icddr,b
KNOWLEDGE FOR GLOBAL LIFESAVING SOLUTIONS

RRC APPLICATION FORM

RESEARCH PROTOCOL NUMBER: 2009-008

FOR OFFICE USE ONLY

RRC Approval:	☒ Yes /	☐ No	Date:29-01-2009
ERC Approval:	☐ Yes /	☐ No	Date:
AEEC Approval:	☐ Yes /	☐ No	Date:
External IRB Approval: ☐ Yes / ☐ No Date: Name of IRB:			

Protocol Title: Inpatient surveillance project for HIV Ward of the Dhaka Hospital of ICDDR,B

Short title (in 50 characters including space): Dhaka Hospital HIV Ward Surveillance Project

Theme: (Check all that apply)

- ☐ Nutrition
- ☒ Emerging and Re-emerging Infectious Diseases
- ☐ Population Dynamics
- ☐ Reproductive Health
- ☐ Vaccine Evaluation
- ☒ HIV/AIDS
- ☐ Environmental Health
- ☒ Health Services
- ☐ Child Health
- ☒ Clinical Case Management
- ☐ Social and Behavioural Sciences
- ☐ Gender
- ☐ Human Rights
- ☐ Others (please specify_____)

Key words: HIV, AIDS, surveillance, opportunistic infections, co-infections, drug-drug interactions, drug intolerance, anti-retroviral therapy, risk reduction, healthcare quality, data analysis, needs assessment

Relevance of the Protocol:
Regular, ongoing quantification of demographic, health-related, and risk reduction data of patients attending the recently established HIV Ward of the Dhaka Hospital, ICDDR,B

Centre's Priority (as per Strategic Plan, to be imported from the attached Separate Word Sheet):
2.3: Improve surveillance for, and prevention and management of sexually transmitted and reproductive tract infections and HIV-AIDS.
4.1: Define the epidemiology and burden of selected infectious diseases and identify effective strategies for prevention and control. These include tuberculosis, diarrhoea, ALRI (pneumonia), typhoid fever, dengue, malaria, kala azar, and drug-resistant infections.
4.4: Enhance the capacity to investigate, study, and manage outbreaks of communicable diseases in the region.
5.5: Improve health information systems and evidence-based decision making.

Programmes:

- ☐ Child Health Programme
- ☐ Nutrition Programme
- ☐ Programme on Infectious Diseases & Vaccine Science
- ☐ Poverty and Health Programme
- ☐ Health and Family Planning Systems Programme
- ☐ Population Programme
- ☐ Reproductive Health Programme
- ☒ HIV/AIDS Programme
- ☐ Gender, Hunman Rights and Health Programme
- ☐ Others (please specify_____)

Principal Investigator (Should be a Centre's staff)
Lars Henning
Address (including e-mail address):
henning@icddrb.org

DIVISION:

- ☒ CSD
- ☐ LSD
- ☐ HSID
- ☐ PHSD

Co-Principal Investigator(s): Internal
Brent Ohata

Co-Principal Investigator(s): External:
(Please provide full official address including e-mail address and Gender)

Co-Investigator(s): Internal:
Brian Cobb, ASG Faruque

Co-Investigator(s): External
(Please provide full official address including e-mail address and Gender)

Student Investigator(s): Internal (Centre's staff):

Student Investigator(s): External:
(Please provide full address of educational institution and Gender)

Collaborating Institute(s): Please Provide full address

Institution # 1

Country	
Contact person	
Department (including Division, Centre, Unit)	
Institution (with official address)	
Directorate (in case of GoB i.e. DGHS)	
Ministry (in case of GoB)	

Institution # 2

Country	
Contact person	
Department (including Division, Centre, Unit)	
Institution (with official address)	
Directorate (in case of GoB i.e. DGHS)	
Ministry (in case of GoB)	

Institution # 3

Country	
Contact person	
Department (including Division, Centre, Unit)	
Institution (with official address)	
Directorate (in case of GoB i.e. DGHS)	
Ministry (in case of GoB)	

Note: If more than 3 collaborating institutions are involved in the research protocol, additional block(s) can be inserted to mention its/there particular(s).

Population: Inclusion of special groups (Check all that apply):

Sex
- ☒ Male
- ☒ Female

Age
- ☒ 0 – 4 years
- ☒ 5 – 10 years
- ☒ 11 – 17 years
- ☒ 18 – 64 years
- ☒ 65 +

- ☒ Pregnant Women
- ☐ Fetuses
- ☐ Prisoners
- ☒ Destitutes
- ☐ Service Providers
- ☒ Cognitively Impaired
- ☒ CSW
- ☐ Others (specify)
- ☐ Animal

NOTE It is the policy of the Centre to include men, women, and children in all research projects involving human subjects unless a clear and compelling rationale and justification (e.g. gender specific or inappropriate with respect to the purpose of the research) is there. Justification should be provided in the `Sample Size' section of the protocol in case inclusiveness of study participants is not proposed in the study.

Project/study Site (Check all the apply):

- ☒ Dhaka Hospital
- ☐ Matlab Hospital
- ☐ Matlab DSS Area
- ☐ Matlab non-DSS Area
- ☐ Mirzapur
- ☐ Dhaka Community
- ☐ Chakaria
- ☐ Abhoynagar
- ☐ Mirsarai
- ☐ Patyia
- ☒ Other areas in Bangladesh: All of Bangladesh
- ☐ Outside Bangladesh
  Name of Country:
- ☐ Multi Centre Trial

(Name other countries involved):

Type of Study (Check all that apply):

- ☐ Case Control Study
- ☐ Community-based Trial/Intervention
- ☐ Program Project (Umbrella)
- ☐ Secondary Data Analysis
- ☐ Clinical Trial (Hospital/Clinic)
- ☐ Family Follow-up Study
- ☐ Cross Sectional Survey
- ☐ Longitudinal Study (cohort or follow-up)
- ☐ Record Review
- ☐ Prophylactic Trial
- ☒ Surveillance/Monitoring
- ☐ Others:

NOTE: Does the study meet the definition of clinical studies/trials given by the International Committee of Medical Journal Editors (ICMJE)? Yes ☐ No ☒

Please note that the ICMJE defined clinical trial as "*Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome*".

If YES, after approval of the ERC, the PI should complete and send the relevant form to provide required information about the research protocol to the Committee Coordination Secretariat for registration of the study into websites, preferably at the www.clinicaltrials.gov. It may please be noted that the PI would require to provide subsequent updates of the research protocol for updating protocol information in the website.

Targeted Population (Check all that apply):

- ☒ No ethnic selection (Bangladeshi)
- ☐ Bangalee
- ☐ Tribal group
- ☒ Expatriates
- ☒ Immigrants
- ☒ Refugee

Consent Process (Check all that apply):

- ☒ Written
- ☐ Oral
- ☐ None
- ☒ Bengali Language
- ☒ English Language

Proposed Sample Size:

Sub-group (Name of subgroup (e.g. Men, Women) and Number

Name	Number	Name	Number
(1) Men/boys	75/year	(3)	
(2) Women/girls	75/year	(4)	

Total sample size: Estimated 150/year

Total sample size: 0

Will the sample(s) be kept for future use? Yes ☐ No ☒

If yes, how long the samples be preserved? _____ years.

Will the consent be obtained from the study participants? Yes ☒ No ☐

What types of tests will be carried out with the preserved samples? _____

_____

Will the samples be shipped to other country(ies)? Yes ☐ No ☒

If yes, name of institution(s) and country(ies): _____

Will the samples be returned to the Centre? Not applicable ☐ Yes ☐ No

Who will be the custodian of the samples? : _____

Who will be the owner of the samples? : _____

Has an MOU been made for the protocol? Yes ☐ No ☒

If yes, has copy of the MOU been submitted to IRB? Not applicable Yes ☐ No ☐

Determination of Risk: Does the Research Involve (Check all that apply**):**

- ☐ Human exposure to radioactive agents?
- ☐ Fetal tissue or abortus?
- ☐ Investigational new device?
  (specify:)
- ☒ Existing data available from Co-investigator
- ☐ Human exposure to infectious agents?
- ☐ Investigational new drug
- ☒ Existing data available via public archives/sources
- ☐ Pathological or diagnostic clinical specimen only
- ☐ Observation of public behaviour
- ☐ New treatment regime

Yes ☒ No ☐ Is the information recorded in such a manner that study participants can be identified from information provided directly or through identifiers linked to the study participants?

Yes ☒ No ☐ Does the research deal with sensitive aspects of the study participants' behaviour; sexual behaviour, alcohol use or illegal conduct such as drug use?

Could the information recorded about the individual if it became known outside of the research:

Yes ☒ No ☐ Place the study participants at risk of criminal or civil liability?

Yes ☒ No ☐ Damage the study participants' financial standing, reputation or employability, social rejection, lead to stigma, divorce etc.?

