PROTOCOL
Soc-Behav-Ed Non-Exempt
Berkeley

Protocol # 2022-09-15642
Date Printed: 06/23/2023

Protocol Title: New Approaches to Estimating Mortality in Humanitarian Crises
Protocol Type: Soc-Behav-Ed Non-Exempt
Date Submitted: 10/16/2022
Approval Period: 02/28/2023-02/27/2033
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* * * Personnel Information * * *

Enter all UC Berkeley study personnel (if not previously entered) and relevant training information. Please read Personnel Titles and Responsibilities: Roles in eProtocol before completing this section.

Note: The Principal Investigator or Faculty Sponsor, Co-Principal Investigator, Student or Postdoctoral Investigator, Administrative Contact, and Other Contact can EDIT and SUBMIT. Other Personnel can only VIEW the protocol.

Principal Investigator or Faculty Sponsor

Name of Principal Investigator	Degree (e.g., MS/PhD)	Title
Dennis Feehan	Ph.D.	Associate Professor
Email	**Phone**	**Fax**
feehan@berkeley.edu		
Department Name	**Mailing Address**	
Demography	94720-2120	

UCB status (select all that apply):

X	Faculty		Postdoc		Grad		Undergrad		Other		

Faculty (with some exceptions), staff, and students engaged in human subjects research must complete either the biomedical or social-behavioral human research course through the online Collaborative Institutional Training Initiative (CITI), depending upon which is most germane to the research. ALL PIs on an NIH award are required to complete either CITI or NIH Training. See Training and Education for more information.

If applicable, please insert date (mm/dd/yy) of completion in appropriate box(es) below:

CITI	NIH	Other Training (title & date completed)
3/17/2019		

Student or Postdoctoral Investigator

NOTE: All Student/Postdoc Investigators must have a Faculty Sponsor who will serve as the "responsible researcher." If NOT a student or postdoc project, enter student(s) and/ or postdoc(s) under Other Personnel below.

Name of Student/Postdoc Investigator	Degree	Title
Casey Breen		Ph.D. Candidate
Email	**Phone**	**Fax**

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caseybreen@berkeley.edu 8123603930

Department Name **Mailing Address**

The Social Science Matrix

UCB status (select all that apply):

	Faculty		Postdoc	X	Grad		Undergrad		Other	

Faculty (with some exceptions), staff, and students engaged in human subjects research must complete either the biomedical or social-behavioral human research course through the online Collaborative Institutional Training Initiative (CITI), depending upon which is most germane to the research. ALL PIs on an NIH award are required to complete either CITI or NIH Training. See Training and Education for more information.

If applicable, please insert date (mm/dd/yy) of completion in appropriate box(es) below:

CITI	NIH	Other Training (title & date completed)
5/13/2017	3/21/19	

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* * * Vulnerable Subject Checklist * * *

Vulnerable Subject Checklist

Yes	No	
Y		Children/Minors
	N	Prisoners
	N	Pregnant Women
	N	Fetuses
	N	Neonates
Y		Educationally Disadvantaged
Y		Economically Disadvantaged
	N	Cognitively Impaired
	N	Other (i.e., any vulnerable subject population(s) not specified above)

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* * * Study Sites * * *

Study Sites

Select all study sites where data collection via subject interaction will take place:

International

X International Site(s) (specify country, region, and township or village)

Democratic Republic of the Congo, specifically, in three health zones (zones de santé) in the Tanganyika Province: Kalamie, Nyunzu, and Nyemba.

Local

X UC Berkeley

UC Davis

UC Irvine

UC Los Angeles

UC Merced

UC Riverside

UC San Diego

UC San Francisco

UC Santa Barbara

UC Santa Cruz

Lawrence Berkeley National Laboratory

Alameda Unified School District (specify schools below)

Berkeley Unified School District (specify schools below)

Oakland Unified School District (specify schools below)

Other (Specify other Study Sites)

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* * * General Checklist * * *

General Checklist

Yes	No	
	N	Is the research receiving any federal funding (e.g., NIH, NSF, DOD, etc.)
	N	Is another UC campus relying on UC Berkeley for IRB review by means of the UC System Memorandum of Understanding (MOU)?
Y		Is another institution relying on UC Berkeley for IRB review by means of an Inter-institutional IRB Authorization Agreement?
	N	Will subjects be compensated for participation?

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* * * Funding * * *

Funding Checklist

If the research is not funded, check the "Not Funded" box below. If the research is funded, add the funding source to the appropriate table below.

NOTE: Only the Principal Investigator (PI) of the grant or subcontract can add his or her own SPO Funding information in this section. The PI of the grant must also be listed in the Personnel Information section of the protocol in one of the following roles: Principal Investigator or Faculty Sponsor, Student or Postdoctoral Investigator, Co-Principal Investigator, Administrative Contact, or Other Contact. Training Grants can be added by anyone in one of the aforementioned roles. For step-by-step instructions, see Add SPO Funding Quick Guide

Not Funded

SPO - Funding

Funding - Other

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Funding Type	Sponsor/Provider	#	Title	Amount	Begin	End	Narrative Description	Lead PI (If different from Protocol PI)
Funding from NGO	IMPACT Initiatives		NGO Funding				IMPACT Initiatives is funding the study. This group will pay for all survey staff and data collection. No money is being routed through UC Berkeley's Sponsored Project Office (SPO).	

Funding - Other

Funding Type — **Other**
Funding from NGO
Sponsor/Provider — IMPACT Initiatives
#
Title — NGO Funding
Amount
Begin
End

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Narrative Description

IMPACT Initiatives is funding the study. This group will pay for all survey staff and data collection. No money is being routed through UC Berkeley's Sponsored Project Office (SPO).

Lead PI
(If different from Protocol PI)

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* * * Expedited Paragraphs * * *

Request for Expedited Review

An expedited review procedure consists of a review of research involving human subjects by the IRB Chair, or by one or more experienced reviewers designated by the Chairperson from among the members of the committees.

In order to be eligible for expedited review, ALL aspects of the research must include activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures included in one or more of the specific categories listed below.

If requesting Expedited Review, select one or more of the applicable paragraph(s) below.
(DO NOT select any paragraph(s) if your protocol does not qualify for expedited review. Protocols that do not qualify for expedited review will be reviewed by the full (convened) Committee.)

1. Clinical studies of drugs and medical devices only when conditions (a) or (b) are met.

   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   b) Research on medical devices for which
      i) an investigational device exemption application (21 CFR Part 812) is not required; or
      ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

   b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

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3. **Prospective collection of biological specimen for research purposes by non-invasive means.**

   Examples:

   a) hair and nail clippings in a non-disfiguring manner;
   b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   c) permanent teeth if routine patient care indicates a need for extraction;
   d) excreta and external secretions (including sweat);
   e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
   f) placenta removed at delivery;
   g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
   i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth
   j) sputum collected after saline mist nebulization.

4. **Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)**

   Examples:

   a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject of an invasion of the subject's privacy;
   b) weighing or testing sensory acuity;
   c) magnetic resonance imaging;
   d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this paragraph may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)**

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6. Collection of data from voice, video, digital, or image recordings made for research purposes.

X 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
b) Where no subjects have been enrolled and no additional risks have been identified; or
c) Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

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* * * Purpose, Background, Collaborative Research * * *

Old CPHS # (for Protocols approved before eProtocol)

Study Title

New Approaches to Estimating Mortality in Humanitarian Crises

Complete each section. When a question is not applicable, enter "N/A". Do not leave any sections blank.

1. Purpose

Provide a brief explanation of the proposed research, including specific study hypothesis, objectives, and rationale.

We will conduct a study in Democratic Republic of Congo to assess the performance and financial feasibility of different methods for estimating mortality rates in humanitarian crises. Specifically, we will benchmark the performance of two novel methods (network survival method and informant method) for estimating mortality rates against a conventional method (retrospective household survey). The study's overarching aim is to provide a detailed report summarizing the performance (accuracy, cost, etc.) of these new methods against conventional methods.

2. Background

Give relevant background (e.g., summarize previous/current related studies) on condition, procedure, product, etc. under investigation, including citations if applicable (attach bibliography in Attachments section).

Reliable estimates of mortality are critical for assessing the severity of a humanitarian crisis and effectively targeting aid, yet logistical and security challenges often preclude the use of conventional mortality estimation methods. New methods to estimate mortality in humanitarian crises have been proposed by the research community (Feehan 2017, Checchi 2017), but they have not been systematically validated in humanitarian crises settings. To address this gap, this study will assess the performance of several methods for estimating mortality rates in the Democratic Republic of the Congo, where estimates of mortality rates are in high demand. A summary of the three methods this study will assess is given below.

Method 1, Network Survival Method: The network survival method asks survey respondents to report on others in their personal network who have died in a specified time frame. The respondents are also asked a series of questions about how many people they know in groups of known size ("How many school teachers do you know?"). These aggregate relational data are used to estimate a respondent's personal network sizes. The number of deaths a respondent reported and the personal network size are combined to estimate population mortality rates.

Method 2, Key informant method: The key informant method first identifies "key informants" in the population who can accurately report deaths within a community. The key informants then report

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exhaustively on the deaths they are aware of, including a shortened verbal autopsy questionnaire. The count of reported deaths is then combined with auxiliary estimates of population size to estimate mortality rates.

Method 3, Household Mortality Survey: A household survey will be administered over the population of interest. The household survey will ask about deaths in the household in the past three months and collect other sociodemographic and health-related information about the household members.

