individuals of Cambodian Khmer and one of Thai descent. Students’ family sizes were generally small. In most instances at least one parent/guardian had completed higher/tertiary education (61%) and in 148/402 (37%) of the families for whom classification was possible, at least one parent/guardian was employed in a managerial/professional capacity.

Figure 2 presents information on the provinces across Vietnam from which 412/429 (96%) of the students originated (*i.e.* the family home location), plus an assessment of socio-economic status for the students who provided information in this domain. A majority had been brought up in provinces in southern or central Vietnam, with relatively few from Northern provinces. Around 35% were from the South-East region (which includes HCMC), with another 25% coming from the Mekong Delta and 25% from the South-Central Coastal region.

A total of 256 students (60% of the cohort) provided information on socio-economic status, and among this group almost all families fell within the low-normal or high-normal categories (see extended data for definitions²⁴); only 8/256 (3%) came from “poor” families and 10/256 (4%) from “wealthy” families. A “poor” family background was most evident among students from the North/South-Central Coastal areas or from the Central Mountains, where the regional poverty rate is reported to be 1.5 to 2 times higher than the national average^{38,39}. “Wealthy” families were also identified in the Central Coastal provinces, as well as in the South-East around HCMC, in keeping with published literature indicating these areas as among the most affluent in Vietnam⁴⁰.

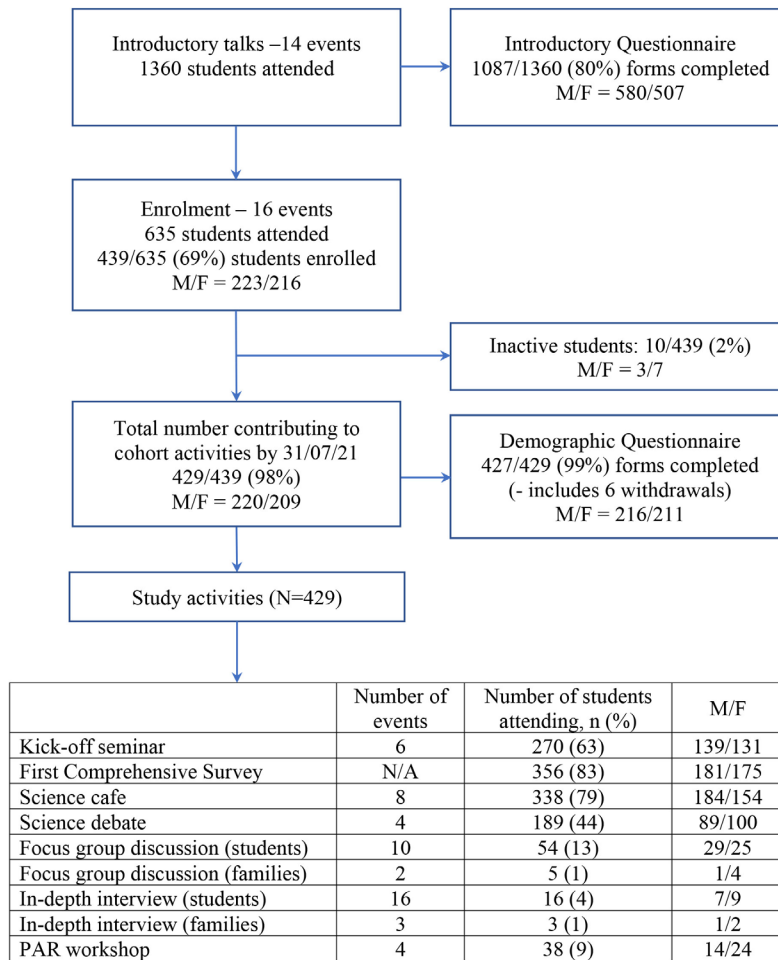


Figure 1. Flow chart of recruitment numbers and cohort activities up to 31st July 2021.