Do you consider this research (Check one):

☐ Greater than minimal risk ☐ No more than minimal risk

☒ Only part of the diagnostic test

Minimal Risk is "a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical, psychological examinations or tests. For example, risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as a part of routine physical examination".

Yes/ No

☐ ☒ Is the proposal funded?

If yes, sponsor Name: (1)

(2)

Yes/No

☒ ☐ Is the proposal being submitted for funding?

If yes, name of funding agency: (1) NIH (USA)

(2)

Do any of the participating investigators and/or member(s) of their immediate families have an equity relationship (e.g. stockholder) with the sponsor of the project or manufacturer and/or owner of the test product or device to be studied or serve as a consultant to any of the above? No.

IF YES, a written statement of disclosure to be submitted to the Centre's Executive Director.

Dates of Proposed Period of Support: Ongoing

(Day, Month, Year - DD/MM/YY)

Beginning Date : 01/01/09

End Date : 31/12/13

Cost Required for the Budget Period ($): 106205/5 years

Years	Direct Cost	Indirect Cost	Total Cost
Year-1	18427	1474	19901
Year-2	17705	1416	19122
Year-3	18913	1513	20426
Year-4	20205	1616	21822
Year-5	23088	1847	24935
Total	98338	7867	106205

Certification by the Principal Investigator

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept the responsibility for the scientific conduct of the project and to provide the required progress reports including updating protocol information in the SUCHONA (Form # 2) if a grant is awarded as a result of this application.

_____ _____

Signature of PI **Date**

Approval of the Project by the Division Director of the Applicant

The above-mentioned project has been discussed and reviewed at the Division level as well by the external reviewers. The protocol has been revised according to the reviewers' comments and is approved.

Dr. Mohammed Abdus Salam

Name of the Division Director Signature Date of Approval

Table of Contents

☒ Check here if appendix is included

Project Summary

Describe in concise terms, the hypothesis, objectives, and the relevant background of the project. Also describe concisely the experimental design and research methods for achieving the objectives. This description will serve as a succinct and precise and accurate description of the proposed research is required. This summary must be understandable and interpretable when removed from the main application.

Principal Investigator(s): Lars Henning
Research Protocol Title: Inpatient surveillance project for HIV Ward of the Dhaka Hospital of ICDDR,B
Total Budget US$: 106,205 USD/5 years Beginning Date: January 2009 Ending Date: December 2013
ICDDR,B recently opened a HIV ward within its Dhaka Hospital. Current patient occupancy is highly variable, ranging from 0-9 patients. We have no method to predict current and future estimates on possible patient load, which is why we are creating a surveillance project. In order to assess future needs, plan future research initiatives, evaluate trends within our patient base, characterize opportunistic infection patterns in our population, identify the frequencies of drug-drug interactions and drug intolerances, and plan accordingly for the necessity of alternative drug regimens, a surveillance project examining HIV patients admitted to the ward is necessary. We will invite every patient admitted to the HIV ward for informed consent, and will then complete a survey on the willing individuals. The survey will capture demographic information, major health problems experienced by the patient, CD4 count on admission, disease-transmitting behaviors practiced by the patient, final diagnoses, and significant investigation results. This is not a research study per se, but an ongoing surveillance to assess who is coming to our ward, how many people are coming, what their health status is, and if their disease-transmitting behaviors are changing. This will allow us to identify new problems of our HIV patients in the future and provide data for the national surveillance. Last but not least we will use our surveillance data for the quality control.

KEY PERSONNEL (List names of all investigators including PI and their respective specialties)

Name	Professional Discipline/ Specialty	Role in the Project
1. Lars Henning	Medicine	Principal Investigator
2. Brent Ohata	Medicine	Co-principal investigator
3. Brian Cobb	Intensive Care, Emergency Medicine	Co-investigator
4. ASG Faruque	Internal Medicine	Co-investigator
5.		
6.		
7.		
8.		
9.		
10.		

Description of the Research Project

Hypothesis to be Tested:

Concisely list in order, the hypothesis to be tested and the Specific Aims of the proposed study. Provide the scientific basis of the hypothesis, critically examining the observations leading to the formulation of the hypothesis.

This is not a research study, and thus we do not have any hypothesis to test.

The specific aims of the proposed surveillance system are as follows:

1. Monitor trends in our patient base. Every month we will record how many patients were admitted to the HIV ward and capture their demographic information to understand better their characteristics. We will also evaluate their health conditions. We would like to examine the patients' presenting complaints and the opportunistic infections they have experienced. We will determine the severity our patients' HIV upon arrival, as determined by CD4 counts. Finally, we will examine our patients' disease-transmitting behaviors, with a specific interest in assessing possible changes over time.
2. Plan for future needs: We will use the information captured to predict future needs and mobilize resources in advance. Information on the number of patients admitted to the ward will allow us to mobilize manpower and other needed resources. Using the information gathered about common presenting complaints, we can anticipate future medication requirements. Assessment of patient outcomes can be used to identify the strengths and weaknesses of the unit, which can then serve as the basis for future capacity building activities.
3. Lay the foundation for future research activity. Our surveillance programme will allow us to identify the most urgent AIDS-related illnesses present in Bangladesh, upon which we should be focusing most of our research efforts. We will be able to pick up trends in the health status of our patients that deserves further investigation. Information gathered about patient demographics and changes in their disease-transmitting behaviors may be useful in public health projects.
4. Linkage with all relevant stakeholders in the field for better clinical management of HIV-patients in Bangladeah. Establish a close relationships with other hospitals which in future will take care of HIV-patients. The proposed study could serve as a starting point for a national data base.

Specific Aims:

Describe the specific aims of the proposed study. State the specific parameters, biological functions/ rates/ processes that will be assessed by specific methods.

The previous section requested an elaboration of the specific aims of this project. We may summarize the specific aims as follows:

- Assess and analyze trends over time regarding the care, support and treatment of HIV patients admitted at the HIV-ward.
- Assess and analyze trends over time regarding the health status, socioeconomic status, awareness, risk behavior , health seeking behavior, etc. of HIV patients admitted to the HIV ward
- Assess and analyze trends over time regarding opportunistic infections in patients admitted at the HIV-ward

In order to achieve the specific aims outlined in the previous section, we will assess the following specific parameters:

- Demographic information including age, sex, education

- Presenting complaints, past history of opportunistic infections
- Duration of known HIV positivity, antiretroviral therapy regimen (if any), medication compliance
- CD4 count
- Prevalence of disease-transmitting behaviors and risk factors
- Final diagnoses, patient outcomes, complications, and pertinent investigation findings at discharge from hospital

Background of the Project including Preliminary Observations

Describe the relevant background of the proposed study. Discuss the previous related works on the subject by citing specific references. Describe logically how the present hypothesis is supported by the relevant background observations including any preliminary results that may be available. Critically analyze available knowledge in the field of the proposed study and discuss the questions and gaps in the knowledge that need to be fulfilled to achieve the proposed goals. Provide scientific validity of the hypothesis on the basis of background information. If there is no sufficient information on the subject, indicate the need to develop new knowledge. Also include the significance and rationale of the proposed work by specifically discussing how these accomplishments will bring benefit to human health in relation to biomedical, social, and environmental perspectives.

HIV-positive patients are more prone to infections than the general population, both because their disease-transmitting behaviors expose them to co-infections, and also because their immunosuppression makes them susceptible to opportunistic infections. Co-infections vary by route of transmission and frequency of high-risk activity, and may include hepatitis A, hepatitis B, hepatitis C, syphilis, chlamydia, gonorrhea, and herpes simplex. As patients' CD4 counts decline, they become increasingly more susceptible to opportunistic diseases. Common opportunistic diseases encountered in HIV-positive patients include tuberculosis, *Mycobacterium avium* infections, *P. jiroveci* pneumonia, toxoplasmosis, cryptosporidiosis, candidiasis, cytomegalovirus infections, herpes simplex infections, varicella-zoster infections, progressive multifocal leukoencephalopathy, Kaposi's sarcoma, cryptococcal meningitis, and lymphoma. Antiretroviral therapy (ART), typically consisting of three drugs, is essential for decreasing the viral load and increasing the CD4 counts of HIV-positive patients, thereby improving the immune status of these patients and decreasing the occurrence of opportunistic infections. In the absence of antiretroviral therapy, patients with viral loads between 50-30,000 can be expect to have decreases in their CD4 count of 44.8-64.8 per year (Mellors et al). These patients progress from initial HIV seroconversion to AIDS over a median span of 10 years, although the natural history of the disease varies considerably between patients (Munoz et al, Phair et al, Sheppard et al). Although ART and the many other medications taken by HIV-positive patients are necessary for the prolongation of life, they are also associated with adverse events sometimes requiring admission. Significant events associated with various anti-retroviral drugs include hepatic failure, pancytopenia, Stevens-Johnson syndrome, pancreatitis, dyslipidemia, lactic acidosis, hypersensitivity reactions, and neurological complaints. For these reasons, inpatient admission of HIV-positive patients can be both frequent, challenging and complex.