Method 4, Verification Interviews: We will conduct follow-up interviews with households of deceased individuals who had been reported through Methods 1, 2, and 3. The teams will only follow up with the household of the deceased if the reporting key informant gave consent for additional follow-up. In the follow-up interview, we will perform a verbal autopsy, asking questions about cause and place of death. We note that this "method" is more of a quality control check than an independent method for estimating mortality.

Feehan, Dennis M., Mary Mahy, and Matthew J. Salganik. 2017. "The Network Survival Method for Estimating Adult Mortality: Evidence From a Survey Experiment in Rwanda." Demography 54(4):1503–28. doi: 10.1007/s13524-017-0594-y.

Checchi, Francesco, Abdihamid Warsame, Victoria Treacy-Wong, Jonathan Polonsky, Mark van Ommeren, and Claudine Prudhon. 2017. "Public Health Information in Crisis-Affected Populations: A Review of Methods and Their Use for Advocacy and Action." Lancet (London, England) 390(10109):2297–2313. doi: 10.1016/S0140-6736(17)30702-X.

Checchi, Francesco, Bayard Roberts, Oliver Morgan. A New Method to Estimate Mortality in Crisis-Affected Populations: Validation and Feasibility Study Version 2. FANTA. March 2009

3. Collaborative Research

a) If any non-UCB institutions or individuals are engaged in the research, explain their human research roles and what human subjects training they have/PI has planned to provide.

IMPACT Initiatives, a leading humanitarian research group, will be engaged in recruiting and interviewing participants. Co-investigator Saeed Rahman, Dr. Jonathan Polonsky, and Dr. Joeri Smits, Christina Kay, Mory Keita, Stephen Ahuka, and Yoann Martin have human subjects training.

Researchers affiliated with IMPACT Initiatives:

Mr. Saeed Rahman: CITI 2/25/2016, Record ID 15658462
Dr. Joeri Smits: NIH 11/03/2017, Certification Number: 2550638
Dr. Jonathan Polonsky: Completed the OHRP's online training (Lessons 1-5)
Ms. Christina Kay: CITI 1/25/2019, Record ID 30276127
Dr. Mory Keita: Completed the OHRP's online training (Lessons 1-5)
Mr. Yoann Martin Completed the OHRP's online training (Lessons 1-5)

Researchers affiliated with University of Kinshasa School of Public Health in DR Congo:

Dr. Stephen Ahuka: Completed the OHRP's online training (Lessons 1-5)

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In addition, Olivier Cecchi (Senior Research Manager at IMPACT Initiatives) and Louna Longquer (Data Officer) will have access to the study records as part of routine data management processes at IMPACT Initiatives.

This project was jointly initiated by IMPACT Initiatives and UC Berkeley. A local IRB protocol is currently under review at the University of Kinshasa School of Public Health in DR Congo. An Amendment Application will be submitted to upload a copy of the approval letter (in English) to section 17, and to include IRB approval and expiration dates in the table underneath section 3b, once local IRB approval has been obtained.

The study will employ several enumerators, who will be recruited and affiliated with IMPACT Initiatives at the country level. Prior to the course of the work, enumerators and all other field staff involved will be subject to a Research Ethics training. This training will be led by and administered by UC Berkeley affiliated team members and will use the human subjects training powerpoint from OPHS.

b) If any non-UCB institutions or individuals are collaborating in the research, complete the table below and attach any relevant IRB approvals in the Attachments section.

Non-UCB institutions

Institution Name	Individual Contact/ Affiliate of Institution	FWA #	Local IRB Review? (Y or N)	IRB Approval Date	IRB Approval Expiration Date
University of Kinshasha School of Public Health	Stephen Ahuka		Y	01/19/2023	01/18/2024
IMPACT Initiatives			N		

4. Qualifications of Study Personnel

a) Explain expertise of Principal Investigator, Student/Postdoc Investigator, Faculty Sponsor (if applicable), any Co-Investigators or other key personnel listed in the application, and how it relates to their specific roles in the study team.

PI Dennis Feehan is an expert in sampling and network-based methods for mortality estimation. Co-investigator Casey Breen is an expert on network-based methods for enumerating and sampling hard-to-reach populations. Affiliated researchers Saeed Rahman, Jonathan Polonsky, Joeri Smits, Christina Kay, Stephen Ahuka, and Mory Keita are experts on mortality estimation in humanitarian crises. Yoann Martin has extensive experience supervising and training survey enumerators.

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(1) Casey Breen will design the study, assist with data collection, intervention and/or interaction with human subjects, and conduct the data analysis.

(2) Dennis Feehan will supervise designing the study and analyzing the data.

(3) Saeed Rahman will design the study, assist with data collection, intervention and/or interaction with human subjects, and conduct the data analysis.

(4) Dr. Jonathan Polonsky will design the study, assist with data collection, intervention and/or interaction with human subjects, and conduct the data analysis.

(5) Dr. Mory Keita, will work with project oversight at the country level, analysis and reporting.

(6) Dr. Joeri Smits will design the study, assist with data collection, intervention and/or interaction with human subjects, and conduct the data analysis.

(7) Christina Kay will oversee training and data collection tasks at the country level, analysis and reporting.

(8) Dr. Stephen Ahuka will work with project oversight at the country level, analysis and reporting.

(9) Mr. Yoann Martin will be the lead field officer, and will help supervise survey enumerators.

b) In case of International research, describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this subject population, including specific qualifications (e.g., relevant coursework, background, experience, training). Also, explain your knowledge of local community attitudes and cultural norms, and cultural sensitivities necessary to carry out the research. See CPHS Guidelines on Research in an International Setting

Affiliated researchers Saeed Rahman and Dr. Jonathan Polonsky are experts on mortality estimation in public health settings, and they have worked extensively with local partners in a variety of humanitarian settings.

All study researchers will be collaborating closely with local experts. Specifically, IMPACT Initiatives teams will collaborate with co-investigators at the University of Kinshasa (Dr. Stephen Ahuka) through the in-country IRB review processes, analysis and reporting. Additionally, our field teams may seek guidance from the Provincial Health Department of Tanganyika Province on our study. However, the Provincial Health Department of Tanganyika Province will not be involved in human subjects research or study design.

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* * * Subject Population * * *

5. Subject Population

a) Describe proposed subject population, stating age range, gender, race, ethnicity, language and literacy.

The proposed population will be individuals in three health zones (zones de santé) in the Tanganyika Province of DRC: Kalamie, Nyunzu, and Nyemba, with a focus on Kalamie Town.
All primary subjects will be over the age of 18. The primary languages spoken a Swahili, French, and a few other local languages. The second Demographic and Health Survey (DHS) in DRC in 2013-2014 estimated a literacy rate of 42.2% among females aged 15-49 and 71.0% among males in Katanga province (which was in 2015 partitioned into Tanganyika province and three other provinces). The literacy rate in the Tanganyika province is 40.0%, based on 2020 estimates from the Sustainable Development Goals. The literacy rate for females may have increased slightly; for reference, the World Bank's country-wide literacy rate estimate for females aged 15 and above was 73% in 2011 and 75% in 2018 (for males aged 15 and above, it was 86% in 2011 and 86% in 2018). The ethnic breakdown is roughly about 85% Bantu and 15% Twa (based on 2009 estimates).

b) State the maximum number of subjects planned for the study. This number should account for all subjects to be recruited, including those who may drop out or be found ineligible. Explain how number of subjects needed to answer the research question was determined.

The maximum number of primary subjects for this study will be approximately 6,182 (1,500 + 225 + 3,222 + 1,245). The number of secondary research subjects will be 21,991 (5,881 + 16,110). For each method, we anticipate having the following number of primary and secondary subjects:

Method 1, Network Survival survey: We anticipate there will be 1,500 respondents for the network survival method.

Method 2, Key Informant: 225 key informants. The key informants are the primary research subjects. Households in their communities they are reporting on would be considered secondary research subjects they are reporting about. Estimating approximately 75 households per community, and 3 key informants per community, this would yield approximately 5,625 households as secondary research subjects. In each household, we will collect the name of the household head, resulting in 5,625 secondary subjects. In addition, we will collect information on secondary subjects who had measles, cholera, or who were born after the reference period (Jan 1, 2023) in each household. Because we are collecting the name of the household head, we will treat these subjects as secondary subjects. Assuming a measles rate of 3/1,000, a cholera rate of 0.5/1,000, and a birth rate of 42/1000, and 3 children per household we estimate a maximum of 256 additional secondary subjects. All population rates come from the World Bank and measles and cholera rates were calculated by the study team based on worst-case outbreak scenarios. In total, we anticipate a maximum 5,881 secondary research subjects.

Method 3, Household Mortality Survey: 3,222 households, where one person from each household will complete the survey. This will result in 3,222 primary research subjects. In addition, assuming a household size of 6, this will result in approximately 16,110 secondary subjects.

Method 4, Verification Interviews: For Verification Interviews, we will recruit individuals from households of

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deceased individuals reported by subjects who were surveyed for Methods 1, 2, and 3. In addition, we will recontact Method 3 subjects who reported death(s) in their own households and ask them to additionally participate in a Verification Interview. To participate in Verification Interviews, subjects must have had a death occur in their household on or after January 1, 2023. Assuming mortality rates from 2021, we estimate that we will interview a maximum of 450 (informant method) + 285 (household survey) + 500 (network survival method) for a total of 1,235 new survey respondents. There will be no secondary subjects for method 4.

c) **If any proposed subjects are children/minors, prisoners, pregnant women, those with physical or cognitive impairments, or others who are considered vulnerable to coercion or undue influence, state rationale for their involvement.**

In the household survey (method 3), subjects will report on children under 18 years of age; therefore, our study will include children as secondary research subjects. In the mortality household survey, we will ask information about all living household members including children under-18 years of age in order to understand the demographic compositions of the household. In our key informant methods, the key informant will be asked to report suspected cholera or measles, births, and known in or out-migration for each specific household including minors. We will collect age and sex for measles, cholera, and births only. Understanding the household composition (i.e., how many adults and how many children) and number of measles and cholera cases is critical for a complete understanding of health within communities.