Discussion

Here we have outlined the methods used to develop a large social-science-oriented student cohort at the University of Medicine and Pharmacy at Ho Chi Minh City, which aims to investigate students' views of clinical research in human subjects and have described the general structure of the cohort after one year. Although efforts to explore students' opinions on various aspects of research ethics are becoming more common, most studies have been cross-sectional and have focussed on specific topics^{41–43}, and often have involved only small numbers of participants^{44–46}. To our knowledge this is the first time this approach, *i.e.* exploring the youth viewpoint on a range of complex ideas related to clinical research among a large number of university students and specifically incorporating a longitudinal perspective, has been employed.

We hoped to include a broadly representative group of Vietnamese students with an interest in biomedical research, ideally engaging with individuals from a wide spectrum

of geographic locations and social backgrounds across the country. Although UMP has a broad recruitment and admissions policy, representation from northern Vietnam has proved to be limited, probably reflecting the fact that many students from the north choose to attend universities that are closer to home. However, the cohort does include members from all 37 provinces across southern and central Vietnam. This is relevant given our particular focus on dengue research. Dengue is hyperendemic in southern Vietnam, and common in the central region, so it is likely that some cohort members will have had personal experience of dengue within their circle of family and friends, that may shape their knowledge and attitudes. Analysis of the accumulating data will take such prior exposure into account, potentially providing interesting insights into the effects of personal experience on the views expressed by students.

Identifying socioeconomic status was complex; many students were unaware of the precise details of their parents'

Table 1. Overview of the demographic characteristics of students in the cohort on 31st July 2021, stratified by their academic year at enrolment.

| | N | First year (n=204) | N | Third year (n=223) |
|---|-----|--|-----|---|
| Age | 203 | 18 (18 – 19) | 222 | 21 (20 – 21) |
| Gender - male | 204 | 101 (50) | 223 | 115 (52) |
| Year enrolled at UMP | 204 | - 2019: 22 (11) - 2020: 182 (89) | 223 | - 2017: 56 (25) - 2018: 167 (75) |
| Department[§] - Medicine - Preventive Medicine - Public Health - Nutrition | 204 | - 139 (68) - 22 (11) - 25 (12) - 18 (9) | 223 | - 163 (73) - 34 (15) - 18 (8) - 8 (4) |
| Ethnicity - Kinh - Hoa - Khmer - Other | 203 | - 182 (90) - 13 (6) - 4 (2) - 4 (2) | 221 | - 197 (89) - 11 (5) - 5 (2) - 8 (4) |
| Family size - Adults living in family home - Children living in family home | 199 | - 2 (2 – 3) - 1 (0 – 1) | 222 | - 3 (2 – 4) - 0 (0 – 1) |
| Educational level of parent/guardian* - Primary education - Secondary education - Higher/tertiary education | 170 | - 16 (9) - 46 (27) - 108 (64) | 203 | - 31 (15) - 52 (26) - 120 (59) |
| Occupational category of parent/guardian*^{&} - Managerial/professional - Technical and clerical support, service and sales - Skilled workers - Unskilled workers - Armed forces - Unknown | 204 | - 66 (32) - 68 (20) - 34 (12) - 16 (7) - 3 (1) - 17 (8) | 223 | - 82 (37) - 71 (32) - 47 (21) - 10 (4) - 5 (2) - 8 (4) |

Data are presented as median (interquartile range) for continuous variables and number (percentage) for categorical variables.

Note that 2 of the 429 students enrolled in the cohort by the 31st July 2021 did not complete the demographic questionnaire.