As of 2007, it has been estimated that 12,000 Bangladeshis are living with HIV/AIDS (UNAIDS). Major population subgroups include prostitutes, injection drug users, and overseas workers. Of these infected persons, less than 200 are thought to be on anti-retroviral therapy, equal to 10% of the population requiring these drugs at best. 500 people are thought to have died of AIDS until 2007, and the rate of death is increasing steadily (UNAIDS). Bangladesh is still experiencing a concentrated epidemic in its at-risk population, but, in view of all risk factors present, we can assume our patient load will increase with time. For the few HIV-positive Bangladeshis who receive ART, only first-line drug combinations exist, the most common being zidovudine + lamivudine + nevirapine, with one substitution drug (efavirenz) available; no second-line regimens and few modified first-line regimens exist in the country for patients with virological failure, drug intolerance, or contraindicative drug-drug interactions. The modified first line treatment is only available for a handful of patients, mainly

due to financial and logistical constraints. In view of the limited availability and selection of antiretroviral drugs, we speculate that a significant number of HIV-positive patients will require inpatient treatment for co-infections, opportunistic infections, and drug-related complications. However, a systematic characterization of HIV-related health complications in Bangladesh has never been undertaken. To our knowledge, ICDDR,B's HIV ward is the only inpatient hospital facility in Bangladesh dedicated to the inpatient treatment of complicated HIV patients where patients are ensured adequate and comprehensive care. AITEM is the only hospital we are aware of that provides surgical care to HIV-positive patients. Anecdotally, many hospitals in Bangladesh are known to refuse treatment to HIV-positive patients, but a comprehensive study has never been performed. Therefore ICDDR,B's HIV ward is well-positioned to examine HIV-associated complications in Bangladesh. The patient load in the HIV ward is highly variable, and ranges from 0-9 patients per day. The problems encountered are equally variable, including drug-drug interactions, drug intolerances, co-infections, opportunistic infections, psychiatric complaints, and immune reconstitution syndrome, with multiple problems often occurring at the same time. We have successfully treated all of these classes of problems. Patients have been referred to our ward from hospitals throughout the country and every NGO in Bangladesh that offers ART.

Based on the success of the diarrhea surveillance system of the Dhaka Hospital, we want to introduce a similar surveillance system to our inpatient ward. The HIV surveillance project is essential for the delivery of high quality healthcare to our patients (Langmuir, Thacker et al). Until now there is only sporadic and anecdotal information about the health status, opportunistic infections, health-seeking behavior and treatment options of people living with HIV/AIDS (PLWHA) in Bangladesh. A surveillance system will enable us to characterize scientifically our patient base.

HIV/AIDS surveillance systems have been established in many developed countries, including the United States and European countries (Glynn et al, Gupta et al). The surveillance systems have been used to estimate incidence and prevalence (Gieseke et al, Gill et al, Nicoll et al, Unlinked Anonymous Surveys Steering Group), and also to identify at-risk subgroups within the population (CDC Morb Mortal Wkly Rep 2006, Nicoll et al), the success or failure of public health campaigns (Nicoll et al), health outcomes (Lee et al), and estimated rates of disease progression (Hall et al, Nicoll et al). Most importantly, surveillance systems provide a dynamic, as opposed to static, perspective on all these variables, and allow clinicians to identify trends in their community (Brown et al, Nicoll et al). However, most HIV/AIDS surveillance systems in other countries are meant to track HIV specifically. We aim to estimate disease frequencies within the HIV-positive population, which is less frequently monitored.

Existing HIV/AIDS surveillance systems have common structural features. They all have safeguards to ensure patient confidentiality, but they may nonetheless collect information using name-based identifiers, non-name-based unique identifiers, or be completely unlinked and anonymous (CDC MMWR Recomm Rep 1999, Gill et al, Greenspan). Non-name-based identifiers have not been proven to provide a comparable level of data quality as name-based systems and often double-count patients (Buehler et al, Jara et al, Klevens et al, Marsh et al, Meyer et al, Rosenblum et al). The advantage of non-name-based systems is that they guarantee anonymity, however, in regions that practice name-based surveillance systems, breaches in confidentiality have been infrequent and can be avoided with reasonable safeguards (Torres et al). Therefore, name-based systems are often preferred since they provide better data quality and rarely compromise patient confidentiality. Existing HIV/AIDS surveillance systems typically collect the following information from their patients: identity, age, sex, date of HIV and/or AIDS diagnosis, demographic information, residence, HIV transmission risk factors, date of death (CDC MMWR Recomm Rep 1999, Greenspan). Consecutive CD4 counts are also collected from patients and analyzed sequentially to determine disease progression (Gupta et al). Data collected from HIV/AIDS surveillance systems can be used by researchers to develop new research proposals, design new intervention strategies, and formulate policy recommendations (UK Departments of Health 1995, Wellings et al).

Research Design and Methods

Describe in detail the methods and procedures that will be used to accomplish the objectives and specific aims of the project. Discuss the alternative methods that are available and justify the use of the method proposed in the study. Justify the scientific validity of the methodological approach (biomedical, social, or environmental) as an investigation tool to achieve the specific aims. Discuss the limitations and difficulties of the proposed procedures and sufficiently justify the use of them. Discuss the ethical issues related to biomedical and social research for employing special procedures, such as invasive procedures in sick children, use of isotopes or any other hazardous materials, or social questionnaires relating to individual privacy. Point out safety procedures to be observed for protection of individuals during any situations or materials that may be injurious to human health. The methodology section should be sufficiently descriptive to allow the reviewers to make valid and unambiguous assessment of the project.

The HIV surveillance project is focused in its scope and is only intended to capture large-scale demographic trends in our inpatient ward over time. We will adopt a "take all" strategy and ask every patient admitted to the HIV ward for informed consent, and then complete a survey on consenting individuals. We feel this is feasible since we only have a 10-bed unit. There are no inclusion or exclusion criteria. Patients will have the opportunity to decline participation at any time during the questioning with no adverse consequences on the quality of their healthcare at the ward. Patients who agree to participate will receive a card with a unique study identification number. This ID number will allow us to identify returning patients and patients will be asked to bring the card on subsequent visits. The card will not contain anything written that might give away information on the patient's health status. Three questionnaires will be utilized. If the patient is new to the HIV ward, an "initial visit questionnaire" consisting of 26 questions will be completed on arrival. It will take approximately 1 hour to complete the questionnaire. This questionnaire will capture demographic information, socioeconomic status, past medical history, chief complaints, recent CD4 counts, and disease-transmitting risk factors. Only legal adults will be asked questions about disease-transmitting risk factors. If the patient has been admitted to the HIV ward in the past, they will complete a "follow-up visit questionnaire", which omits previously collected demographic information but is otherwise identical to the "initial visit questionnaire". The nurses and doctors on our ward will complete the "initial visit questionnaire" and "follow-up visit questionnaire" and will be trained to complete these forms. At discharge, doctors will complete a "discharge questionnaire", which captures final diagnoses, relevant investigation results from the patient's hospital chart, medications prescribed, and complications. Once the hospital medical record system has been digitalized, redundant sections of the questionnaires will be eliminated and data will be imported directly from the electronic hospital database. The informed consent explicitly notifies patients that information from their chart will be collected, in addition to the answers they provide in the questionnaires. The data we will collect is identical to the data we would need to collect in order to provide comprehensive, state-of-the-art clinical care to the patients. Once per month, data from the surveillance project will be checked for quality and analyzed by the investigators. We are looking to assess who is coming to our ward, how many people are coming, what their health status is, what their outcome is on discharge, and if their disease-transmitting behaviors are changing. A more extensive surveillance tool could be designed, but we chose a concise format that we believe captures all relevant data and maintains the highest standard of scientific quality without being too much of a time burden on healthcare personnel. We therefore do not envision any limitations to our design in achieving our objectives. We do not see any ethical dilemmas stemming from our methodology, since all patients will receive the same standard of care regardless of their participation in this study. We do not think our proposal presents any threat to patient safety, since all patients will receive the same standard of care regardless of their participation in this study, and no additional investigation will be ordered or medications administered above and beyond standard practice.