6. Recruitment

a) **Explain how, where, when, and by whom prospective subjects will be identified/selected and approached for study participation. If researcher is subject's instructor, physician, or job supervisor, or if vulnerable subject groups will be recruited, explain what precautions will be taken to minimize potential coercion or undue influence to participate. See CPHS Guidelines on Recruitment for more information.**

There will be several approaches for recruiting subjects, depending on the specific method.

Method 1, Network Survival Methods: We will set up enumerators at transit areas — such as bus stops, ports, health facilities — who will approach eligible subjects coming through areas. Enumerators will be trained to spot eligible participants (adults age 18+), coming in and out of these locations. Respondents will begin our survey and answer a preliminary set of questions. After answering these preliminary questions, the enumerator will decide whether to administer the full interview. Eligibility for the full interview will depend on the major demographic characteristics (gender, place of residence) of who has already completed the interview. For example, if many men and no women have completed our survey, we will begin screening out men to obtain a more representative sample of the population. This is a standard practice known as quota sampling.

Method 2, Key Informant Method, key informants will be qualitatively recruited based on their ability to accurately report on mortality within their community (e.g., village chiefs, religious leaders, or school teachers). An initial list of village chiefs or community leaders will be attained through local authorities or the health department. We will identify additional key informants through snowball sampling. Specifically, we will ask key informants to recommend other key informants (teachers, health care workers, etc.) to participate in the study. While the contact information for many of these newly-referred key informants will be publicly available from the Tanganyika health department, we cannot guarantee all contact information

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is publicly available. Therefore, we will additionally require the all original key informants to obtain permission from others to pass along their private contact information (first name and telephone number) to the researchers.

Method 3, Household Survey: For the household survey, we will use a two-stage cluster sampling design over the assessment area. In the first stage, villages will be the primary sampling unit (PSU), and will be sampled with probability proportional to size (PPS) sampling. In the second stage, households will be randomly sampled from household listings constructed with the village chief. At the sampled household, enumerators will go door-to-door and verbally recruit subjects. In each household, a single consenting respondent, 18 years or older, will answer on behalf of the household. A trained survey enumerator will conduct the interview. All household members will be secondary research subjects, and basic information such as their sex, age, date of birth for children under 5 years of age, in- or out-migration status, will be collected. Given the minimal risk and infeasibility of getting informed consent for these subjects, we have requested waivers of consent for secondary subjects.

Method 4, Verification Interviews: Enumerators will recruit subjects who were identified as having a death occur in their household on or after Jan. 1, 2023 by subjects who participated in surveys for Methods 1, 2, and 3. Investigators will re-contact subjects who participated in the Method 3 Household Mortality Survey and reported that a death occurred in their own household on or after January 1st, 2023, to ask that they participate in the Method 4 Verification Interview as well. The verification interviews will take place at least 1 month after a death but no more than than 4 months, per WHO recommendation. Interviews will take place over the phone, when possible. When phone interviews aren't successfuly, we will send enumerators to conduct the interview at the household.

Enumerators will obtain the contact information name, phone numbers, and potentially household location of potential participants from subjects who participated in surveys for Methods 1, 2, and 3. We will ask the respondent whether they consent to us contacting the household. This is a standard practice conducted by health departments in Tanganyika Province, and this approach has already been approved by the local IRB at University of Kinshasa.

b) **Describe any recruitment materials (e.g., letters, flyers, advertisements [note type of media/where posted], scripts for verbal recruitment, etc.) and letter of permission/cooperation from institutions, agencies or organizations where off-site subject recruitment will take place (e.g., another UC campus, clinic, school district). Attach these documents in Attachments section. Please see eProtocol Attachments Check List for Non-Exempt Applications for more information.**

We will not use additional recruitment materials such as letters, flyers or advertisements. For Methods 1, we will directly approach subjects at transit stations and use the verbal recruitment script. For Method 2, we will call subjects and use the verbal recruitment script.

For Method 3, we will visit households and read the verbal recruitment scripts on the corresponding consent forms.

For Method 4, we will call households and read the verbal recruitment script. If we are unable to reach a household, we will follow-up by having an enumerator visit the household and read the recruitment script. The respondents recruited will be new survey participants with the exception of individuals who reported a death in their household in Method 3. In that case, we will re-interview the same survey participant if they consented to be re-interviewed. We will contact them using their provided phone number (or address if

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they don't have a phone number).

Verbal scripts will be used for both in-person and phone recruitment will be used for recruitment of Method 4 participants who were identified by Methods 1, 2, and 3 subjects as having a death occur in their household.

Recruitment scripts are included on the first page of each survey instrument, and that they will be read aloud to potential subjects by the enumerators before informed consent is obtained. We will use no additional recruitment materials (e.g., letters, flyers, advertisements, etc.)

c) **Will anyone who will be recruiting or enrolling human subjects for this research receive compensation for each subject enrolled into this protocol? If yes, please identify the individual(s) and the amount of payment (per subject and total).**

No.

7. Screening

a) **Provide criteria for subject inclusion and exclusion. If any inclusion/exclusion criteria are based on gender, race, or ethnicity, explain rationale for restrictions.**

For method 1, in addition to being at least 18 years of age, we will try to ensure that our non-probability sample is as representative of the general population as possible. This will mean that we will potentially screen out respondents based on their gender and place of residence if they are overrepresented. For method 3, age will be the only exclusion criteria (we will not sample anyone under age 18). For method 2, key informants will be purposefully included based on their position and knowledge of deaths within the community, and if they are at least 18 years of age. For method 4, participants must also be 18 years of age or older, and that they must have had a death in their household occur on or after Jan. 1, 2023.

b) **If prospective subjects will be screened via tests, interviews, etc., prior to entry into the "main" study, explain how, where, when, and by whom screening will be done. NOTE: If screening data will be used for research purposes beyond determining eligibility, consent must be obtained for screening procedures as well as "main" study procedures. As appropriate, either: 1) create a separate "Screening Consent Form;" or 2) include screening information within the consent form for the main study.**

For Method 1 Network Survival: Survey enumerators will be trained to visually assess the gender of the potential participant. They will then potential respondents about their place of usual residence (administrative area aire de santé). The place of usual residence and gender will only be used to determine eligibility for this research study, and that screening data will be destroyed as soon as possible after eligibility is determined. Eligibility will be based on tracked targets for interviews during a given reporting period, where the study team will aim for a target number of interviews per aire de ante (administrative area) and gender of respondent. These targets will be tracked on a daily and weekly basis to guide the study team on which types of key informants they should be trying to recruit each day. This procedure of "quota sampling" will allow us to screen out groups that are overrepresented in our sample, and ensure a more representative sample overall. For example, if we are sampling too many men and not enough women, we will begin excluding men to make our sample more representative of the general population.

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Enumerators will ensure that all respondents are over 18 by asking them directly asking them their age. In DR Congo, it is very unlikely that potential respondents will be carrying ID, so there is no option to request that they present identification.

8. Compensation and Costs

a)

Describe plan for compensation of subjects. If no compensation will be provided, this should be stated. If subjects will be compensated for their participation, explain in detail about the amount and methods/ terms of payment.

Include any provisions for partial payment if subject withdraws before study is complete.

When subjects are required to provide Social Security Number in order to be paid, this data must be collected separately from consent documentation. If applicable, describe security measures that will be used to protect subject confidentiality.

If non-monetary compensation (e.g., course credit, services) will be offered, explain how

No compensation will be provided to participants.

b) **Discuss reasoning behind amount/method/terms of compensation, including appropriateness of compensation for the study population and avoiding undue influence to participate.**

N/A

c) **Costs to Subjects. If applicable, describe any costs/charges which subjects or their insurance carriers will be expected to pay. (If there are no costs to subjects or their insurers, this should be stated.)**

No costs to subjects.

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* * * Study Procedures, Alternatives to Participation * * *

9. Study Procedures

a) **Describe in chronological order of events how the research will be conducted, providing information about all study procedures (e.g., all interventions/interactions with subjects, data collection procedures etc.), including follow-up procedures. If any interviews, questionnaires, surveys, or focus groups will be conducted for the study, explain and attach one copy each of all study instruments (standard and/or non-standard) in the Attachments section. Please see eProtocol Attachments Check List for Non-Exempt Applications for more information. If the proposed research involves use of existing data/specimens, describe how data/specimens will be acquired.**

Research Methods 1 and 2 will be implemented over a six-month period of time simultaneously as described below. At the end of the period, method 3 (household survey) will be used to retrospectively assess population mortality over the same time period as methods 1 and 2 were employed. It will take approximately 1 month to carry out the full household survey. Method 4 will be employed one month after method 1 and 2 and will continue for 10 months (3 months after the household survey ends).

The enumerators will be recruited by IMPACT initiatives (https://www.impact-initiatives.org/), which has worked extensively with enumerators in the DRC.

Method 1, Network Survival method: trained, professional survey interviewers ("enumerators") will identify potential respondents from key locations such as bus stops, ports, and health facilities. Enumerators will perform a screening process to identify whether the potential respondent is eligible for participation. Respondents will give informed consent by reading a form and then providing a signature; if a respondent cannot give a signature, we will collect a thumb impression. After respondents give consent, enumerators will conduct the interview and responses will be recorded using smartphones with the Open Data Kit (ODK) application and uploaded to a Kobo server account. We anticipate the survey will take about 10-15 minutes to complete. Please see attached (section 17) survey instrument: method1_Network Survival Key Informant Questionnaire. This survey instrument asks respondents to report on deaths to their family and neighbors and questions about how many deaths, births, in- or out-migration and other health events (suspect measles or cholera outbreaks) since January 1st, 2023.

