University of Basel

Application Form for the Ethics Commission of the University of Basel for research with human subjects

General Information

Project Title	xxx	
Expected start date and end date of project	xxx	
Expected start date and end date of data collection	xxx	
Type of review	☐ Pre-Review (at proposal stage, voluntary) ☒ Full Review (required before the project starts)	
Principal Investigator	Name	
	Department	
	Email	
Co-Investigator(s)	Name	
	Department	
	Email	
Project members (names, function)	+	
Study Type	☐ Monocenter study ☐ Switzerland ☐ EU Country, specify: ☒ Non-EU country, specify ☐ Multicenter study ☐ Switzerland ☐ EU Country, specify: ☐ Non-EU country, specify:	
External Partners	☐ No ☐ Yes *Enter name(s) and institutions and explain how they are involved*	

University of Basel

Funding	*Explain how the study will be financed* The study is financed by xxx
Project review	Project has already been reviewed by a funding organization or other entity ☒ No ☐ Yes (Please include the part(s) of the project review report relevant for the Ethics Committee)

1. Study Rationale

1.1 Background

Explain the background and scientific relevance of the planned research so that readers can get a sufficient understanding of the performed research in the area and the research question of this project

Interest in the history of diseases has increased in recent years, both in research and among the public. However, so-called neglected tropical diseases (NTDs), are often absent from both academic and popular considerations.
This dissertation project addresses this desideratum by investigating the historical construction and reconstruction of NTDs in local and global contexts, enquiring into the meaning of 'neglected' and the process through which certain diseases become designated as such. It does so through a focus on responses to the parasitic worm disease xxx from xxx.

The thesis proposes that xxx in this setting serves as a telling example of how a disease came to be constructed as an NTD through (re)definition by various external actors – xxx – during the xxx. Through their plans and interventions, these actors have not only drastically increased the prevalence of a disease that was previously not very widespread, but also introduced xxx as a tangible, serious entity to the xxx people. Local 'auxiliaries' also played a crucial role in the success and longevity of health interventions – an aspect that has received little attention in scholarship to date.

1.2 Study objectives

Explain the aims and objectives of your study

This project combines xxx local medical history with global history and analyses the different practices and bodies of knowledge that define NTDs on multiple levels. Next to archival research and the review of historical biomedical literature, oral history interviews with former participants in xxx projects, local 'auxiliaries' of international xxx, community health workers and scientists, health policy makers and members of health organisations will allow this study to examine the perceptions and course of the disease in xxx. These interviews will further provide insights into the ways in which local practices, knowledge production, transnational collaboration and the institutionalisation of health care influenced the disease, its spread, and its effects. The project pays special attention to the interviewees' personal experiences with Western disease control projects and their perceptions xxx. Through this research, the understanding and knowledge surrounding the notion of 'neglected tropical diseases' is expected to deepen.

University of Basel

1.3 Ethical reflection

Please provide an ethical reflection on the justification of your research proposal. Ethical issues at stake may include, but are not narrowed to the following principles: social value, scientific validity, fair subject selection, favourable risk-benefit ratio and respect for subjects.

The Covid-19 crisis has increased public and academic interest in the history of epidemics and pandemics. Interconnections between health, environment and globalisation have become apparent, and the state of health care systems is being discussed worldwide. My study contributes to these discussions and, more specifically, to a better understanding of the history of neglected diseases. The example of xxx illustrates global and transnational dynamics of prioritising or neglecting specific diseases and the effects this has at a local level – insights that are relevant to ongoing public health debates and policy makers' attempts to devise programmes that are better tailored to people's needs.

The goal of this study is a historical analysis that reaches into the present. To reach this goal, qualitative methods are needed: oral history interviews and participative observation. Only in-depth interviews with people directly affected by xxx can provide a comprehensive understanding of the history of xxx in xxx. In order to analyse this qualitative data, the interviews have to be recorded and transcribed.

The validity of my empirical data will be ensured by including as many different perspectives on the topic as possible, while also paying attention to maintaining a gender and age balance. Actors from at least four different groups (former participants of xxx, former local 'auxiliaries' working in such interventions, scientists working on xxx and xxx) will be interviewed, which allows for the representation of different perspectives.
Further, I will make sure to follow up on variances across the different accounts and to continuously reflect critically on the collected data to safeguard its 'depth'. Other important aspects include critically reflecting on my own position and biases that might influence the results, and considering the limitations of my research before drawing more general conclusions.