Sample Size Calculation and Outcome Variable(s)

This is intended to be an ongoing surveillance project. We anticipate the variety of presenting complaints to change in Bangladesh as patients are diagnosed with HIV earlier, patients begin ART earlier, and patients have a wider variety of antiretroviral drugs to choose from. Anecdotally, nearly all the patients on our ward are on one of two ART regimens, and most have critically low CD4 counts as a result of late diagnosis/treatment initiation. We predict that this will change, and would like to capture data on these changing trends. Therefore, it will be necessary to continuously enroll first-time patients in order to compare their problems to those of previous patients. A systematic review of the literature revealed no previous surveillance systems examining HIV-related complaints on which to base sample size calculations. As many patients as possible will be enrolled in order to capture the most accurate information pertaining to our patient population. We anticipate 100-150 patients to be admitted to the HIV ward within its first year of inception. Given the size of our patient base, we will have the capacity to interview all patients admitted. We believe it is essential to interview all patients that come to our ward, since it is feasible and since they present with an extreme heterogeneity of complaints. If our patient base expands, we might not interview all patients. In that case we will notify the RRC and ERC accordingly.

Facilities Available

Describe the availability of physical facilities at the place where the study will be carried out. For clinical and laboratory-based studies, indicate the provision of hospital and other types of patient's care facilities and adequate laboratory support. Point out the laboratory facilities and major equipment that will be required for the study. For field studies, describe the field area including its size, population, and means of communications.

Patients will be questioned in ICDDR,B's HIV ward in a location that ensures the patients' privacy. Since we will only be examining patients who already meet the criteria for admission to the HIV ward, no additional space will be required by our study. No additional laboratory facilities our equipment will be required, as we will only collect routine investigations required for the treatment of our patients, and will not request additional investigations beyond the routine.

Data Safety Monitoring Plan (DSMP)

All clinical investigations (biomedical and behavioural intervention research protocols) should include the Data and Safety Monitoring Plan (DSMP) to provide the overall framework for the research protocol's data and safety monitoring. It is not necessary that the DSMP covers all possible aspects of each elements. When designing an appropriate DSMP, the following should be kept in mind.

a) All investigations require monitoring;
b) The benefits of the investigation should outweigh the risks;
c) The monitoring plan should commensurate with risk; and
d) Monitoring should be with the size and complexity of the investigation.

Safety monitoring is defined as any process during clinical trails that involves the review of accumulated outcome data for groups of patients to determine if any treatment procedure practised should be altered or not.

Although this is not an interventional trial we will analyze morbidity and mortality data monthly. Every complication or adverse outcome, including but not limited to death, will be examined in the Dhaka Hospital Setup. The data collected will be used to improve the quality of the healthcare delivered to our patients. We will use the data collected from the HIV surveillance project to identify the strengths and weaknesses of the healthcare we provide, thereby allowing us to design capacity-building trainings for our staff.

Data Analysis

Describe plans for data analysis. Indicate whether data will be analyzed by the investigators themselves or by other professionals. Specify what statistical software packages will be used and if the study is blinded, when the code will be opened. For clinical trials, indicate if interim data analysis will be required to monitor further progress of the study.

Relevant data will be directly entered into SPSS, and analyzed with that software. The investigators will not be blinded. Data collection will begin as soon as ERC/RRC approval has been granted. 2 databases will be maintained: 1 password-protected database containing identifying information of patients only and 1 password-protected database containing all other data. A data entry specialist will be responsible for entering data into the databases, and this data will be examined on a regular basis by the database manager to ensure that a high standard of data quality is met. Similarly, the principal investigator will examine questionnaires regularly to ensure questionnaires are properly filled out; the senior physician on the HIV ward will be responsible for resolving any issues surrounding improperly completed questionnaires. Data will be analyzed at least monthly and access restricted to qualified researchers. Frequency of patient visits, in addition to age, sex, demographic information, diagnoses, risk factors, presenting complaints, past medical history, ART regimen, and outcome will be examined serially. Frequencies alone of patient visits, presenting complaints, drug regimens, etc. will be analyzed at least on a monthly basis in order to adequately characterize our patient population and predict future needs. At least once every quarter year more rigorous statistical analyses will be performed to assess trends, clarify significant differences between patient subpopulations, and scrutinize patient outcomes. D'Agostino's K-squared test and Pearson's chi-squared test will be utilized to determine the normality of various parameters' distributions. Differences between continuous parameters of Gaussian distribution will be detected by the Student's T-test, Fisher's analysis of variance, and the Wilcoxon signed rank test; differences between categorical variables will be analyzed by the Pearson's chi-square test; correlations including trends over time will be analyzed by Spearman rank correlation, Pearson correlation, least-squares fit, and multivariable linear regression analysis; assuming the continuity of this project in the long-term, Kaplan-Meier estimates can be used to compare mortality in specific subpopulations. When found to be relevant and significant, all models will be adjusted for age, gender and other parameters.

Ethical Assurance for Protection of Human Rights

Describe in the space provided the justifications for conducting this research in human subjects. If the study needs observations on sick individuals, provide sufficient reasons for using them. Indicate how subject's rights are protected and if there is any benefit or risk to each subject of the study.

The HIV surveillance project is essential for the delivery of high quality healthcare to our patients, and it would be unwise to establish this HIV ward without some form of surveillance monitoring (see external review #2). The surveillance project will establish a system of quality control in clinical care on our ward that should be universal, and will characterize problems that have never been described in this country, yet need to be illuminated for future planning purposes. The informed consent protects the right of patients to participate, not participate, or withdraw participation in the project. All risks and benefits are described clearly in the informed consent, and patients have the option to opt out of the project with no adverse effects on their standard of care. The patients will have no additional medical risks from participating in this project, since no interventions are involved; the study itself is comprised of data collection exclusively, not any interventions. Additionally, we will collect patient data in a manner that ensures confidentiality. The data collection poses no greater risk to the patient than they would face from standard hospital record-keeping. Access to personal patient data will be limited, and original questionnaires will be kept locked as per international standards. Information on confidentiality safeguards is outlined in the informed consent, and patients who are uncomfortable with these measures may opt out of participation. The patients themselves will receive no immediate benefit from study participation, and have no incentives to persuade them into enrolling in a study in which they might otherwise not agree to enroll. However, their participation will benefit future

patients by improving patient care and assisting in future planning. Patients can withdraw from this surveillance and will still receive the same care and treatments as before.

Use of Animals

Describe in the space provided the type and species of animals that will be used in the study. Justify with reasons the use of particular animal species in the experiment and the compliance of the animal ethical guidelines for conducting the proposed procedures.

No animals will be used in this project.

Literature Cited

Identify all cited references to published literature in the text by number in parentheses. List all cited references sequentially as they appear in the text. For unpublished references, provide complete information in the text and do not include them in the list of Literature Cited. There is no page limit for this section, however exercise judgment in assessing the "standard" length.

Brown AE, Sadler KE, Tomkins SE, McGarrigle CA, LaMontagne DS, Goldberg D, Tookey PA, Smyth B, Thomas D, Murphy G, et al. Recent trends in HIV and other STIs in the United Kingdom: data to the end of 2002. Sex. Transm. Inf., 2004; 80(3): 159 - 166.

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Mellors JW, Munoz A, Giorgi JV, Margolick JB, Tassoni CJ, Gupta P, et al. Plasma viral load and CD4+ lymphocytes as prognostic markers of HIV-1 infection. Ann Intern Med 1997;126:946-54.

Meyer PA, Jones JL, Garrison CZ. Completeness of reporting of diagnosed HIV-infected hospital patients. J Acquir Immune Def Syndr 1994;7:1067-73.

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The public health applications of unlinked anonymous seroprevalence monitoring for HIV in the United Kingdom.
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Wellings K, Field B. Stopping AIDS: AIDS/HIV Public Education and the Mass Media in Europe. London: Longman, 1997.

Dissemination and Use of Findings

Describe explicitly the plans for disseminating the accomplished results. Describe what type of publication is anticipated: working papers, internal (institutional) publication, international publications, international conferences and agencies, workshops etc. Mention if the project is linked to the Government of the People's Republic of Bangladesh through a training programme.

Data collected from the HIV surveillance project will be for internal use primarily, and may have a secondary role in future external publications. We specifically state in the informed consent that information collected may be used in publications. Based on the open data policy of ICDDR,B, we will grant access to internal and external scientists. We aim to make quarter-yearly presentations on surveillance findings to all clinical staff of the hospital. Additionally, we will make our findings available to the Government of Bangladesh, all HIV-related NGOs in the country, and any interested donor organizations.

Collaborative Arrangements

Describe briefly if this study involves any scientific, administrative, fiscal, or programmatic arrangements with other national or international organizations or individuals. Indicate the nature and extent of collaboration and include a letter of agreement between the applicant or his/her organization and the collaborating organization.

This project is currently for internal assessment purposes only, and does not involve any collaborations. Once the program is established and generating sufficiently high-quality data, we may look to expand the program beyond ICDDR,B, with proper consent and approval by RRC/ERC.