Method 2, Key Informant Method: A minimum of 25 clusters (distinct villages or enumeration areas with approximately 100-150 households) will be sampled over the study area. Key informants will first be identified by research staff based on their ability to accurately report on deaths in their community. The informants will be asked to build a comprehensive list of all households in their community. This list will only ask individuals to provide some unique identifier such as the name of head of household for each household. The list of households will be used by data collection teams for probing during interviews, but will not be digitized or kept after the study. Each month, the informants will report on births, deaths, known in or out-migration, or suspect cholera or measles cases in each household. For each death, the informant will report detailed information on each descendant (names and death dates). Respondents will give verbal informed consent after the study team has read and explained the informed consent form over the phone, as this data collection activity is intended to be completely remote. Key informant follow-up calls will continue monthly for the six-month study period. We anticipate the initial interview may take between 30-60 minutes, and later follow-up interviews to be 15-30 minutes. We Please see attached (section 17) survey instrument: method2_informant_method.pdf. This survey instrument contains questions about any mortality and outbreaks of measles and cholera that has occurred since January 1st, 2023 in the

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mortality and outbreaks of measles and cholera that has occurred since January 1st, 2023 in the community. Responses will be recorded using smartphones with the Open Data Kit (ODK) application and uploaded to a Kobo server account.

Method 3, Household survey: The study area will be limited to the Kalamie, Nyunzu, and Nyemba regions of Tanganyika Province. Our study will use a two-stage cluster sampling design. First, a set of villages will be randomly selected using probability proportional to size (PPS) sampling. Next, households will be selected via random sampling. Within each household, a survey respondent of at least 18 years of age, who can speak for the household, will be interviewed. Respondents will give informed consent by reading a form and then providing a signature; if a respondent cannot give a signature, we will collect a thumb impression. After respondents give consent, enumerators will conduct the interview and responses will be recorded using smartphones with the Open Data Kit (ODK) application and uploaded to a Kobo server account. We anticipate a household interview will take between 15-20 minutes, with the possibility of follow up with Method 4 if a death is reported in the household since January 1st, 2023. Please see attached (section 17) survey instrument: method3_ mortality_HH_survey.pdf. This survey instrument contains questions about mortality in the household and collects basic demographic and health information on all members of the household.

Method 4, Verification interview: Enumerators will recruit subjects who were identified as having a death in the family since Jan. 1, 2023 from subjects who participated in surveys for Methods 1, 2, and 3, and enumerators will recontact Method 3 survey participants who reported a death in their own household (on or after Jan. 1, 2023) to additionally participate in Method 4 Verification Interviews. If respondents provide the phone number of the household of the death, we will directly contact the household by phone. If not, then teams will follow up at the community level with face-to-face interviews. Please see attached (section 17) survey instrument: method4_verbal_autopsy_questionnaire.pdf. This survey instrument contains questions about deaths, such as time of death and cause of death. Responses will be recorded using smartphones with the Open Data Kit (ODK) application and uploaded to a Kobo server account. If the interview is administered in person, respondents will give informed consent by signing a form (or providing a thumbprint, if they aren't able to sign). If the interview is administered over the phone, we will ask the potential respondent if they verbally consent, and if yes, enumerators will sign the consent form certifying that they verbablly consented to participate in the study. Regardless of mode, we anticipate the survey will take between 20-40 minutes to complete.

For Methods 1, 3 and 4 (household-version only), we note that collecting thumbprints for document consent is legal in DRC.

b) Explain who will conduct the procedures, where and when they will take place. Indicate frequency and duration of visits/sessions, as well as total time commitment for the study.

For the network survival survey (method 1) and the household survey (method 3), the survey will be administered by trained enumerators. The network survival method will take approximately 10-15 minutes to complete. The household survey will take approximately 15-20 minutes to complete. Respondents can only respond to these surveys once.

The key informant method procedure will occur monthly. During the first session, the key informant will be asked to put together a list of all households they will be reporting on in addition to follow up questions on deaths. We anticipate this will take 30-60 minutes. Key informants will only be asked to do this once during the first session. Subsequent interviews will only update the list of all households and ask follow-up

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questions about deaths, births, in- or out-migration and other health events (suspect measles or cholera outbreaks). The time it takes the key informant to provide information on each death in their community will vary depending on the number of deaths in their community. We anticipate it will take on average 15-30 minutes per monthly session. The total time commitment for key informants will be 1 hour (first session) + 30 hour * 5 sessions = 3.5 hours total time commitment.

Verification interviews will occur only once with households of the deceased, and depending on the answer route may take from 20-40 minutes. Respondents from the household survey (method 3) who reported a death within their household during the time period may be asked to conduct a verification interview as well, so may be subject to a maximum of 60 minutes of time commitment.

- Method 1, Network Survival Surveys, in-person at a public location
-Method 2, Key Informant Surveys, over the phone
-Method 3, Household Surveys, in-person at the subject's place of residence
-Method 4, Verification Interviews, over the phone or in-person at the subject's place of residence

c) **Identify any research procedures that are experimental/investigational. Experimental or investigational procedures are treatments or interventions that do not conform to commonly accepted clinical or research practice as may occur in medical, psychological, or educational settings. Note: if the study only involves standard research or clinical procedures, enter "N/A" here.**

N/A

d) **If any type of deception or incomplete disclosure will be used, explain what it will entail, why it is justified, and what the plans are to debrief subjects. See CPHS Guidelines on Deception and Incomplete Disclosure for more information. Any debriefing materials should be included in the Attachments section.**

N/A

e) **State if audio or video recording will occur and for what purpose (e.g. transcription, coding facial expressions).**

N/A

10. **Alternatives to Participation**

Describe appropriate alternative resources, procedures, courses of treatment, if any, that are available to prospective subjects. If there are no appropriate alternatives to study participation, this should be stated. If the study does not involve treatment/intervention, enter "N/A" here.

N/A

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* * * Risks and Discomforts * * *

11. Risks and Discomforts

a) Describe all known risks and discomforts associated with study procedures, whether physical, psychological, economic or social (e.g., pain, stress, invasion of privacy, breach of confidentiality), noting the likelihood and degree of potential harm.

Uncomfortable with Questions - Respondents may feel uncomfortable or uncomfortable answering questions like “How many people do you know who have died in the past year?” because this may involve reporting on the death of a close friend or family member. For example, respondents in household surveys may be triggered reporting about familial deaths in their household. To address this concern, we will let the respondents know they can conclude the interview at any time.

Breach of Confidentiality - In the unlikely event of a confidentiality breach, there will be little potential for harm. For the remote mortality methods, if a household of the reported deceased discovers that a key informant reported on the death, it could pose a risk for the key informant depending on their relationship with the household, the deceased or the community. We explicitly ask subjects for their consent for us to follow up with households of the deceased. We only collect baseline and sociodemographic characteristics and reports about deceased individuals.

COVID-19 Exposure - COVID-19 is a serious disease that has affected the world since March 2020, and can be spread through air and water droplets from an infected person. There will always be some inherent risk for spreading COVID-19 when our teams conduct face-to-face interviews, so measures will be taken in line with global and in-country guidance to mitigate the risk of exposure.

Verbal autopsy - While conducting the verbal autopsy, we will ask about ways in which family members - including infants and children - have died, some of which are very violent and/or traumatic. These questions may be triggering and/or cause psychological distress.

b) Discuss measures that will be taken to minimize risks and discomforts to subjects. In terms of minimizing a confidentiality breach, simply refer to section 13 (Confidentiality).

We discuss confidentiality in Section 13. We will make sure all respondents consent before taking the survey, and will let respondents know they can end the survey at any point.

COVID-19 Mitigation - Data collection teams will conduct daily temperature checks, and take protection measures such as masks and hand sanitizer in order to prevent any spread to the community. The interview will also take place outdoors, and our team will maintain a distance of at least 1.5 meters from the respondent at all times. If any IMPACT staff become sick from COVID-19, we will inform any key informants that s/he had contact with.

Verbal autopsy - While conducting the verbal autopsy, we will ask about ways in which family members - including infants and children - have died, some of which are very violent and/or traumatic. To minimize these risks, enumerators have been trained to ask about these questions as considerately as possible, paying careful attention to the tone and body language of respondents and ending the interview if

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paying careful attention to the tone and body language of respondents and ending the interview if respondents appear uncomfortable. Additionally, enumerators have undergone psycho-social training on how best to address emotional distress from respondents who become upset or distraught during the interview.

c) **Discuss plans for reporting unanticipated problems involving risks to subjects or others, or serious adverse events, to CPHS. (This applies to all types of research.) See Adverse Event and Unanticipated Problem Reporting.**

An initial report will be made by mail/delivery, phone, or email to the Director, Research Subject Protection as soon as possible, but within no more than one week (7 calendar days) of the Principal Investigator learning of the incident. The initial report will be followed by a formal written report within no more than two weeks (14 calendar days) of the Principal Investigator learning of the incident.

d) **Describe plans for provision of treatment for study-related injuries, and how costs of injury treatment will be covered. If the study involves more than minimal risk, indicate that the researchers are familiar with and will follow University of California policy in this regard, and will use recommended wording on any consent forms (see CPHS Informed Consent Guidelines).**

N/A

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* * * Benefits, Confidentiality * * *

12. Benefits

Describe any potential benefits to the individual subject, group of subjects, and/or society. If subjects will not benefit directly from study procedures, this should be stated.