All participants will be informed about the research aims and goals, the pseudonymisation procedure and my data management strategy. Participation in the study is voluntary. I will pseudonymise all information that might reveal the identity of the participants. Participants will be reminded that they do not need to reveal any sensitive information regarding their health if they don't wish to do so. Also, after the interview, participants can ask for the removal of any information they consider to be breaching the confidentiality clauses and disclosure agreements they have signed or given oral consent to.

Authorisations by the data protection authority *xxx* and by the *xxx* will be obtained before the start of the fieldwork.

2. Research Protocol

2.1 Study type

☒ Prospective

☐ Retrospective

In case of retrospective study, please explain how you obtained the permission to use the data and, if applicable, how participants gave their consent to use their data.

2.2 Research techniques, instruments & equipment

☐ Questionnaire (include as annex), specify:

☒ Interview (include as annex), specify: Semi-structured in-depth interviews about xxx

☒ Participant observation/tracking, specify: Participative observations in order to understand the nature of xxx.

☐ Behavioural experiments/manipulation, specify:

☒ Video/Audio recordings, specify: The interviews will be recorded (audio). Videos and photographs may be taken in appropriate situations.

☐ Social Media data, specify:

☐ Data sets with personal data, specify:

☐ Imaging, specify:

☒ Other, please specify: Archival research plays an important role not only for historical contextualisation but also for identifying key actors and possible interview partners.

2.3 Research method

Present the methodologies and practical procedures.

In order to collect data, the project utilises archival research, oral history / narrative interviews, participative observation and audio/video recording.

One strong focus of this project is archival research. Archives will be consulted in xxx and in xxx. I will clarify the copyright status for all archival material that I will use in my project.

The interviews will be conducted in different regions of xxx in order to understand personal perceptions of xxx in its different forms, as well as to evaluate developments of xxx. Potential regions include xxx.

Depending on their background, interviewees are invited to reflect on their experiences with xxx in the past and present or on xxx.

Potential interview partners will either be approached in xxx, xxx or xxx. Should my xxx skills be insufficient to conduct an interview, interpreters will be used. The interpreters will be fully briefed on the research project and the confidentiality of the interviews in advance.

After approaching potential interviewees, I will explain the context and aim of my project and arrange the interview at the interviewee's time and place of choice. There are no COVID-restrictions in place anymore that would complicate the conduction of interviews, but should the participant wish masks should be worn, this will be complied with. If either side shows symptoms, the interview will be postponed.
Before starting the interview, I will ask them to re-confirm their participation in the interview and for permission to record it. Then I will explain the protection/storage of the collected data and the pseudonymisation process. After providing any additional information about the whole process, the interviewees will be asked to sign the information letter and the consent form.
In cases where written consent is not suitable (xxx), oral consent will be obtained. In that case, the consent process will be recorded, i.e. after introducing myself and the consent process, I will ask for permission to turn the recorder on. I will make sure that the explanation of my project, the pseudonymisation process, data storage and the consent procedure is recorded before participants will be asked to orally confirm their consent.
The interview may last between one and two hours, but the participants can pause, end or reschedule the interview at any time. After the interview, I will answer any follow-up questions the participants may have, give them my contact details and inform them that I will stay available for any further questions and for updates about the outcomes of the study.

If the opportunity arises, I will conduct research as a participative observer. This method of research may allow me to become a participant in particular settings of xxx and thus provide me with insights into xxx research and into the experiences of xxx.
In the case of participative observation situations, I will make sure to first seek consent from the relevant authority (e.g. village elders, community leaders xxx.) and from anyone involved with the activity. Anyone who could potentially be observed by me will be informed of my role and my research purposes. Anyone will be free to withdraw from the activity/setting if it's an open setting, or ask me to withdraw from my participation if they object to being observed in a closed setting.

As is often the case with participative observation, pictures or video recordings may be made of the research setting. Similar to the participative observation procedure, I will first ask permission from the relevant authority and from the participants who may potentially appear in the pictures/videos, i.e. I will ask all the people involved for their consent.

After the end of the data collection, the pseudonymised interview transcripts as well as the pictures and videos (with blurred faces where necessary) will be used to analyse and understand how xxx, how xxx, what kind of xxx.

3. Data handling and management

3.1 Data Types

Explain which type of data you are using

☐ Anonymized data, please specify:

☒ Pseudonymized (coded) data, specify: Personally identifiable information in the interview recordings will be pseudonymised during the transcription process. Faces in pictures and photographs will be blurred.

☒ Non-coded data, specify: The interviews will be recorded using a recording device. They will then be transcribed and pseudonymised. The audio files will be encrypted and stored on the internal servers of the University of Basel (SWITCHdrive).