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

(Note: Biography of the external Investigators may, however, be submitted in the format as convenient to them)

1 Name: Lars Henning

2 Present Position: Scientist

3 Educational background:
(last degree and diploma & training relevant to the present research proposal)

Degree	Year	Institute	Disciplines
MD	2006	University of Basel	Medicine
MBBS	2004	University of Heidelberg	Medicine
PhD	2003	University of Witten/Herdecke	Virology
Diplom	1998	University of Witten/Herdecke	Biochemistry

4.0 List of ongoing research protocols

(start and end dates; and percentage of time)

4.1. As Principal Investigator

Protocol Number	Starting date	End date	Percentage of time
2006028	01/07/07	09/30/09	50%

4.2. As Co-Principal Investigator

Protocol Number	Starting date	End date	Percentage of time

4.3. As Co-Investigator

Protocol Number	Starting date	End date	Percentage of time
2004028	11/01/04	06/30/07	1%

5 Publications

Types of publications	Numbers
a. Original scientific papers in peer-review journals	5
b. Peer reviewed articles and book chapters	
c. Papers in conference proceedings	
d. Letters, editorials, annotations, and abstracts in peer-reviewed journals	
e. Working papers	
f. Monographs	

6 Five recent publications including publications relevant to the present research protocol

Azim T, Khan SI, Haseen F, Huq NL, Henning L, Pervez MM, Chowdhury ME, Sarafian I. HIV and AIDS in Bangladesh. J Health Popul Nutr. 2008 Sep;26(3):311-24.

Dittmar MT, Eichler S, Reinberger S, Henning L, Kräusslich HG. A recombinant virus assay using full-length envelope sequences to detect changes in HIV-1 co-receptor usage. Virus Genes. 2001 Dec;23(3):281-90.

Färnert A, Arez AP, Babiker HA, Beck HP, Benito A, Björkman A, Bruce MC, Conway DJ, Day KP, Henning L, Mercereau-Puijalon O, Ranford-Cartwright LC, Rubio JM, Snounou G, Walliker D, Zwetyenga J, do Rosario VE. Genotyping of Plasmodium falciparum infections by PCR: a comparative multicentre study.Trans R Soc Trop Med Hyg. 2001 Mar-Apr;95(2):225-32.

Henning L, Felger I, Beck HP. Rapid DNA extraction for molecular epidemiological studies of malaria. Acta Trop. 1999 Mar 15;72(2):149-55.

Henning L, Schellenberg D, Smith T, Henning D, Alonso P, Tanner M, Mshinda H, Beck HP, Felger I. A prospective study of Plasmodium falciparum multiplicity of infection and morbidity in Tanzanian children. Trans R Soc Trop Med Hyg. 2004 Dec;98(12):687-94.

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

(Note: Biography of the external Investigators may, however, be submitted in the format as convenient to them)

1 Name: Brent Ohata

2 Present Position: Fellow

3 Educational background:
(last degree and diploma & training relevant to the present research proposal)

MD	2010	McGill University	Montreal	Medicine
Certificate	2004	Columbia University	New York	Premedical Science
Fellow	2001	Fulbright Scholar	Romania	Ethnography/Anthropology
BA	2000	Yale University	New Haven	Musicology

4.0 List of ongoing research protocols

(start and end dates; and percentage of time)

4.4. As Principal Investigator

Protocol Number	Starting date	End date	Percentage of time

4.5. As Co-Principal Investigator

Protocol Number	Starting date	End date	Percentage of time

4.6. As Co-Investigator

Protocol Number	Starting date	End date	Percentage of time

5 Publications

Types of publications	Numbers
g. Original scientific papers in peer-review journals	
h. Peer reviewed articles and book chapters	1
i. Papers in conference proceedings	1
j. Letters, editorials, annotations, and abstracts in peer-reviewed journals	
k. Working papers	
l. Monographs	

6 Five recent publications including publications relevant to the present research protocol

1) Sinha AK, Hemmerling TM, Ohata BR. Post-Operative Acute Anterior Spinal Artery Syndrome After Right Upper Lobectomy Complicated By Pulmonary Artery Injury. Presented at the Canadian Anesthesiologists' Society Annual Meeting

2) Izadnegahdar R, Correia S, Ohata B, et al. Global Health in Canadian Medical Education: Current Practices and Opportunities. Acad. Med. In press.

3)

4)

5)

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

(Note: Biography of the external Investigators may, however, be submitted in the format as convenient to them)

1 Name: Dr. ASG Faruque

2 Present Position: Scientist

3 Educational background:
(last degree and diploma & training relevant to the present research proposal)

School of Hygiene and Public Health, MPH
The Johns Hopkins University,
USA.

Rajshahi Medical College, MBBS
Rajshahi University,
Bangladesh.

Training in Epidemiology and research methodology:

1. Attended a workshop on the "Design of Intervention Studies on Diarrhoeal Diseases" organized by WHO in Fortaleza, Brazil, 3-13 July, 1989.

2. Attended a workshop on the "Clinical Research Methods in Diarrhoeal Diseases" organized by ICDDR,B in Dhaka, Bangladesh, 19-27 November, 1989.

3. Attended a workshop on “The Fundamentals of International Clinical Research” organized by Family Health International, USA in Bangkok, Thailand, February 16-20, 2004.

4.0 List of ongoing research protocols
(start and end dates; and percentage of time)

4.7. As Principal Investigator

Protocol Number	Starting date	End date	Percentage of time
2006-032	09/01/2006	12/31/2009	20%
1992-011	04/01/1992		18%

4.8. As Co-Principal Investigator

Protocol Number	Starting date	End date	Percentage of time
2005-030	05/01/2005	04/30/2010	12%

4.9. As Co-Investigator

Protocol Number	Starting date	End date	Percentage of time
			5%

5 Publications

Types of publications	Numbers
m. Original scientific papers in peer-review journals	126
n. Peer reviewed articles and book chapters	-
o. Papers in conference proceedings	12
p. Letters, editorials, annotations, and abstracts in peer-reviewed journals	3
q. Working papers	2
r. Monographs	-

6 Five recent publications including publications relevant to the present research protocol

1) Faruque ASG, Ahmed AMS, Tahmeed A, Islam MM, Hossain MI, Roy SK, Alam N, Kabir I, Sack DA. Nutrition: basis for healthy children and mothers in Bangladesh. J Health Popul Nutr 2008; 26: 325-339
2) Sears CL, Islam S, Saha A, Arjumand M, Alam NH, Faruque AS, Salam MA, Shin J, Hecht D, Weintraub A, Sack RB, Qadri F. Association of enterotoxigenic Bacteroides fragilis infection with inflametory diarrhea. Clin Infect Dis. 2008 Sept 15; 47(6):797-803.
   PMID: 18680416 [PubMed-in process]
3) Hashizume M, Wagatsuma Y, Faruque ASG, Hayashi T, Hunter PR, Armstrong B, Sack
   DA. Factors determining vulnerability to diarrhoea during and after severe floods in Bangladesh. J Water and Health 2008; 06.3
4) Chowdhury F, Khan AI, Harris JB, LaRocque RC, Chowdhury MI, Ryan ET, Faruque ASG, Calderwood SB, Qadri F. A comparison of clinical and immunological features in children and older patients hospitalized with severe cholera in Bangladesh Paed Infect Dis J (in press).
5) Zaman K, Sack DA, Yunus M, Arifeen SE, Podder G, K Neuzil, Datta SK, Delem A, Suryakiran PV, Bock HI, Azim T, Faruaue ASG, Lubby S, Brieman RF, Karim S, Successful co-administration of a human rotavirus and oral poliovirus in infants in a 2-dose schedule at 12 and 16 weeks of age (in press).

Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

(Note: Biography of the external Investigators may, however, be submitted in the format as convenient to them)

1 Name: Brian Cobb, M.D.

2 Present Position: Consultant

3 Educational background:
(last degree and diploma & training
relevant to the present research proposal)

MD, residency in internal medicine, fellowship in anesthesia/critical care, University of South Florida, Tampa, FL USA

4.0 List of ongoing research protocols
(start and end dates; and percentage of time)

4.10. As Principal Investigator

Protocol Number	Starting date	End date	Percentage of time

4.11. As Co-Principal Investigator

Protocol Number	Starting date	End date	Percentage of time

4.12. As Co-Investigator

Protocol Number	Starting date	End date	Percentage of time

5 Publications

Types of publications	Numbers
s. Original scientific papers in peer-review journals	3
t. Peer reviewed articles and book chapters	1
u. Papers in conference proceedings	12
v. Letters, editorials, annotations, and abstracts in peer-reviewed journals	
w. Working papers	
x. Monographs	

6 Five recent publications including publications relevant to the present research protocol

1)

2)

3)

4)

5)

Budget Justifications

Please provide one page statement justifying the budgeted amount for each major item. Justify use of human resources, major equipment, and laboratory services.