NOTE: Do not include compensation/payment of subjects in this section, as remuneration is not considered a "benefit" of participation in research.

Subjects will not benefit directly from study procedures. More broadly, society will benefit from a rigorous assessment of methods for estimating mortality in the humanitarian crises. Accurate estimates of mortality rates can help policymakers and public health officials make the best possible decisions about allocating aid during a humanitarian crisis.

13. Confidentiality and Privacy

NOTE: See CPHS Data Security Policy and Guidelines before completing this section.

a) **What identifiable participant data will you obtain? Note: Audio, photo, and video recordings are generally considered identifiable unless distinguishing features can be successfully masked.**

Network Survival Method: We will collect age, sex, and geographic identifiers including village and aire de sante (administrative area) for all respondents. If a death is reported, the team may collect mobile contact information for the household of the deceased, or other information to allow follow-up with the household for verification interviews.

Key Informant Method: We will collect age, sex, and geographic identifiers including village and aire de sante (administrative area) of all participants. Additionally, we will collect a full list of the names of heads of household in each sampled community. We will also collect information about symptoms of people with suspected cholera or measles in a way that could potentially identify who those secondary subjects are. If a death is reported, the team may collect additional information to allow follow-up with the household of the deceased for verification interviews. This may include mobile contact information for the household of the deceased or mobile contacts for other community contacts who can put our teams in touch with the household of the deceased. Additionally, we will collect descriptive information that would allow IMPACT teams to follow up at the community level to identify the household (e.g. near the church, east side of the road, etc.), as we anticipate there will not be addresses in this setting.

Household Survey: We will collect first and last name, exact date of birth, age, sex, and geographic identifiers including village and aire de sante (administrative area) of all participants. We will additionally collect GPS coordinates for the point of interview, at the household. For secondary research subjects, we

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will also collect only the first name of living household members or those who have recently left the household, only to keep track during the interview, however these names will not be saved in the form or uploaded to Kobo. The sex, age, dates of birth of secondary research subjects will be kept however for analysis purposes.

Verification Interviews: We will collect age, sex, and geographic identifiers including village and aire de sante (administrative area) of all participants. The verbal autopsy will include questions on location, time, and exact cause of death. Please see attached questionnaire "Tool 4a WHO 2016 Verbal Autopsy Questionnaire.docx" for more details.

b) If obtaining existing data/specimens, will you have access to identifiers? Please see The Industry Alliance Office website for requirements when receiving existing data/specimens for research.

N/A

c) Explain how the confidentiality of subject information will be maintained. Include:

i. Who will have access to study records/specimens?

Only investigators listed on this protocol and limited research staff including IMPACT field officers (supervising data collection activities) and data officers (facilitating data management) will have access to the records with personally identifiable information.

We are currently negotiating a joint data ownership agreement between UC Berkeley and IMPACT Initiatives. The Berkeley Industry Alliance is facilitating this agreement.

ii. How the records will be secured (e.g., password-protected computer, encrypted files, locked cabinet). Response should be consistent with CPHS Data Security Policy.

The survey will be collected on smartphones and stored on a secure Kobo server. This server is owned and operated by the United Nations Office for the Coordination of Humanitarian Affairs (UN OCHA), which they host at a data center in Ireland. The Kobo server is dedicated for humanitarian use and is provided as an open platform for humanitarian actors to use for needs assessments, research, information management, etc. Globally, access to these accounts are administered by our Senior Research Manager, Olivier Cecchi, and only he can give access to individuals, including for this research project. IMPACT Initiatives's Research Department will be responsible for giving out access to data rights. Secure passphrases will be used to protect the electronic data files, and the computers used are password-protected.

There are 3 locations where data may be stored:

— Locked storage cabinet for informed consent forms and other paper documents
— Secure Kobo server, with limited access rights. All data will be encrypted prior to being uploaded to the Kobo Server.
— Password-protect One-Drive Folder with limited access rights. We recognize that Microsoft is not one of Berkeley's approved vendors, and we have initiated a vendor security review with ISO.

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one of Berkeley's approved vendors, and we have initiated a vendor security review with ISO.

Only individuals listed on this protocol will have access to the study research data. However, we may create an anonymized dataset with no personal identifiable information for public release to the broader research community.

Additionally, we will follow the best practices suggested by campus policy, making sure all laptops meet the Minimum Security Standards for Electronic Information and Minimum Security Standards for Networked Devices. We will also backup and securely store our data keys.

iii. How long study data will be retained, including signed consent forms. Data retention specifications should adhere to the regulatory requirements applicable to the study (e.g. DHHS, OCR [HIPAA], FDA, etc.).

The raw study data with identifiers will be retained for up to one year by IMPACT Initiatives after the study has been published. Consent forms will be scanned and the physical copies will be destroyed 6 months after the end of data collection. Eventually, a de-identified version of the datasets will be made publicly available to the research community.

iv. When audio/video recordings will be transcribed and when they will be destroyed (if ever).

N/A

d) Identifiers should be removed from data/specimens as soon as possible following collection, except in cases where the identifiers are embedded (e.g., voices in audio or faces in video recordings). If data are coded in order to retain a link between the data and identifiable information, explain where the key to the code will be stored, how it will be protected, who will have access to it, and when it will be destroyed.

The data will be stripped of identifiers (name, address, phone number) and assigned a unique identifier (a randomly generated number). This identifier can be used to link personal identifiers onto the general survey data. The identifiers will be kept in a separate file, and the key to the data will be stored and protected on PI's personal encrypted laptop and will be shared through an encrypted network only with other investigators listed on this protocol. This key will be deleted 2 years after the study has been published.

Quantitative data, including personally identifiable information, will be stored on a secure Kobo server, with limited access rights. Only two investigators listed on this protocol (Saeed, Christina) will have direct access to download the data. When downloading data, specific columns can be selected for export. For protection purposes, three types of export will be done:

1. Coded, Anonymized Dataset - The dataset where all identifiable information has been removed, except geographic information which will remain in this dataset. This will be exported daily or weekly and stored in a secure Microsoft OneDrive folder.

2. Identifiable Dataset with Personally Identifiable Information - The dataset where only the identifiable information is included, excluding geographic information which will be in the coded dataset. This will be exported only as needed for analysis, and an aggregated dataset will be processed with an R script for

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deaths reported across data collection methods. This will be exported and stored in a secure OneDrive folder with access limited to only two investigators. These investigators will work with and share hard copy excerpts of this data with field officers for verification interviews only as needed, and copies of those excerpts will be destroyed the same day immediately after use.

3. Linkage Keys - For linking the Anonymized and Identifiable Datasets. This will be exported from the Kobo server, password protected and stored on a secure IMPACT Initiatives work computer.

e) **Describe how identifiable data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit (e.g., prior encryption). If not applicable, enter N/A.**

Encrypted data will be uploaded to a secure server.

f) **Will subjects be asked to give permission for release of identifiable data (e.g., for publications or presentations), now or in the future? If so, explain here and include appropriate statements in the consent materials. See Media Records Release Form template for guidance.**

We will never release the identifiable data in publications or presentations. We hope to release the non-identifiable data for the broader research community to analyze, allowing our research to be replicated and extended.

g) **Explain how subject privacy will be protected (e.g., conducting interviews in a discreet location).**

Given the potentially sensitive nature of the interviews (e.g., reporting on deaths), interviews will be conducted in discreet locations to provide subjects privacy. Specifically, we will identify a discreet location with enough space to set up a small table with chairs to conduct the interview.

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* * * Potential Financial Conflict of Interest * * *

14. Potential Financial Conflict of Interest

Individuals who have independent roles in projects and who are responsible for the design, analysis, conduct, or reporting of the results of research performed (or to be performed) under a human subjects protocol must disclose whether or not they have a financial interest in or association with a sponsor, a company supplying or manufacturing materials, drugs, or devices being tested under the protocol, or any intellectual property used in the project. This checklist pertains to the entire project team working under the protocol. Any individual who has such an interest and/or potential conflict must comply with University regulations and procedures for disclosure of financial conflict of interest.

See Conflict of Interest Committee Website for more information.

Please answer the following questions:

Does any member of the project team (defined as UCB or non-UCB personnel working under the protocol) with substantive responsibility for the design, conduct, or reporting of activities under the protocol, or any member of their immediate family (defined as spouse, dependent child or registered domestic partner) have any of the following:

1. N **Positions of management (e.g., board member, scientific advisor, director, officer, partner, trustee, employee, consultant) at a non-UC entity financing the research to be done under the protocol or at a non-UC entity supplying or manufacturing materials, drugs, or devices being tested under the protocol.**
2. N **Equity interest (e.g., stock, stock options, investment, or other ownership) in a non-UC entity financing the research to be done under the protocol or in a non-UC entity supplying or manufacturing materials, drugs or devices being tested under the protocol.**
3. N **Intellectual property used in the protocol, such as rights to a pending patent application or issued patent to any invention(s), or license rights or copyright for software that has a direct relationship to the project proposed.**

If the answer to any of the above is Yes, then each individual with any "Yes" response(s) must submit a Human Subjects Financial Conflict of Interest Form and include it in the Attachments section of the protocol.

NOTE: When review by the COI Committee is required, CPHS approval of protocols will be contingent upon the disclosure and resolution of all financial conflicts of interest, as determined by the COI Committee.

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* * * Informed Consent * * *

15. Informed Consent

Add the consent documents and/or waivers needed for this research using the table at the bottom of the page, including any translated versions. For any translated consent, include an affirmation of the translation's accuracy, indicating who is affirming the accuracy (PI, Co-PI, or Student Investigator), in the Consent/Waiver Description or in the Attachment section. Describe the consent process and provide justification for any waivers for each consent document, translation, and/or waiver. The various consent/waiver options are described below.