[§]: The Public Health Faculty includes the departments of preventive medicine, public health and nutrition

*: For each family, the highest attainment for either parent (or a guardian) is presented

[&]: Occupational status was classified in line with the International Labour Organization's recommended system, ISCO-08 (see extended data for details)^{24,47}.

educational background and income or were unwilling to disclose this information. It is common across many cultures to be guarded about revealing personal financial information⁴⁸. Additionally, many Vietnamese families engage in informal small-medium business activities alongside regular employment so it might be difficult for students to assess their families' overall income⁴⁹. Although socioeconomic determinants clearly influence many aspects of an individual's life (including access to higher education in Vietnam⁵⁰, determining appropriate ways to assess socioeconomic status in a particular context is not straightforward^{51,52}. However, although use of poorly defined, potentially inadequate, indicators of socioeconomic status may influence research findings^{53,54}, such data can still be useful to describe a research population and ensure that different community groups are well represented⁵¹. In our study, for the 58% of the cohort from whom we obtained some data allowing us to infer socioeconomic

status, the relative proportions of the different strata were in keeping with what might be expected in different parts of the country. Thus, while recognizing the limitations of the socioeconomic assessment we suggest that participants in our FGDs and IDIs (selected on this basis) are broadly representative of the socioeconomic distribution of the cohort.

However, it is also important to note that most cohort participants were raised in households with a background of high educational achievement and/or professional careers among the parents/guardians. This pattern is not typical of current Vietnamese society, where only 13% of Vietnamese adults have attended tertiary education⁵⁵. Since young people often follow the career paths of their parents⁵⁶, and since we are approaching students enrolled in courses at a prestigious university in HCMC with high educational entrance requirements, these findings are not unexpected. It is likely