The expenditures of the HIV surveillance project consist of personnel salaries and clerical supplies. Five salaries have been included in the budget. Brent Ohata and Lars Henning were the primary architects of this project, and will be actively involved in data interpretation, report writing, quality assurance, and initiating future applications of the data in research and planning. ASG Faruque directs the diarrhea surveillance project, and will assist in the incorporation of the HIV surveillance into the pre-existing diarrhea surveillance framework. He will oversee a data analyst's entry of data, whose salary is also included in our budget. Brian Cobb is managing the HIV ward where our data will be collected, and therefore will be involved in this project. He will facilitate the collection of data from patients by his staff, and will utilize the findings from the HIV surveillance project to improve the standard of care in the HIV ward.

The HIV surveillance project requires a minimum number of initial capital expenditures. A computer—including monitor, keyboard, mouse, and printer—will need to be purchased for data entry at the beginning of the study and replaced every 4 years thereafter. A lockable file cabinet will also need to be purchased to store the completed questionnaires. The prices quoted for the computer and file cabinet reflect average current prices for these items if purchased new in the United States.

The HIV surveillance project will have recurrent expenditures on clerical supplies. Paper, pencils, and pens will be purchased to complete the questionnaires. CD-RW will be purchased to backup our data. Printer cartridges will also need to be purchased. Of all these items, paper and printer cartridges are expected to incur the majority of the money allocated to these expenditures.

An 8% indirect cost has been added to the budget as per NIH policy.

Other Support

Describe sources, amount, duration, and grant number of all other research funding currently granted to PI or under consideration.

None.

icddr,b
KNOWLEDGE FOR GLOBAL LIFESAVING SOLUTIONS

Check-List

CHECK-LIST FOR SUBMISSION OF RESEARCH PROTOCOL FOR CONSIDERATION OF RESEARCH REVIEW COMMITTEE (RRC)

[Please check (X) appropriate box]

1. Has the proposal been reviewed, discussed and cleared at the Division level?

   Yes ☒ No ☐

   If No, please clarify the reasons:

2. Has the proposal been peer-reviewed externally?

   Yes ☒ No ☐

   If the answer is 'No', please explain the reasons:

   If yes, have the external reviews' comments and their responses been attached

   Yes ☒ No ☐

3. Has the budget been cleared by Finance Department?

   Yes ☒ No ☐

   If the answer is 'No', reasons thereof be indicated:

4. Does the study involve any procedure employing hazardous materials, or equipments?

   Yes ☐ No ☒

   If 'Yes', fill the necessary form.

5. Has the Ethics Certificate(s) been attached with the Protocol?

   Yes ☒ No ☐

   If the answer is 'No', please explain the reasons:

_____ _____

Signature of the Principal Investigator Date

icddr,b
KNOWLEDGE FOR GLOBAL LIFESAVING SOLUTIONS

APPENDIX 1: Voluntary Consent Forms

Protocol Number: 2008-060
Protocol Title: Inpatient HIV surveillance project for the ICDDR,B HIV Ward
Investigators: Henning L, Ohata B, Faruque ASG, Cobb B

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH (ICDDR,B)
Consent Form for Administration of HIV Surveillance Questionnaire (Adults)

Some people in Bangladesh have human immunodeficiency virus (HIV), and their numbers are increasing. Patients with HIV get sicker than normal people.

At this Dhaka Hospital of ICDDR,B (Cholera Hospital), we are conducting a survey to learn more about the health problems in HIV patients. We are inviting you to participate in our survey because you have been diagnosed with HIV and have been admitted to our hospital for treatment.

If you agree, we will ask you some questions related to your health problems, your personal background and habits. We would also like to ask you similar questions if you are admitted again to ICDDR,B in the future. We would then fill out a similar questionnaire. We will conduct your interview today in a place in this hospital that assures privacy. It will take about one hour. We will also collect some information from your hospital record and use it in this survey. We will keep all of your information completely confidential. Only people involved in this survey will have an access to this information. You are the only one to decide for or against participation in this survey, and you would also be able to stop answering questions at any time. Some questions are sensitive and personal. You may choose to skip any questions in the survey. If you do not participate in this survey or if you withdraw your consent after initial participation, you will continue to get the same care and treatment at this hospital and at the NGO that has referred you to this hospital as patients who take part in the survey.

We will enter your information into a computer. We will keep all your information confidential. Surveys will be locked in a secure location. Information in the computer will only be accessible by special people with a password. Only HIV researchers will have access to this information. No one will publish your name with this information. However, once we have collected your answers and entered them into our computer, we will not be able to remove them if you decide to discontinue the participation. We may or may not contact you in the future to participate in future research studies. If you decline participation in these future studies, there will be no change in the quality of your treatment and you still will receive treatment when you need admission.

There is no physical risk from participating in this survey. There will be no associated physical examination. You will not receive any special treatment or special medications if you answer the survey. You will also not get money or any other type of benefit from participating in this survey. However, your participation would improve our knowledge specifically to understand how patients in Bangladesh are affected by HIV. This will help us provide better care, treatment and support in the future for all HIV patients in Bangladesh.

Please feel free to ask any questions about the survey and your health problems that you might have. If you have some questions later you can always ask the nurse or doctor who is in charge of you. You can also contact the hospital administrator of Dhaka Hospital. If you want to know more about your rights as a survey participant, you might contact M. A. Salam Khan, at the Research Administration office of ICDDR,B personally or at following telephone numbers: 9886498 (direct), mobile: 01711428989. You may also contact the principal investigator, Lars Henning, with any questions. Lars Henning and Salam Khan both can be contacted at this hospital. The address is ICDDR,B, 68 Shaheed Tajuddin Ahmed Sharani, Mohakhali, Dhaka 1212. If you voluntarily agree to participate in this survey please indicate that by putting your signature or left thumb impression at the specified space below.

Thank you very much for your cooperation.

Comments:

_____	_____	_____
Patient's signature/left thumbprint	Signature of witness	Date

Protocol Number: 2008-060
Protocol Title: Inpatient surveillance project for the ICDDR,B HIV Ward
Investigators: Henning L, Ohata B, Faruque ASG, Cobb B

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH (ICDDR,B)
Consent Form for Administration of HIV Surveillance Questionnaire (Adults)

HIV- chv‡e¶b ckc‡Î (cvß eq¯‹) AskMn‡bi Ab‡gv`b cÎ

evsjv‡`‡ki wKQ †jvK** HIV- **Øviv Avµvš Ges Zv‡`i msL¨v †e‡o Pj‡Q| HIV- Avµvš †ivMxiv mwavib †jvK‡`i Zjbvq Am¯ n‡q c‡o|

AvB.wm.wW.wW.Avi.we- Gi XvKv nvmcvZv‡j (K‡jiv nvmcvZvj) Avgiv HIV- **Avµvš †ivMx‡`i ¯v¯¨ mgm¨v wb‡q Rwic Pvjw”Q| Avgiv Avcbv‡K Avgv‡`i Rwi‡c Avgšb Rvbw”Q KviY Avcwb** HIV- **Øviv AvKvš Ges Avgv‡`i nvmcvZv‡j wPwKrmvi Rb¨ fwZ n‡q‡Qb|**

hw` Avcwb m¤§Z nb, Avgiv Avcbv‡K Avcbvi ¯v¯¨ mgm¨v, e¨w³MZ cUfwg Ges AvPiY m¤ú‡K wKQ ck wR‡Ám Ki‡ev| Avcwb hw` fwel¨‡Z Avevi AvB.wm.wW.wW.Avi.we- †Z fwZ nb Z‡e Avgiv cbivq Avcbv‡K GKB iKg ck Ki‡Z cwi| Avgiv ZLb GKB iK‡gi ckcÎ cib Ki‡ev| Avgiv AvR Avcbvi m¶vrKvi Ggb GKwU ¯v‡b wb‡ev hv ‡MvcbxqZv i¶v Ki‡e| Bnv GK N›Uvi gZ mgq wb‡e| Avgiv nvmcvZv‡ji bw_ n‡Z wKQ Z_¨ msMn Ki‡ev| Avgiv Avcbvi mKj Z_¨ msM‡n m¤úY †Mvcbxqvi i¶v Kie| ïagvÎ GB Rwi‡ci mv‡_ mswkéivB GB Z_¨ Rvbvi AwaKvi ivL‡e| GB Rwi‡c AskMnb ev AskMnY bv Kivi wm×vš ïagvÎ Avcbvi Ges Avcwb PvB‡j †h †Kvb mgq c‡ki DËi †`lqv †_‡K weiZ _vK‡Z cv‡ib| wKQ ck ms‡e`bkxj Ges e¨w³MZ, †m‡¶‡Î Rwi‡ci †h‡Kvb ck ev` w`‡q Ab¨ c‡k †h‡Z cv‡ib| Avcwb hw` Rwi‡c AskMnb bv K‡ib A_ev Avcbvi AskMnb cZ¨vnvi K‡ib, †m‡¶‡Î Avcwb GB nvmcvZvj †_‡K Ges †h GbwRI Avcbv‡K GB nvmcvZ‡j cwV‡q‡Q Zv‡`i KvQ †_‡K GKB †mev Ges wPwKrmv †c‡q hv‡eb|