Note: DO NOT include child assent documents, parent permission documents or waivers here (these are addressed in the next section). The eProtocol system will prevent submission if this section is incomplete. If your study involves only children and no adult subjects, select "Consent Waiver" for the consent type (as this will not require that a document be attached), and put "No Adult Subjects" as the Consent/Waiver Description.

Altered and Unsigned Consent - A consent document that has omitted required information and does not include a place for a participant's signature. This means that CPHS is being asked to waive one or more elements of consent in addition to the requirement for documented consent.

Altered Consent Form - A consent form that has omitted required information. This means that the CPHS is asked to waive one or more required elements of informed consent. For example, if the purpose of the study will not be disclosed to participants in order to avoid bias, this option should be selected because disclosure of the "purpose" is a required element of informed consent. The form must include a signature line and date line for the individual to sign if he or she agrees to participate.

Consent Form - A standard consent document that embodies all of the required information (elements of informed consent) designed to help an individual make an informed decision about whether or not to participate in the research. The form must include a signature line and date line for the individual to sign if he or she agrees to participate. The Consent Form can also be presented as a "short form" document stating that the required elements of informed consent have been presented orally to the participant. When the short form method is used, a "summary" of the information that is presented to the participant must also be provided for CPHS approval and there must be an impartial witness to the oral presentation. The witness must sign the summary as well as the short form and the participant must sign the summary. The "short form" method may be used in circumstances where oral presentation of consent is preferable or necessary, e.g., subjects are illiterate in English or their native language.

Consent Waiver - No consent will be sought at all. This means that the CPHS is asked to waive the requirement for informed consent. This option is often appropriate for research that involves use of existing data or samples

Unsigned Consent - A document that embodies all of the required information (elements of informed consent), but does not include a place for a participant to indicate with a signature that he or she agrees to take part in the research. This means that the CPHS is asked to waive the requirement for documented

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(signed) consent. For example, if consent will be obtained verbally or using a button on the web, this option should be selected.

•Informed Consent Guidelines, Templates and Sample Forms

•Informed Consent Policies and Procedures

Informed Consent

Consent/Waiver Description	Consent Document
Consent waiver for secondary research subjects	
Method 2 Key Informant ICF English	method2_icf_InformantMethod_clean_english
Method 1 Network Survival ICF English	method1_icf_NetworkSurvial_clean_english
Method 2 Key Informant ICF French	method2_icf_InformantMethod_clean_french
Method 2 Key Informant ICF Swahili	method2_icf_InformantMethod_clean_swahili
Method 1 Network Survival ICF French	method1_icf_NetworkSurvial_clean_french
Method 1 Network Survival ICF Swahili	method1_icf_NetworkSurvival_clean_swahili
Method 3 Household Survey ICF English	method3_icf_HouseholdSurvey_clean_english
Method 3 Household Survey ICF French	method3_icf_HouseholdSurvey_clean_french
Method 3 Household Survey ICF Swahili	method3_icf_HouseholdSurvey_clean_swahili
Method 4 Verbal Autopsy (Household) ICF English	method4_icf_VerificationInterview_household_clean_english
Method 4 Verbal Autopsy (Household) ICF French	method4_icf_VerificationInterview_household_clean_french
Method 4 Verbal Autopsy (Household) ICF Swahili	method4_icf_VerificationInterview_household_clean_swahili
Method 4 Verbal Autopsy (Phone) ICF French	method4_icf_VerificationInterview_phone_clean_french
Method 4 Verbal Autopsy (Phone) ICF Swahili	method4_icf_VerificationInterview_phone_clean_swahili
Method 4 Verbal Autopsy (Phone) ICF English	method4_icf_VerificationInterview_phone_clean_english

Informed Consent

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Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)
Consent waiver for secondary research subjects

Consent Type
Consent Waiver

For CPHS to approve a waiver of one or more elements of informed consent, one of the below criteria must be met. Select the applicable criterion and provide justification in the box below.

Y **A.** (1) The research involves no more than minimal risk of harm to the subjects;

(2) The research could not practicably be carried out without the requested waiver or alteration;

(3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(5) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

For secondary research subjects, there is only minimal to no risk. We are only collecting minimal amount of data on secondary subject living in the household - specifically, names, basic demographic and economic characteristics, and subjects' symptoms of disease or sickness. There is no practical way we could obtain consent for all secondary research subjects in a household, as secondary subjects may not be around for the time of the interview. Therefore, this research could not practically be carried out without the requested waiver. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

For the household survey (method 3), the research could not be carried out without collecting the identifiable information of secondary subjects as it is critical to collect names of each individual living in a household when conducting a household survey. Respondents cannot accurately report on all other members of their household unless they are prompted with specific names of household members. This is especially true in contexts such as DR Congo, where respondents may have large households and easily get confused during interviews. Additionally, there is a chance we will need this information to follow-up with participants. For the Key Informant survey (Method 2), the research could not be carried out without collecting the identifiable information of secondary subjects as we need to know information about secondary subjects who had measles and cholera. Because we are collecting the name of the household head, we will treat these subjects as secondary subjects. Without the name of the household head, it would be impossible for the key informant to report on each household.

B. 1. The research or demonstration project is to be conducted by or subject to the approval of state or local officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or service; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration.

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If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)	Method 2 Key Informant ICF English
Consent Type	Unsigned Consent

Attach Consent Document (in PDF format)	X	Consent Document	method2_icf_InformantMethod_clean_english

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

For method 2, informed consent will be obtained over the phone by the survey enumerators. The full information form and consent form will be read to the respondent by the enumerator. The respondent will be given the opportunity to ask any questions they might have. The enumerator will confirm that the respondent understands (1) the purpose of the study; (2) why they were selected as a participant; (3) confidentiality and voluntary participation; (4) who to contact if they have further questions; (5) whether the respondent gives informed consent to participate in the study. The enumerator will then sign a form confirming the respondent gave verbal informed consent to participate.

For CPHS to approve a waiver of the requirement for documented (signed) consent, one of the below criteria must be met. Select the applicable criterion and provide justification in the box below.

A. The only record linking the subject and the research would be the consent document AND the principal risk of the research would be potential harm resulting from a breach of confidentiality.

Y **B.** The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

Respondents will only be reporting about deaths in their community and outbreaks of Measles and Cholera. This presents no more than minimal risk to subjects. This research also involves no procedures for which written consent is normally required outside of the research context.

C. Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk of harm to subjects and an appropriate alternative mechanism for documenting that informed consent was obtained will be used.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)	Method 1 Network Survival ICF English
Consent Type	Consent Form

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Attach Consent Document (in PDF format)	X	Consent Document	method1_icf_NetworkSurvial_clean_english

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Potential respondents will be identified at transportation sites, health facilities, markets, and other locations of public services within Kalemie town. Informed consent will be administered in a private, discrete location. Respondents will be invited to participate in the study and informed consent form would be applied by an enumerator.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C) Method 2 Key Informant ICF French

Consent Type Unsigned Consent

Attach Consent Document (in PDF format)	X	Consent Document	method2_icf_InformantMethod_clean_french

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Consent process is the same as English language form. Casey Breen (student investigator) conferred with a professional translator to confirm the translations were accurate.

For CPHS to approve a waiver of the requirement for documented (signed) consent, one of the below criteria must be met. Select the applicable criterion and provide justification in the box below.

A. The only record linking the subject and the research would be the consent document AND the principal risk of the research would be potential harm resulting from a breach of confidentiality.

Y **B.** The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

Same as English version form.

C. Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk of harm to subjects and an appropriate alternative mechanism for documenting that informed consent was obtained will be used.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C) Method 2 Key Informant ICF Swahili

Consent Type Unsigned Consent

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Attach Consent Document (in PDF format)	X	Consent Document	method2_icf_InformantMethod_clean_swahili

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Consent process is the same as for English version. Casey Breen (student investigator) conferred with a professional translator to confirm the translations were accurate.

For CPHS to approve a waiver of the requirement for documented (signed) consent, one of the below criteria must be met. Select the applicable criterion and provide justification in the box below.

A. The only record linking the subject and the research would be the consent document AND the principal risk of the research would be potential harm resulting from a breach of confidentiality.

Y **B.** The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

Same as English version.

C. Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk of harm to subjects and an appropriate alternative mechanism for documenting that informed consent was obtained will be used.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)	Method 1 Network Survival ICF French

Consent Type		Consent Form	
Attach Consent Document (in PDF format)	X	Consent Document	method1_icf_NetworkSurvial_clean_french

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Same as English version. Casey Breen (student investigator) conferred with a professional translator to confirm the translations were accurate.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)	Method 1 Network Survival ICF Swahili

Consent Type		Consent Form	
Attach Consent Document (in PDF format)	X	Consent Document	method1_icf_NetworkSurvival_clean_swahili

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Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Same an English version. Casey Breen (student investigator) conferred with a professional translator to confirm the translations were accurate.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)	Method 3 Household Survey ICF English

Consent Type		Consent Form	
Attach Consent Document (in PDF format)	X	Consent Document	method3_icf_HouseholdSurvey_clean_english

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Informed consent will be administered by survey enumerators outside potential respondent's houses to one household members over age 18. Enumerators will ensure the survey is administered is a discrete location, if the respondent's household is not sufficiently private. Additionally, enumerators will administer informed consent from a paper form, taking care to answer any of the respondent's questions. If the respondent consents, enumerator will share a copy of the signed informed consent form with them.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)	Method 3 Household Survey ICF French

Consent Type		Consent Form	
Attach Consent Document (in PDF format)	X	Consent Document	method3_icf_HouseholdSurvey_clean_french

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Same as English version. Casey Breen (student investigator) conferred with a professional translator to confirm the translations were accurate.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)	Method 3 Household Survey ICF Swahili

Consent Type	Consent Form

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Attach Consent Document (in PDF format)	X	Consent Document	method3_icf_HouseholdSurvey_clean_swahili

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Same as English version. Casey Breen (student investigator) conferred with a professional translator to confirm the translations were accurate.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C): Method 4 Verbal Autopsy (Household) ICF English

Consent Type		Consent Form	
Attach Consent Document (in PDF format)	X	Consent Document	method4_icf_VerificationInterview_household_clean_english

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Informed consent will be administered by survey enumerators outside potential respondent's houses to one household members over age 18. Enumerators will ensure the survey is administered is a discrete location, if the respondent's household is not sufficiently private. Additionally, enumerators will administer informed consent from a paper form, taking care to answer any of the respondent's questions. If the respondent consents, enumerator will share a copy of the signed informed consent form with them.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C): Method 4 Verbal Autopsy (Household) ICF French

Consent Type		Consent Form	
Attach Consent Document (in PDF format)	X	Consent Document	method4_icf_VerificationInterview_household_clean_french

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Same as English version. Casey Breen (student investigator) conferred with a professional translator to confirm the translations were accurate.