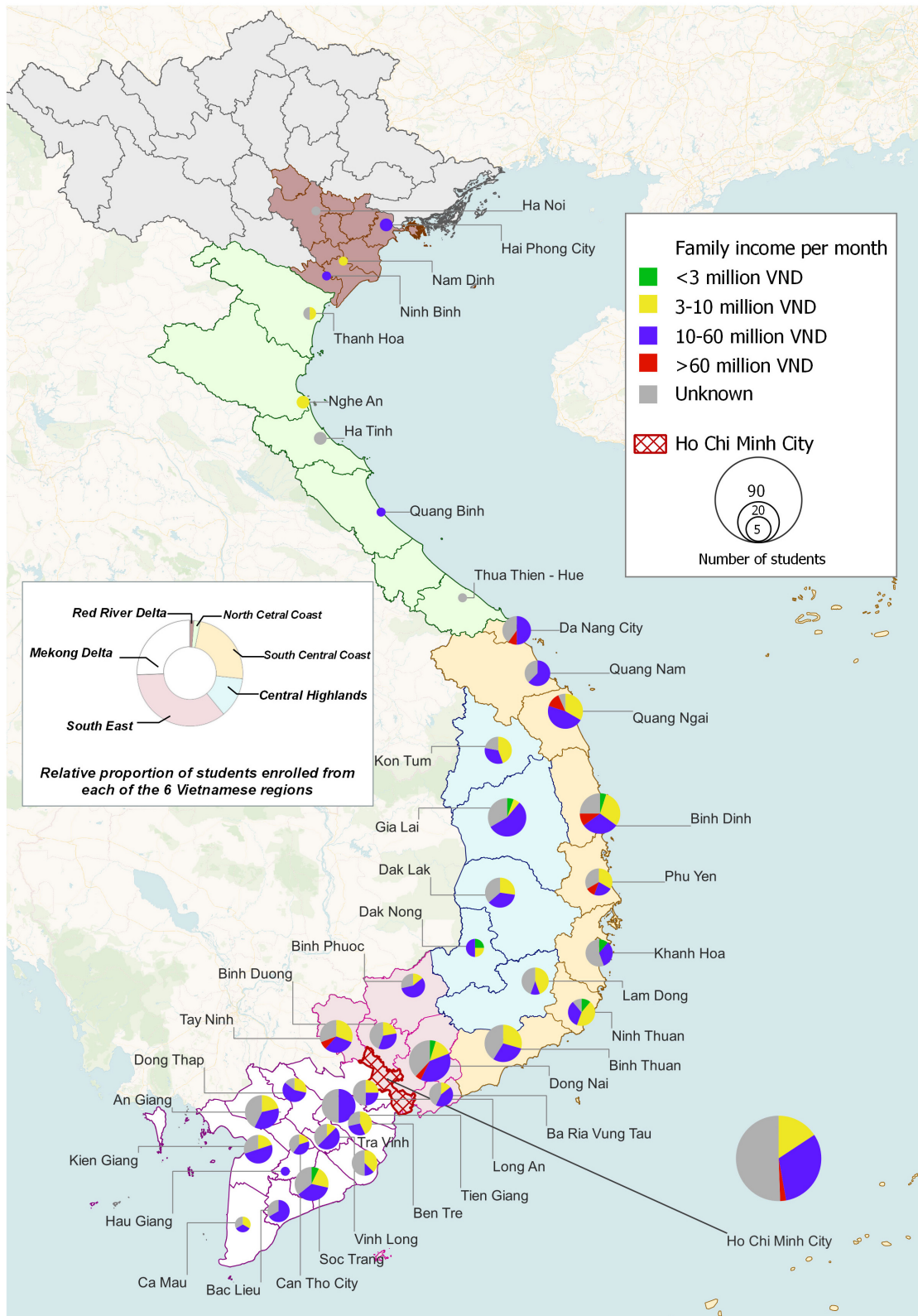


Figure 2. Distribution of students' home addresses across Vietnam. The map depicts the distribution of students' home addresses across Vietnam, at province level, for the 412/429 (96%) of students who enrolled during the first year of the cohort and declared this information. The students' personal assessments of their families' monthly income in Vietnamese Dong is also presented, as a proxy for socio-economic status. Note that only 256/412 (62%) of the students provided information in this domain.

that some of these students may become Vietnamese thought leaders of the future so exploring and understanding their developing views on clinical research and research ethics is valuable in itself; however, we recognize that the findings may not be applicable among young people generally across the country.

Given that many of the concepts proposed for discussion with the student body are complex and/or novel, and that cohort members are recruited from different year groups and from a range of medical and public health disciplines, we elected to use an approach relying on deliberative engagement prior to our FGDs and IDIs. This is a relatively new technique designed to educate and inform participants in a balanced non-directed way about a particular topic⁵⁷, thereby laying the groundwork for use of formal qualitative data-collection methods to explore participants' thoughts and ideas more effectively later – *i.e.* students attending the FGD/IDIs are already relatively familiar with the primary themes and are thus more likely to be prepared to talk about their own views on complex issues during the interviews. Although public engagement is increasingly being employed to improve acceptability and implementation of innovative scientific and health-related research efforts^{58–60}, as well as to support introduction of new public health and/or disease prevention strategies^{61–63}, deliberative techniques also enable the public to be involved in shaping novel research programmes and potentially in contributing to shared decision-making about what is appropriate in a particular context. Since the information presented in the engagement activities may bias subsequent discussions, we take care to present both positive and negative aspects of each topic, and also encourage the attendees to review a range of literature and audio-visual material covering the full spectrum of views on the topic before attending an FGD or IDI. Overall, the deliberative paradigm helps to overcome knowledge gaps, improves data quality, and encourages participants to become more involved in the conversation^{57,64–66}.

From the outset we recognized that developing practical and efficient communication pathways with cohort members would be essential to the success of the project. The various methods we employed were quite effective during the initial phase, and were subsequently augmented by positive reviews from the ambassadors' group as the project became more established. Later, when all of our activities had to move to an online platform, the Facebook group proved to be an ideal tool to interact with students in a meaningful way. Utilising different features of Facebook (comment, share, polls), we created various campaigns and activities to keep students engaged and interested in the project despite an extended period of social distancing, successfully maintaining the 2-way relationship between students and project staff during this time.