3.2 Data Management

Explain how the privacy of the participants is being protected, how the data is safely stored, who has access to the data, and what will happen to the data at the end of the project. If possible, attach Data Management Plan.

The interviews will be recorded using a private digital audio recorder after the participants have given their consent. I will simultaneously make notes in my personal notebook. The audio files will not be transferred automatically to a cloud service and will initially only be saved on the audio recorder's SD card.
The same applies to photo or video recordings, which will be made using a personal smartphone.

After each interview, the corresponding audio file will be reviewed for quality and completeness (using the open-source software *Audacity*) and then saved in an encrypted form in my institutional SWITCHdrive cloud account, provided by the University of Basel. The servers are based in Switzerland. In case there is no stable and secure internet connection during my fieldwork in xxx, the files will be *temporarily* stored on a private encrypted USB-drive – however, this should be the exception and not the rule.
In case pictures or video recordings were made, they will also be encrypted and stored in my secure SWITCHdrive cloud account.
Handwritten notes will be typed up and stored similarly.
Only I will have access to all the files and they will be deleted after the completion of the dissertation project.

In order to guarantee the privacy of participants, the data will be pseudonymised during further processing. From then on, the attribution of data to a specific interview subject can only be done via the pseudonymisation key. Pseudonymisation will be achieved by attributing random fictious names to the interview participants. The key (consisting of a table of the assigned names) will be stored in the form of an encrypted PDF in a folder separate from the original (raw) data as well as separate from the processed data on my secure SWITCHdrive cloud account provided by the University of Basel.
I alone will be responsible for the pseudonymisation process and the processing of all data.
No one else will have access to any of the data as well as to the pseudonymisation key. In case pictures or video recordings were made, they will be anonymised (i.e. blurring faces using the open-source software *OpenShot*).
I will only use pseudonyms in any presentation of my research (oral or written).

In case of revocation of consent by the interview participants, all corresponding data will be immediately deleted from my audio recording device as well as from the cloud storage. Similarly, corresponding handwritten notes will be destroyed.

There will be no sharing of sensitive personal data (raw or pseudonymised) with other researchers and institutions. Raw data obtained from archives such as the national archives may be shared with partners in the case of a joint publication, after the copyright status has been clarified.

I am aware that I will be collecting data in xxx and transfer it to Switzerland. This is permitted by xxx law if the receiving country provides an adequate level of protection for privacy and fundamental rights and liberties. Both the collection of sensitive health data as well as the cross-country transfer of personal data are subject to authorisation by the data protection authority *xxx*. These authorisations will be obtained before commencing fieldwork.

4. Participants

4.1 Inclusion and exclusion criteria

List details such as age, sex, ethnic / socio-demographic background, life style factors, etc., under which a participant is deemed to be suitable to participate in the study. Make a statement on the vulnerability of participants. Indicate as well the anticipated number of participants.

Ideally, I will interview members of (provisionally) four different groups: the first group consists of xxx, because first-hand experiences xxx are often overlooked. The second group is made up of former 'auxiliaries' of international programmes. As is the case with experiences of the local population, the role and experiences of local 'auxiliaries' is often neglected in the evaluation xxx. As a third group, scientists xxx will be interviewed to gain an understanding of the current status of xxx research in xxx as well as their opinion on the past and future of xxx research. Lastly, the fourth group consists of xxx. With their interviews, the development of health policies concerning xxx will be examined, as well as the organisation and implementation of control programmes and interventions.

All interviewees will be over the age of 18 and will be fully aware of what they are agreeing to by participating in my interviews. They will be able to understand informed consent and data protection. My study targets no specific ethnicity, nationality, lifestyle or socio-demographic background. It does however target people who have been xxx and who fit the criteria of the four groups described above. I will aim for a gender and age balance.

4.2 Sample Size

Please specify the number of participants enrolled in the sample(s) of your study.

At this stage of my project, it is not yet possible to estimate the number of participants in study. Ideally, at least five to ten interviews per targeted group (see box 4.1) will be conducted; these numbers have no upper limit.

4.3 Recruitment

Specify who will recruit the participants, how, where and by whom the participants will be approached for inclusion and obtainment of informed consent.

1.) Archives: Archival research may help me to identify xxx.

2.) Direct contacts: during my preparatory visit in xxx I have been able to meet several potential future interview participants, including xxx. Additionally, institutes, international organisations in xxx or relevant companies might be contacted through their means of communication. I will inform potential interview candidates about the goal of my study and the pseudonymisation process, guaranteeing them anonymity and confidentiality.