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Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C) Method 4 Verbal Autopsy (Household) ICF Swahili

Consent Type		Consent Form	
Attach Consent Document (in PDF format)	X	Consent Document	method4_icf_VerificationInterview_household_clean_swahili

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Same as English version. Casey Breen (student investigator) conferred with a professional translator to confirm the translations were accurate.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C) Method 4 Verbal Autopsy (Phone) ICF French

Consent Type		Unsigned Consent	
Attach Consent Document (in PDF format)	X	Consent Document	method4_icf_VerificationInterview_phone_clean_french

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Consent process is the same as English version. Casey Breen (student investigator) conferred with a professional translator to confirm the translations were accurate.

For CPHS to approve a waiver of the requirement for documented (signed) consent, one of the below criteria must be met. Select the applicable criterion and provide justification in the box below.

A. The only record linking the subject and the research would be the consent document AND the principal risk of the research would be potential harm resulting from a breach of confidentiality.

Y **B.** The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

Same as English version.

C. Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk of harm to subjects and an appropriate alternative mechanism for documenting that informed consent was obtained will be used.

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Date Submitted: 10/16/2022
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Important Note: **This Print View may not reflect all comments and contingencies for approval. Please check the comments section of the online protocol.
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Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)	Method 4 Verbal Autopsy (Phone) ICF Swahili
Consent Type	Unsigned Consent

Attach Consent Document (in PDF format)	X	Consent Document	method4_icf_VerificationInterview_phone_clean_swahili

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

Consent process is the same as for English version. Casey Breen (student investigator) conferred with a professional translator to confirm the translations were accurate.

For CPHS to approve a waiver of the requirement for documented (signed) consent, one of the below criteria must be met. Select the applicable criterion and provide justification in the box below.

A. The only record linking the subject and the research would be the consent document AND the principal risk of the research would be potential harm resulting from a breach of confidentiality.

Y **B.** The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

Same as for English version.

C. Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk of harm to subjects and an appropriate alternative mechanism for documenting that informed consent was obtained will be used.

Consent/Waiver Description (e.g. Consent for Group A, Waiver for Group B, Surrogate Consent for Group C)	Method 4 Verbal Autopsy (Phone) ICF English
Consent Type	Unsigned Consent

Attach Consent Document (in PDF format)	X	Consent Document	method4_icf_VerificationInterview_phone_clean_english

Explain how, where, when, and by whom informed consent will be obtained. If any vulnerable subject groups are involved, discuss relevant considerations. Note: If attaching multiple consent forms and consent process has already been described for another consent form, simply refer to the other form (e.g., consent process is the same as for Group A).

For method 4 (phone), informed consent will be obtained over the phone by the survey enumerators. The full information form and consent form will be read to the respondent by the enumerator. The respondent will be given the opportunity to ask any questions they might have. The enumerator will confirm that the respondent understands (1) the purpose of the study; (2) why they were selected as a participant; (3) confidentiality and voluntary participation; (4) who to contact if they have further questions; (5) whether the respondent gives informed consent to participate in the study. The enumerator will then sign a form confirming the respondent gave verbal informed consent to participate.

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For CPHS to approve a waiver of the requirement for documented (signed) consent, one of the below criteria must be met. Select the applicable criterion and provide justification in the box below.

A. The only record linking the subject and the research would be the consent document AND the principal risk of the research would be potential harm resulting from a breach of confidentiality.

Y **B.** The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

Respondents will only be reporting about deaths in their immediate household. This presents no more than minimal risk to subjects. This research also involves no procedures for which written consent is normally required outside of the research context.

C. Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk of harm to subjects and an appropriate alternative mechanism for documenting that informed consent was obtained will be used.

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* * * Child Assent & Parent Permission * * *

16. Child Assent and Parent/Guardian Permission

Add each child assent document, parent/guardian permission document, and/or waiver needed for this research using the table at the bottom of the page, including any translated versions. For any translated consent, include an affirmation of the translation's accuracy, indicating who is affirming the accuracy (PI, Co-PI, or Student Investigator), in the Consent/Waiver Description or in the Attachment section. Describe the consent process and provide justification for any waivers for each consent document, translation, and/or waiver. The various consent/waiver options are described below.

Altered and Unsigned Parent/Guardian Permission Form - A parent permission document that has omitted required information (elements) and does not include a place for a parent to indicate with a signature that he or she agrees to permit the child's participation. This means that CPHS is being asked to waive one or more elements of consent in addition to the requirement for documented consent.

Altered Parent/Guardian Permission Form - A permission form that has omitted required information (elements). This means that the CPHS is asked to waive one or more required elements of informed consent. However, the form must include signature and date lines for the parent(s)/guardian(s) to sign if the child is permitted to take part in the research.

Assent Document - A form or script of the information that will be conveyed to the child about the study. In general, researchers must obtain the affirmative agreement of children ages seven years and older for their participation. Assent forms should be written at a level understandable to the child. If the study includes a broad age range of children, more than one assent form may be needed (i.e., an assent form suitable for a 15 year old is not usually suitable for a 7 year old child).

Assent Waiver - No child assent will be sought at all. This means that CPHS is asked to waive the requirement for child assent. Among other circumstances, this option is appropriate when the capability of the child to understand the research is too limited or when the research holds out a prospect of direct benefit that is important to the health or well being of the child.

Parent/Guardian Permission Form - A document that embodies all of the required information (elements of informed consent) designed to help the parent/guardian of a child make an informed decision about whether or not to permit the child's participation in the research. The form must include signature and date lines for the parent(s)/guardian(s) to sign if the child is permitted to take part in the research.

Permission Waiver - No parent/guardian permission will be sought at all. This means that the CPHS is asked to waive the requirement for parent/guardian permission. This option, for example, is often appropriate for research designed to study conditions in children or a study population for which parental permission is not a reasonable requirement to protect the children (e.g., neglected or abused children).

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Unsigned Parent/Guardian Permission Form - A parent permission document that embodies all of the required information (elements of informed consent), but does not include a place for a parent to indicate with a signature that he or she agrees to permit the child's participation. This means that the CPHS is asked to waive the requirement for documented (signed) consent.

- **Child Assent and Parent Permission Guidelines, Templates, and Sample Forms**

•Policies and Procedures on Child Assent and Parent Permission

Documents and Waivers

Permission/Assent Description	Assent or Permission Type	Assent/ Permission Document

Documents and Waivers

Permission/Assent Description (e.g. Assent for Group A, Permission for Group A, Waiver of Parent Permission for Group B, Assent for Group B etc) — Waiver of permission

Assent or Permission Type — Permission Waiver

For CPHS to approve a waiver of parent permission (e.g. no permission from the parent or legal guardian will be obtained for the child's participation), either criterion A, B or C must be met. Select the applicable criterion and provide justification in the box below.

Y **A.** (1) The research involves no more than minimal risk of harm to the subjects;

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(2) The research could not practicably be carried out without the requested waiver or alteration;

(3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(5) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

We are requesting a waiver of parental consent, as there is only minimal to no risk for secondary children subjects. We are only collecting a minimal amount of data on secondary subject living in the household - specifically, names, basic demographic and economic characteristics, and detailed or specific information about symptoms the secondary subject may have experienced while sick.

There is no practical way we could obtain permission from parents for all children in a household because many parents may not be alive to give permission or other caretakers (grandparents, cousins, etc.) living in the household would be answering the survey. This is highly common in DR Congo. Therefore, this research could not practically be carried out without the requested permission waiver. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

The research could not be carried out without collecting the identifiable information of secondary subjects as it is critical to collect names of each individual living in a household when conducting a household survey. Respondents cannot accurately report on all other members of their household unless they are prompted with specifics name. This is especially true in contexts such as DR Congo, where respondents may have large households and easily get confused during interviews. In addition, there is a chance we will need this information to follow-up with participants.

B. (1) The research or demonstration project is to be conducted by or subject to the approval of state or local officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or service; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

C. The research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), and also finds that: (i) an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted; and (ii) the waiver is not inconsistent with federal, state, or local law.

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The choice of an appropriate substitute mechanism will depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

Permission/Assent Description (e.g. Assent for Group A, Permission for Group A, Waiver of Parent Permission for Group B, Assent for Group B etc)	Assent Waiver
Assent or Permission Type	Assent Waiver

For CPHS to approve a waiver of child assent (e.g. no assent will be obtained from child/minor at all), one of the below criteria must be met. Please check the applicable criterion and provide justification in the box below.