Avgiv Avcbvi Z_¨ GKwU Kw¤úDUv‡i ivL‡ev| Avgiv Avcbvi †`qv Z_¨mg‡ni †Mvcbxqvi i¶v Ki‡ev| Z_¨mgn GKUv miw¶Z RvMvq Zvjve× K‡i ivLv n‡e| GB Z_¨mgn ïagvÎ wKQ we‡kl †jvKRbB cvmlqv‡Wi gva¨‡g Kw¤úDUv‡i e¨envi Ki‡Z cvi‡e| ïagvÎ GBPAvBwf M‡elKMY GB Z_¨mgn e¨envi Ki‡e| GB Z_¨mg‡ni mv‡_ †KD-B Avcbvi bvg cKvk Ki‡e bv| Avcbvi DËi msMn Ges Kw¤úDUv‡i msi¶‡bi ci Avcwb AskMn‡Y Awb”QK n‡jl Avgiv Zv g‡Q †djt‡Z cvi‡ev bv| fwel¨‡Zi bZb M‡elYvq AskMn‡Yi Rb¨ Avgiv Avcbvi m‡½ cieZ‡Z †hvMv‡hvM Ki‡Zl cwi A_ev bvl Ki‡Z cwi| Avcwb hw` fwel¨‡Zi M‡elbv Kv‡h AskMn‡b A¯xKwZ Rvbvb †m‡¶‡Îl Avcbvi wPwKrmv Kv‡hi ¸bMZ gv‡bi †Kvb cwieZb n‡e bv Ges c‡qvR‡b Avcwb nvmcvZv‡j fwZ n‡q wPwKrmv †mev †c‡Z cvi‡eb|

Rwi‡c AskMn‡b †Kvb kwiixK SwK †bB| Gi m‡½ m¤ú³ †Kvb kwiixK cwi¶v †bB| Avcwb Rwi‡c Ask wb‡j †Kvb we‡kl ai‡bi wPwKrmv ev Jla cv‡eb bv| Avcwb Rwi‡c AskMnb Ki‡jl †Kvb A_ ev AY¨vb¨ m‡hvM mweav cv‡eb bv| wKš Avcbvi AskMnb Avgv‡`i Ávb, weKv‡k we‡klZt evsjv‡`‡ki gvbl wKfv‡e HIV- **Øviv AvKvš nq Zv Rvb‡Z mnvqZv Ki‡e| Bnv Avgv‡`i fwel¨‡Z** HIV- **†ivMx‡`i DbZ †mev, wPwKrmv Ges mnvqZv c`v‡b mvnvh¨ Ki‡e|**

Rwic Ges Avcbvi ¯v¯¨ mgm¨v m¤úwKZ †h‡Kvb ck wbw`avq Ki‡Z cv‡ib| cieZx‡Z wKQ Rvb‡Z PvB‡j Avcbvi `wq‡Z wb‡qwRZ _vKv bvm A_ev Wv³vi‡K wR‡Ám Ki‡Z cv‡ib| Avcwb XvKv nvmcvZ‡ji cav‡bi mv‡_l †hvMv‡hvM Ki‡Z cv‡ib| Avcwb Rwi‡c AskMnbKvix wn‡m‡e Avcbvi AwaKvi m¤ú‡K Av‡iv Rvb‡Z PvB‡j AvB.wm.wW.wW.Avi.we- Gi M‡elbv ckvlb Kvhvj‡qi Gg.G. mvjv‡gi m‡½ e¨w³MZ fv‡e A_ev wbæwjwLZ bv¤v‡i †hvMv‡hvM Ki‡Z cv‡ib| †dvbt 9886498 (mivmwi), †gvevBjt 01711428989| ‡h †Kvb c‡ki Rb¨ Avcwb wcwÝcvj Bb‡fwó‡MUi jvm †nwbs Gi mv‡_ †hvMv‡hvM Ki‡Z cv‡ib| jvm †nwbs Ges mvjvg Lvb-Gi mv‡_ GB nvmcvZv‡jB †hvMv‡hvM

Ki‡Z cv‡ib| Zv‡`i wVKvbvUv n‡jv: AvBwmwWwWAvi,we, 68 kwn` ZvRDwÏb Avn‡g` ¯§iYx, gnvLwj, XvKv 1212| Avcwb hw` ¯ZtùZ fv‡e GB Rwi‡c AskMn‡bi B”QK nb, Z‡e AbMn K‡i Avcbvi ¯v¶i A_ev evg nv‡Zi e×v½‡j i Qvc wb‡Pi wb‡`wkZ ¯v‡b c`vb Ki“b|

Avcbvi mn‡hwMZvi Rb¨ A‡kl ab¨ev`|

gše¨t

‡ivMxi ¯v¶i /
evg nv‡Zi e×v½‡j i Qvc

¯v¶xi ¯v¶i

ZwiL

Protocol Number: 2008-060
Protocol Title: Inpatient HIV surveillance project for the ICDDR,B HIV Ward
Investigators: Henning L, Ohata B, Faruque ASG, Cobb B

INFORMED CONSENT: HIV SURVEILLANCE QUESTIONNAIRE
PEDIATRIC PARENT/GUARDIAN VERSION

Some people in Bangladesh have human immunodeficiency virus (HIV), and their numbers are increasing. Patients with HIV get sicker than normal people.

At this Dhaka Hospital of ICDDR,B (Cholera Hospital), we are conducting a survey to learn more about the health problems in HIV patients. We are inviting your child to participate in our survey because he/she has been diagnosed with HIV and has been admitted to our hospital for treatment.

If you agree, we will ask your child some questions related to his/her health problems, his/her personal background and habits. We would also like to ask your child similar questions if your child is admitted again to ICDDR,B in the future. We would then fill out a similar questionnaire. We will conduct your child's interview today in a place in this hospital that assures privacy. It will take about one hour. We will also collect some information from your child's hospital record and use it in this survey. We will keep all of your child's information completely confidential. Only people involved in this survey will have an access to this information. You are the only one to decide for or against participation in this survey, and you and your child would also be able to stop answering questions at any time. You and your child may choose to skip any questions in the survey. If your child does not participate in this survey or if you withdraw his/her consent after initial participation, your child will continue to get the same care and treatment at this hospital and at the NGO that has referred your child to this hospital as patients who take part in the survey.

We will enter your child's information into a computer. We will keep all your information confidential. Surveys will be locked in a secure location. Information in the computer will only be accessible by special people with a password. Only HIV researchers will have access to this information. No one will publish your name with this information. However, once we have collected your child's answers and entered them into our computer, we will not be able to remove them if you decide to discontinue the participation. We may or may not contact your child in the future to participate in future research studies. If your child declines participation in these future studies, there will be no change in the quality of your child's treatment and your child still will receive treatment when your child needs admission.

There is no physical risk from participating in this survey. There will be no associated physical examination. Your child will not receive any special treatment or special medications if your child answers the survey. Your child will also not get money or any other type of benefit from participating in this survey. However, your child's participation would improve our knowledge specifically to understand how patients in Bangladesh are affected by HIV. This will help us provide better care, treatment and support in the future for all HIV patients in Bangladesh.

Please feel free to ask any questions about the survey and your child's health problems that you or your child might have. If you or your child have some questions later you can always ask the nurse or doctor who is in charge of you. You can also contact the hospital administrator of Dhaka Hospital. If you want to know more about your child's rights as a survey participant, you might contact M. A. Salam Khan, at the Research Administration office of ICDDR,B personally or at following telephone numbers: 9886498 (direct), mobile: 01711428989. You may also contact the principal investigator, Lars Henning, with any questions. Lars Henning and Salam Khan both can be contacted at this hospital. The address is ICDDR,B, 68 Shaheed Tajuddin Ahmed Sharani, Mohakhali, Dhaka 1212. If you voluntarily agree to allow your child to participate in this survey please indicate that by putting your signature or left thumb impression at the specified space below.

Thank you very much for your cooperation.