3.) Snowball: After their interviews, the interviewees will be given the option to recommend other potential candidates. They will be contacted either in person, by e-mail or by phone call. Neither do I disclose to the potential new participants that the person recommending them has already taken part in the study, nor do they need to disclose this fact, if they do not wish to do so. The potential new participants will be assured that the participation in the study is completely voluntary and that a refusal to take part will not affect their relationship with the initial referral or with me as the researcher. They will be provided with information about the goal of the study, the form of the interview and will be guaranteed anonymity and confidentiality.

5. Participant Information

Include your Informed Consent form(s) and information letter(s) as annex and describe your Informed Consent procedure in detail.

I will inform the interview participants in advance about the nature and goals of the study. The information will be given during a pre-interview conversation orally and in the information letter attached to the consent form. I will communicate that participation in the study is voluntary and anonymous. Participants will be made familiar with the pseudonymisation procedure that will be used and how their data is going to be stored.
I will underline that the interview can be stopped, paused or postponed and that participants have the right to withdraw their consent at any time. I will also make clear that the original audio recording is going to be used only for transcription purposes and deleted after the completion of the project. They will be further informed that they can refuse to answer questions and ask for further clarification if needed.
If the participants decide to take part in the study, they will be asked to read and sign the consent agreement or to give oral consent recorded on my recording device. If needed, the agreement will be explained in a simple language to make sure that the participants understand its content. They will be

given a copy of the agreement, which includes an explanation of their rights. After signing the agreement or giving recorded oral consent, the participants still have the right to withdraw from the interview. One copy of the agreement will remain with the participants, and the other one will be scanned and stored in an encrypted form on the server of the University of Basel.

6. Research involving deception

Will participants be deceived?

☒ No
☐ Yes – explain why deception is necessary in this study and how participants will be deceived.

7. Debriefing

Which information is given to participants during debriefing and how will this be provided?

After the interviews, I will express my gratitude for the participants' time and information and I will stress the importance of their contribution to my study. I will also remind them that the interviews are confidential and pseudonymised. They will be given my contact details and they will be invited to contact me if they have any further questions about how I am going to store, process and analyse their data or if they wish to receive an update on my research. If they wish to have access to the transcript, they will be given a pseudonymised copy of the text afterwards. I will also remind them that they can contact me in case they feel any discomfort as a result of the interview.
They will be asked to leave their contact details, which will be saved in an encrypted form.

8. Risks, discomfort and counselling

Describe possible risks and whether participants might experience (physical or mental) discomfort, embarrassment, confusion etc. during the course of the study or afterwards. Explain how you plan to minimize these risks. Explain if any support our counselling is offered during and after participation.

The study aims to explore xxx, potentially a sensitive health issue. Questions about these experiences could trigger discomfort or negative emotions, especially because xxx.
In order to minimise the risks of psychological discomfort and negative emotions, I will be implementing a series of measures.

1 – The interviews will be conducted at a place of the participant's choice, where they feel comfortable and safe, and at a time of their choice, when they feel ready to talk about this topic.
2 – I will reassure the participants that they have the right to not answer questions and to pause, stop or postpone the interview at any time.
3 – During the interview process, I will show verbally and non-verbally my empathy towards their well-being and in case of an occurrence of negative emotions, I will ask the participant if they would like to pause the interview.
4 – I will make sure to ask more difficult or intimate questions towards the end of the interview,

where a trust relationship between the participant and me will likely have been established.
5 – The interview questions are wide and open-ended, so the participants can decide themselves how much they want to tell and what aspects of their experiences they would like to focus on. This leaves them in control over the type of information they are willing to give.

I will inform interview participants of the possibility to contact me any time after the interview if they experience any discomfort or negative emotions and would like to share their feelings and thoughts with me. I will remain open to conversation regarding the psychological state of the participants after the interview.

9. Remuneration, benefits and study outcome

Will participants receive a remuneration or compensation for their participation?

☐ No – explain:

☒ Yes – cost reimbursement (i.e. transport, food, drinks) – specify: If the participant incurs any costs as part of the interview, I will reimburse them.

☐ Yes – additional compensation (e.g. voucher, course credits, money) – specify:

Are there other benefits to participation in this project?

☒ No
☐ Yes – specify:

Which information is given to participants about the outcome of the study? Will participants receive their individual results or only the overall study results? How will this information be provided?

After the interviews, the participants will be given my contact details so that they can contact me and gain information about the storage, process and analysis of the data as well as about the current stage of the project.

Checklist annexes

☒ Participant information letter(s)
☒ Informed Consent form(s)
☒ Questionnaire(s) or interview format(s)
☒ Supervisor's letter of endorsement (for PhD candidates)
☒ Other documents – specify: Data Management Plan