A. The capability of some or all of the children is so limited that they cannot reasonably be consulted.

B. The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.

Y **C.** (1) The research involves no more than minimal risk of harm to the subjects;

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(2) The research could not practicably be carried out without the requested waiver or alteration;

(3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(5) Whenever appropriate, the subjects or legally authorized representatives will be provided with pertinent information after participation.

We are requesting an assent waiver as there is only minimal to no risk for secondary children subjects. We are only collecting minimal amount of data on secondary subject living in the household - specifically, names, basic demographic and economic characteristics, and detailed or specific information about symptoms the secondary subject may have experienced while sick.

There is no practical way we could obtain assent for all children in a household, as many children will not be at the household during the day when interviews are most likely to take place. Children in these settings in DR Congo often have small jobs or attend school, including in the evenings. Therefore, this research could not practically be carried out without the requested assent waiver. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

The research could not be carried out without collecting the identifiable information of secondary subjects as it is critical to collect names of each individual living in a household when conducting a household survey. Respondents cannot accurately report on all other members of their household unless they are prompted with specific names of household members. This is especially true in contexts such as DR Congo, where respondents may have large households and easily get confused during interviews. In addition, there is a chance we will need this information to follow-up with participants.

D. (1) The research or demonstration project is to be conducted by or subject to the approval of state or local officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or service; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; AND

(2) The research could not practicably be carried out without the waiver or alteration.

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* * * Attachments * * *

17. Attachments

Add appropriate attachments (e.g., advertisements, data collection instruments, IRB approvals from collaborating institutions, etc.) in this section. Attachments MUST be in PDF format. Please see eProtocol Attachments Check List for Non-Exempt Applications for more information.

Inter-institutional Agreement

Document Type	Document Name	Attached Date	Submitted Date
Inter-institutional Agreement	2022-09-15642 (Feehan)_IIA_IMPACT_executed	02/28/2023	02/28/2023

Notice of Intent to Rely Form

Document Type	Document Name	Attached Date	Submitted Date
Notice of Intent to Rely Form	request_review_institution_01292023 df	01/29/2023	02/01/2023

Other Institutions' IRB Approvals

Document Type	Document Name	Attached Date	Submitted Date
Other Institutions' IRB Approvals	kinshasa_local_irb_approval_english	02/27/2023	02/27/2023

Survey Instruments

Document Type	Document Name	Attached Date	Submitted Date
Survey Instruments	Method 1 - survey instrument - Network Survival_02182023_english	02/20/2023	02/20/2023
Survey Instruments	Method 2 - survey instrument - Informant Method_02182023_english	02/20/2023	02/20/2023
Survey Instruments	Method 3 - survey instrument - Household Survey_02182023_english	02/20/2023	02/20/2023
Survey Instruments	Method 4 - survey instrument - Verbal Autopsy_02182023_english	02/27/2023	02/27/2023

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Document Type Inter-institutional Agreement
Document Name 2022-09-15642 (Feehan)_IIA_IMPACT_executed

Document Type Notice of Intent to Rely Form
Document Name request_review_institution_01292023 df

Document Type Other Institutions' IRB Approvals
Document Name kinshasa_local_irb_approval_english

Document Type Survey Instruments
Document Name Method 1 - survey instrument - Network Survival_02182023_english

Document Type Survey Instruments
Document Name Method 2 - survey instrument - Informant Method_02182023_english

Document Type Survey Instruments
Document Name Method 3 - survey instrument - Household Survey_02182023_english

Document Type Survey Instruments
Document Name Method 4 - survey instrument - Verbal Autopsy_02182023_english

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* * * Assurance * * *

Assurance

As Faculty Sponsor, I understand that I am responsible for overseeing the protection of the rights and welfare of the human subjects, and adherence to CPHS requirements, federal regulations, and state statutes for human subjects research.

I hereby assure the following:

1. I have read the protocol.
2. I have discussed with the Student/Postdoc Investigator how to comply with his or her assurances.
3. I will be available throughout the course of the study to provide guidance and consultation.

X **I have read and agree to the above assurances.**

As Student/Postdoctoral Investigator, I am responsible for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to CPHS requirements, federal regulations, and state statutes for human subjects research.

I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.
2. All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.
3. This protocol covers the human subjects research activities described in the grant proposal(s) supporting this research and any such activities that are not covered have been/will be covered by a CPHS approved protocol.
4. The legally effective informed consent of all human subjects or their legally authorized representative

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will be obtained (unless waived) using only the current, approved consent form(s).

5. If any study subject experiences an unanticipated problem involving risks to subjects or others, and/or a serious adverse event, the CPHS will be informed promptly within no more than one week (7 calendar days), and receive a written report within no more than two weeks (14 calendar days), of recognition/ notification of the event.

6. No change in the design, conduct, or key personnel of this research will be implemented without prior CPHS review and approval, unless the changes are necessary to eliminate an apparent immediate hazard to subjects. Changes made to eliminate hazards to subjects will be reported to OPHS/CPHS via the AE/UP reporting process.

7. Applications for continuation review will be submitted in a timely manner prior to the expiration date to allow sufficient time for the renewal process. I understand that if approval expires, all research activity (including data analysis) must cease until I receive notice of re-approval by the CPHS.

8. Participants' complaints or requests for information about the study will be addressed appropriately.

9. I will promptly and completely comply with a CPHS decision to suspend or withdraw its approval for the project.

10. I will submit a study closure form at the conclusion of this project.

X **I have read and agree to the above assurances.**

PROTOCOL
Soc-Behav-Ed Non-Exempt
Berkeley

Protocol # 2022-09-15642
Date Printed: 06/23/2023

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* * * Event History * * *

Event History

Date	Status	View Attachments	Letters
02/28/2023	NEW FORM APPROVED	Y	Y
02/28/2023	NEW FORM REVIEWER(S) ASSIGNED		
02/28/2023	NEW FORM SUBMITTED (CYCLE 5)	Y	
02/28/2023	NEW FORM REVIEWER(S) ASSIGNED		
02/27/2023	NEW FORM SUBMITTED (CYCLE 4)	Y	
02/20/2023	NEW FORM SUBMITTED (CYCLE 3)	Y	
02/01/2023	NEW FORM SUBMITTED (CYCLE 2)	Y	
01/13/2023	NEW FORM SUBMITTED (CYCLE 1)	Y	
11/21/2022	NEW FORM PANEL MANAGER REVIEW		
10/17/2022	NEW FORM PANEL ASSIGNED		
10/16/2022	NEW FORM SUBMITTED	Y	
09/26/2022	NEW FORM CREATED		

PROTOCOL
Soc-Behav-Ed Non-Exempt
Berkeley

Protocol # 2022-09-15642
Date Printed: 06/23/2023

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*** * * Attached Document * * ***

Document Name	Created Date
2022-09-15642 (Feehan)_IIA_IMPACT_executed.pdf	02/28/2023

Institutional Review Board (IRB) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution A):

University of California, Berkeley

UCB IRB Registration #: ***IRB00000455 & IRB00005610*** UCB FWA #: ***FWA00006252***

Name of Institution Relying on the Designated IRB (Institution B):

IMPACT Initiatives
International Environment House 2,
Chemin de Balexert 9,
1219 Geneva,
Switzerland

FWA #: ***FWA00030365***

The Officials signing below agree that Impact Initiatives may rely on the UC Berkeley designated IRBs for review and continuing oversight of its human subjects research described below.

This agreement is limited to the following specific protocol(s):

Name of UCB Principal Investigator: *Dennis Feehan*

Name of Investigator at Relying Institution: *Saeed Rahman, Jonathan Polonsky, Joeri Smits, Christina Kay, Mory Keita, and Yoann Martin*

Name of Research Project(s): *New Approaches to Estimating Mortality in Humanitarian Crises*

eProtocol #(s): *2022-09-15642*

Sponsor or Funding Agency: *IMPACT Initiatives*

Award Number(s), if any: *N/A*

If this study qualifies for flexible processes and determinations under the policies at the University of California, Berkeley (UCB), these flexible processes and determinations will apply to the researchers from Institution B who are under the oversight of UCB's IRB. When applicable, the review performed by UCB's designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA.

The IRB at Institution A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B, as needed and/or requested. Relevant minutes of IRB meetings, other findings and actions will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations, cooperating on any noncompliance investigations, and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution A): _____ Date: 2/28/2023

Print Full Name: ***Rebecca D. Armstrong*** Institutional Title: ***Director, Research Subject Protection***

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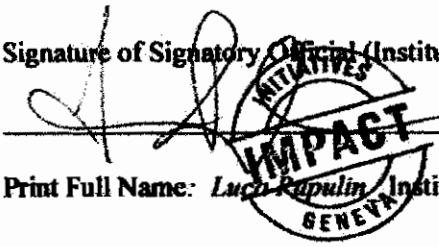
Signature of Signatory Official (Institution B):



Date: _28th Feb 2023__

Print Full Name: *Luca Pupulin* Institutional Title: *_Executive Director_*

Appendix A

Please provide information for the IRB contact persons at Institution A and Institution B who should be included on all correspondence regarding the reliance agreement.

Institution A: **University of California, Berkeley**
Name: **Emily Harden-Antonio**
Email: **irb_reliance@berkeley.edu**
Phone Number: **510-642-7461**

Institution B: **IMPACT Initiatives** for REACH
Name: **Saeed RAHMAN**
Institutional Title: **Global Nutrition and Health Assessment Specialist**
Email: **saeed.rahman@impact-initiatives.org**
Phone Number: **+41(0)225662963**

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