Various adaptations were made to facilitate delivery of the cohort activities virtually, including holding preparatory online meetings to explain procedures and deliver background material prior to big engagement events, use of break-out rooms to provide additional virtual space for group discussion during events, ensuring immediate access to technical support for attendees via a live chat-box *etc.* In addition to COVID risk reduction, online participation saved the students' time travelling to event venues, and offered opportunities to more students to contribute their thoughts, but some individuals clearly found it uncomfortable to express their views on camera, and technical issues related to internet speeds and/or incompatible equipment frequently occurred. Despite these shortcomings, attendance was typically high at these events and the feedback remained generally very positive. However, both the research team and the students recognized that the vibe, inclusivity and liveliness of the interactions between attendees during in-person events could not be maintained to the same degree during virtual events, and the return to in-person events in recent months has been generally welcomed.

Summary

A large mixed-methods cohort study has been established in HCMC, Vietnam, designed to explore the attitudes and perceptions of university students towards a range of important themes relevant to clinical research and medical ethics. The student cohort provides a unique resource to investigate the views of this important but hitherto underrepresented group in Vietnamese society; we anticipate that the ensuing reports will provide rich and rewarding insights from the perspective of young people, as well as encouraging continued civic engagement among the participants. Feedback from the students themselves indicates an overwhelmingly positive response to the cohort activities and a clear interest in contributing thoughts and ideas to the ongoing development of clinical research in Vietnam.

Data availability

Underlying data

Oxford University Research Archive: Demographic data generated from “**Establishing a mixed-methods student cohort in Vietnam**”, <https://doi.org/10.5287/ora-r5b8py5aa24>.

The project contains the following underlying data:

- Demographic_Data+2023.03.27.xlsx

Extended data

Oxford University Research Archive: Oxford University Clinical Research Unit “**Establishing a mixed-methods**

student cohort in Vietnam” supporting documents, <https://doi.org/10.5287/ora-r5b8py5aa>²⁴.

The project contains the following extended data:

- Extended Data_Demographic Questionnaire
- Extended Data_Comprehensive Questionnaire
- Extended Data_Classification of Occupational Status
- Extended Data_Assessment of Socioeconomic Status

Reporting guidelines

Oxford University Research Archive: SRQR checklist for “Establishing a mixed-methods student cohort in Vietnam”, <https://doi.org/10.5287/ora-r5b8py5aa>²⁴.

Data are available under the terms of the [Creative Commons Attribution 4.0 International license \(CC-BY 4.0\)](https://creativecommons.org/licenses/by/4.0/).

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We are most grateful to the many individuals at UMP who facilitated the implementation of the study. Similarly, we would like to express our appreciation of the support received from OUCRU’s Administration and Information Technology staff with respect to event management and logistics arrangements. Lastly, we are especially grateful to all the students involved, in particular the Student Ambassadors, without whose infectious enthusiasm and willingness to contribute, development of the cohort would not have been possible. We would also thank University of Oxford, Oxford, United Kingdom for sponsoring this study.

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Suryane S Susanti

Universitas Indonesia, Depok, West Java, Indonesia

Abstract:

This is very good abstract which has already comprises study background, aims/objectives, methods, results and conclusion. It would be more complete if the authors provide more information on the rational of the study which related to aim and objectives.

Background:

It is a very interesting and important subject where the authors have provided related evidence based. However, the background section is less justification on why it focuses on exploring attitudes and the methods used. I suggest therefore to rephrase the background section to focus on this justification of this study which lead to the study aims and objectives.

Methods:

The authors should elaborate more on the qualitative method. How does the mix method works? Provide more information on how the cohort study works with mix method.

Discussion:

Within the discussion chapter the author should not only describe the findings and when comparing with other study should also include the reason why it is different from the previous study. What make this study different from the previous similar studies? Would be useful if the authors could explain any research gap identified within the study?

Overall this is an interesting and adequate study

Is the rationale for, and objectives of, the study clearly described?

No

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: (maternal health, women health, family and community health, disaster nursing, disability study and spiritual care)

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 03 Apr 2024

Vy Pham-Tram

Thank you for your positive feedback and constructive comments on this article. Below, we address each point of the comment report with our responses formatted in *italics* font. We also made adjustments to our new manuscript version with regards to some of your suggestions.

1. Abstract:

Unfortunately, due to the word count limit we are not able to add further details to the abstract. However, in the Background section we have provided additional details linking the rationale for the study to the aims and objectives – see below.

2. Background:

Thank you for the comment. We have expanded the Introduction to provide better linkage with the study aims, including presenting more information on why understanding attitudes is important. We have also expanded the section discussing the ethical barriers, as per the comment from Reviewer #1.

3. Methods:

Thank you for this suggestion. We have added more detail in the Methods section to describe the rationale for a mixed-methods approach to data collection, as well as to provide clearer information on how we carried out the data collection in practice. We have also clarified our overall approach to the themed interactions with the student cohort members, i.e. we highlight the concept of integrating the two main components (deliberative engagement and mixed-methods data collection) to operate synergistically to explore major ethical themes.

4. Discussion:

Actually, although some reports are emerging that describe cross-sectional or disease-focused studies which specifically explore ethical issues in Vietnamese populations (details now incorporated into the Introduction section), to our knowledge there have never been any longitudinal ethics studies conducted in Vietnam nor any that focus on the youth perspective. We comment on this in the Discussion, and, since comparison with previous studies is not possible,

we focus instead on discussing the importance of the study and review some of the challenges encountered during the first year of implementation. The intention in this paper is to describe the methodology we used to establish the cohort and the techniques we employed to explore the students' views, and also to present a big-picture overview of the structure of the cohort after one year. In subsequent papers we will describe our findings in relation to particular ethical concepts/questions, and at that time we will be in a position to highlight differences from previous work, comment on any research gaps we identified etc.

Competing Interests: No competing interests were disclosed.

Reviewer Report 21 November 2023

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John Noel Viana 

Justice and Technoscience Laboratory (JusTech), School of Regulation and Global Governance (RegNet), College of Asia & the Pacific, Australian National University, Canberra, Australian Capital Territory, Australia

The paper presents the protocol for and first-year progress of a mixed-methods study that explores the attitudes of UMP students on dengue clinical research. Overall, I find the study really interesting and important, given the under-representation of Southeast Asian countries in ethics research. I support the publication of this protocol and study update; however, the authors can make several revisions to further improve the quality of their paper.

First, the abstract should specify that the project is on students' views on dengue research (and not just on dengue, in general).

In the Introduction, the authors could include some statistics on the prevalence and economic impact of dengue in Vietnam. They could also provide more information on the specific types of dengue research, especially the ones supported by OUCRU, in Vietnam and the ethical/societal issues associated with these types of research, as discussed in other contexts/countries. It would also be great if the authors could include additional information on general views of Vietnamese people towards health/medical research; or if this is not available, relevant research on views of people in other Southeast Asian countries.

There are also additional details that the authors could include in their Methods section. They need to explain why they chose to recruit 1st and 3rd year students, in addition to providing a brief background on the four degrees that are covered (Medicine, Preventive Medicine, Public Health, and Nutrition). The authors also need to describe the themes that they intend to explore in the study, and how were these themes identified. Are the authors just planning to discuss ethical

issues in research, or are they also planning to cover issues associated with partnerships between high and middle/low-income countries, given that this was extensively described in the Introduction? It is also a bit unclear who will be interviewed, recruited to participate in a focus group discussion, and/or surveyed. Does each student only have to participate in the kick-off seminar, and they are then free to choose which cohort activity to join? Or are there cohort activities that are required for all participants, especially if the study aims to determine changes in attitudes towards clinical research from participation in different activities? Will the authors be comparing the impact of different kinds of activities on students' attitudes towards/awareness of issues in clinical research? The authors also need to describe if they have a target number of initial interviewees, focus group discussions, and number of participants in a focus group discussion. The authors also need to indicate whether family members that will be interviewed and non-students involved in participatory initiatives will be remunerated.

The section on Study Status should directly include some information on what counts as a "poor" or "wealthy" family. Figure 1 can also be made more comprehensive by adding a column to the left (or boxes) that indicate when (month and year) each phase was conducted. If possible, the flowchart could also include a section indicating planned future activities (after July 31) to help readers visualize the entire project.

In the Discussion, the authors could describe how socio-economic status, educational level of family, ethnicity, and/or home address could impact/influence attitudes towards health/clinical research. They might also briefly touch upon how professional training (public health vs. medicine vs. nutrition) can influence understanding of ethical/societal issues in research.

Finally, the authors might consider double checking their punctuation, especially comma use, for consistency. For instance, a comma should be placed after "of the millennium" in the first sentence of the Introduction. Moreover, "One disease of particular importance" can be replaced with "One disease of particular concern".

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: bioethics, health equity, social studies of science

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have

significant reservations, as outlined above.

Author Response 03 Apr 2024

Vy Pham-Tram

Thank you for your feedback on this article. Here, we'd like to go over each point in the reviewer's report. We will quote the reviewer's comment and provide a response directly below it. 1. "First, the abstract should specify that the project is on students' views on dengue research (and not just on dengue, in general)." >> *Thank you for pointing this out. We have amended this in the abstract.* 2. "In the Introduction, the authors could include some statistics [.....] if this is not available, relevant research on views of people in other Southeast Asian countries." >> *The introduction has been revised and additional text has been incorporated to address these points.* 3. "There are also additional details that the authors could include in their Methods section. They need to explain why they chose to recruit 1st and 3rd year students, in addition to providing a brief background on the four degrees that are covered (Medicine, Preventive Medicine, Public Health, and Nutrition)." >> *More information has been added to the paragraph describing why we recruited students early in their academic careers. Essentially, by recruiting first and third years studying at the medical and public health faculties at UMP and following them over time, after 3 years the cohort including representatives in each academic year studying across the various courses available at UMP. (To approach all the students in all the academic years across both faculties would have involved thousands of students, since UMP admits in excess of 700 students to its various courses each year – this would have been impossible for our team both logistically and financially.) A short summary of relevant information describing the various degrees offered at UMP is provided in the appendix, since including this level of detail in the main text might distract readers from the main content of the manuscript.* 4. "The authors also need to describe the themes that they intend to explore [...] issues associated with partnerships between high and middle/low-income countries, given that this was extensively described in the Introduction?" >> *We have added a short explanation on how the initial themes were selected. As we expected, the structure and quality of research partnerships between HIC and LMIC actors has figured prominently in the students views on the ethics of human subjects' research in the Vietnamese context. However, the primary purpose of this paper is to describe the methods we used to establish the cohort. We intend to publish the detailed findings from our work in a series of related publications in due course.* 5. "It is also a bit unclear who will be interviewed, recruited to participate in a focus group discussion, and/or surveyed." >> *In the section describing "cohort activities" we have added more detail about advertising the engagement events related to a new theme to the whole cohort, then selecting groups of students for these activities from among those who express interest, and subsequently selecting a sub-group of those who participate in an engagement event for the FGDs/IDIs relating to that theme. With respect to the surveys, all students in the cohort are asked to complete the demographic questionnaire and comprehensive survey as soon as possible after enrolment. At the start of each academic year all students still involved in the cohort are asked to complete the comprehensive survey again.* 6. "Does each student only have to participate in the kick-off seminar [...] especially if the study aims to determine changes in attitudes towards clinical research from participation in different activities?" >> *After recruitment (with appropriate consent), all students are encouraged to attend a kick-off seminar, though not all are able to fit this in due to their busy schedules. Later, all the students in the cohort at the time an engagement event is planned for a particular theme, are invited to express*

interest to take part if they wish. However, for each event numbers are limited by the venue capacity and by the number of staff available to support the event. Individual students are then selected to attend on a first come first served basis after ensuring that students who have not been able to take part previously (or recently) are first offered a place. All activities are voluntary, and no student is "required" to attend any event. We have very active student ambassadors who encourage participation, and actually most activities are very oversubscribed. We plan to look at big picture changes in the students' views by examining the serial comprehensive surveys that are completed each year. For the quantitative data, individual themes are being explored sequentially; therefore, although we may see effects related to age/year of study within a theme, we will not attempt to evaluate changes related to exposure to study activities over time. 7. "Will the authors be comparing the impact of different kinds of activities on students' attitudes towards/awareness of issues in clinical research?" >> This is not included as an objective of the main project. However, in a separate piece of work we are exploring the student experience related to membership of the cohort, using a journey mapping approach after their involvement has ended. As part of this effort, we are examining the views of a small number of students about the influence of different activity types and whether they felt being involved changed their views about research in a meaningful way. 8. "The authors also need to describe if they have a target number of initial interviewees, focus group discussions, and number of participants in a focus group discussion." >> The intended numbers of participants for each activity type have been added to the manuscript. 9. "The authors also need to indicate whether family members that will be interviewed and non-students involved in participatory initiatives will be remunerated." >> Family members who participate in FGDs are remunerated the same standard amount for their time as the student participants. The student-led participatory activities are competitive in nature, and the time and effort expended by students is variable. There is no monetary benefit, but comprehensive skills training is provided for those who wish to take part, and a series of prizes is awarded to the best entries in several different categories, as judged by an independent panel. All students who submit an entry also receive a small gift of appreciation and a certificate of recognition for their participation. 10. "The section on Study Status should directly include some information on what counts as a "poor" or "wealthy" family. Figure 1 can also be made more comprehensive [...] include a section indicating planned future activities (after July 31) to help readers visualize the entire project." >> Information on how we classified socio-economic status is included in the Appendix, and we feel adding this level of detail to the main document could distract the reader. Therefore, we prefer to retain this information in the Appendix. Figure 1 is a summary of the events that took place during the first year, indicating the numbers of students exposed to or attending each type of event. Actually, the timing of the various activities overlaps as many events took place in parallel. We have designed a schematic (Supplementary Figure 3) to present the general flow of activities over the first year but feel it would be too confusing for the reader to include all the actual dates in Figure 1. Other than as described in general here, we do not have an overall plan of the entire project. Thematic activities are arranged in a flexible manner, being responsive to the interests of both the research team and student cohort members as the project progresses. 11. "In the Discussion, the authors could describe how socio-economic status[...] how professional training (public health vs. medicine vs. nutrition) can influence understanding of ethical/societal issues in research." >> In the Discussion section we comment on the relevance of demographic and socio-economic characteristics and indicate that these factors can influence individuals' attitudes towards research and research ethics. However, the intention in this paper is to describe the methodology we used to establish the cohort and the techniques we employed to

explore the students' views, and also to present a big-picture overview of the structure of the cohort after one year. In subsequent papers we will describe our findings in relation to particular ethical concepts/questions, and at that time we will explore relationships with these, and other, factors. Regarding the potential impact of professional training, we agree that students' perception may be influenced by knowledge gained through their academic training; when appropriate this will be included in our analyses related to particular topics. 12. "Finally, the authors might consider double checking their punctuation[...] can be replaced with "One disease of particular concern". >> Grammar and syntax are continually evolving and there are differing views on many points - e.g. use of a comma after an introductory prepositional phrase. An "uncluttered" approach tends to be preferred in newer style guides. However, if the journal has an in-house style guide, we would be happy to follow its recommendations.

Competing Interests: No competing interests were disclosed.