Comments:

_____	_____
Parent/Guardian's signature/left thumbprint	Signature of witness
_____	_____
Child's name	Date

Protocol Number: 2008-060
Protocol Title: Inpatient surveillance project for the ICDDR,B HIV Ward
Investigators: Henning L, Faruque ASG, Ohata B, Cobb B

INFORMED CONSENT: HIV SURVEILLANCE QUESTIONNAIRE
PEDIATRIC PARENT/GUARDIAN VERSION

evsjv‡`‡ki wKQ †jvK** HIV- **Øviv Avµvš Ges Zv‡`i msL¨v †e‡o Pj‡Q| HIV- **Avµvš †ivMxiv mwavib †jvK‡`i Zjbvq Am¯ n‡q c‡o|**

HIV- **Avµvš †ivMx‡`i ¯v¯¨ mgm¨v m¤ú‡K AwaKZi Ávb jv‡fi j‡¶¨, Avgiv AvB.wm.wW.wW.Avi.we- Gi XvKv nvmcvZv‡j (K‡jiv nvmcvZvj)** HIV- **Avµvš †ivMx‡`i ¯v¯¨ mgm¨v welqK Rwic Pvjw”Q| Avgviv Avcbvi m»vb‡K Avgv‡`i Rwi‡c Avgšb Rvbw”Q Kvib Avcbvi m»vb** HIV- **Øviv AvKvš Ges Avgv‡`i nvmcvZv‡j wPwKrmvi Rb¨ fwZ n‡q‡Qb|**

hw` Avcwb m¤§Z nb, Avgiv Avcbvi m»vb‡K Zvi ¯v¯¨ mgm¨v, e¨w³MZ cUfwg Ges AvPib m¤ú‡K wKQ ck wR‡Ám Ki‡ev| Avcbvi m»vb hw` fwel¨‡Z Avevi AvB.wm.wW.wW.Avi.we- †Z fwZ nq Z‡e Avgiv cbivq Zv‡K GKB iKg ck Ki‡Z cwi| Avgiv ZLb GKB iK‡gi ckcÎ cib Ki‡ev| Avgiv AvR Avcbvi m»v‡bi m¶vrKvi Ggb GKwU ¯v‡b wb‡ev hv ‡MvcbxqZv i¶v Ki‡e| Bnv GK N›Uvi gZ mgq wb‡e| Avgiv nvmcvZv‡ji bv_ n‡Zl wKQ Z_¨ msMn Ki‡ev| Avgiv Avcbvi m»v‡bi mKj Z_¨ msM‡n m¤úb †MvcbxqZv i¶v Kie| ïagvÎ GB Rwi‡ci mv‡_ mswkóvB GB Z_¨ Rvbvi AwaKvi ivL‡e| GB Rwi‡c AskMnb ev AskMnb bv Kivi wm×vš ïagvÎ Avcbvi Ges Avcwb I Avcbvi m»vb PvB‡j †h †Kvb mgq c‡ki DËi †`Iqv t_‡K weiZ _vK‡Z cv‡ib| wKQ ck ms‡e`bkxj Ges e¨w³MZ, †m‡¶‡Î Rwi‡ci †h‡Kvb ck ev` w`‡q Ab¨ c‡k †h‡Z cv‡ib| Avcwb I Avcbvi m»vb hw` Rwi‡c AskMnb bv K‡ib A_ev Avcwb hw` Avcbvi m»v‡bi AskMnb cZ¨vnvi K‡ib, †m‡¶‡Î Avcbvi m»vb GB nvmcvZvj †_‡K Ges †h GbwRI Zv‡K GB nvmcvZ‡j cwV‡q‡Q Zv‡`i KvQ †_‡K GKB †mev Ges wPwKrmv †c‡q hv‡e|

Avgiv Avcbvi m»v‡bi Z_¨ GKwU K¤úDUv‡i ivL‡ev| Avgiv Avcbvi †`qv Z_¨mg‡ni †MvcbxqZv i¶v Ki‡ev| Z_¨mgn GKUv miw¶Z RvMvq Zvjve× K‡i ivLv n‡e| GB Z_¨mgn ïagvÎ wKQ we‡kl †jvKRbB cvmIqv‡Wi gva¨‡g K¤úDUv‡i e¨envi Ki‡Z cvi‡e| ïagvÎ GBPAvBwf M‡elKMY GB Z_¨mgn e¨envi Ki‡e| GB Z_¨mg‡ni mv‡_ †KD-B Avcbvi bvg cKvk Ki‡e bv| Avcbvi m»v‡bi c‡ki DËi msMn Ges K¤úDUv‡i msi¶‡bi ci Avcwb AskMn‡b Awb”QK n‡jl Avgiv Zv g‡Q †dj‡Z cvi‡ev bv| fwel¨‡Zi bZb M‡elbvq AskMn‡bi Rb¨ Avgiv Avcbvi m‡½ ciewZ‡Z †hvMv‡hvM Ki‡Zl cwi| A_ev bvI Ki‡Z cwi| Avcbvi m»vb hw` fwel¨‡Zi M‡elbv Kv‡h AskMn‡b A¯xKwZ Rvbvb †m‡¶‡Îl Zvi wPwKrmv Kv‡hi ¸bMZ gv‡bi †Kvb cwieZb n‡e bv Ges c‡qvR‡b ‡m nvmcvZv‡j fwZ n‡q wPwKrmv †mev †c‡Z cvi‡e|

Rwi‡c AskMn‡b †Kvb kwiixK SwK †bB | Gi m‡½ m¤ú³ †Kvb kwiixK cwi¶v †bB| Avcbvi m»vb Rwi‡c Ask wb‡j †Kvb we‡kl ai‡bi wPwKrmv ev Jla cv‡e bv| Avcbvi m»vb Rwi‡c AskMnb Ki‡jl †Kvb A_ ev Ab¨vb¨ m‡hvM mweav cv‡eb bv| wKš Avcbvi m» v‡bi AskMnb Avgv‡`i Ávb weKv‡k, we‡klZt evsjv‡`‡ki gvbl wKfv‡e HIV- **Øviv AvKvš nq Zv Rvb‡Z mnvqZv Ki‡e| Bnv Avgv‡`i fwel¨‡Z** HIV-**†ivMx‡`i DbZ †mev, wPwKrmv Ges mnvqZv c`v‡b mvnvh¨ Ki‡e|**

Rwic Ges Avcbvi m»v‡bi ¯v¯¨ mgm¨v m¤úwKZ †h‡Kvb ck wb‡`avq Ki‡Z cv‡ib| cieZx‡Z wKQ Rvb‡Z PvB‡j Avcwb Ges Avcbvi m»v‡bi `wq‡Z wb‡qwRZ _vKv bvm A_ev Wv³vi‡K wR‡Ám Ki‡Z cv‡ib| Avcwb XvKv nvmcvZ‡ji cav‡bi mv‡_l †hvMv‡hvM Ki‡Z cv‡ib| Avcwb Rwi‡c AskMnbKvix wn‡m‡e Avcbvi m»v‡bi AwaKvi m¤ú‡K Av‡iv Rvb‡Z PvB‡j AvB.wm.wW.wW.Avi.we- Gi M‡elbv ckvlb Kvhvj‡qi Gg.G. mvjv‡gi m‡½ e¨w³MZ fv‡e A_ev wbæwjwLZ bv¤v‡i †hvMv‡hvM Ki‡Z cv‡ib| †dvbt 9886498 (mivmwi), †gvevBjt 01711428989| ‡h †Kvb c‡ki Rb¨ Avcwb wcwÝcvj Bb‡fwó‡MUi jvm †nwbs Gi mv‡_ †hvMv‡hvM Ki‡Z cv‡ib| jvm †nwbs Ges mvjvg Lvb-Gi mv‡_ GB nvmcvZv‡jB †hvMv‡hvM Ki‡Z cv‡ib| Zv‡`i wVKvbvUv n‡jv: AvBwmwWwWAvi,we, 68 kwn` ZvRDwÏb Avn‡g` ¯§iYx, gnvLwj, XvKv 1212| Avcwb hw` ¯ZtùZ fv‡e Avcbvi m»vb‡K GB Rwi‡c AskMnb c`v‡b B”QK nb, Z‡e AbMn K‡i Avcbvi ¯v¶i A_ev evg nv‡Zi ex×v½‡ji Qvc wb‡Pi wb‡`wkZ ¯v‡b c`vb Ki“b|

Avcbvi mn‡hvwMZvi Rb¨ A‡kl ab¨ev`|

gše¨t

‡ivMxi wcZv-gvZv / Awffve‡Ki ¯v¶i /
evg nv‡Zi e×v½‡ji Qvc

¯v¶xi ¯v¶i

m»v‡bi bvg

ZwiL

Protocol Number: 2008-060
Protocol Title: Inpatient HIV surveillance project for the ICDDR,B HIV Ward
Investigators: Henning L, Ohata B, Faruque ASG, Cobb B

INFORMED ASSENT: HIV SURVEILLANCE QUESTIONNAIRE
PEDIATRIC ASSENT

Some children in Bangladesh have human immunodeficiency virus (HIV), and their numbers are increasing. Patients with HIV get sicker than normal people.

At this Dhaka Hospital of ICDDR,B (Cholera Hospital), we are asking patients questions to learn more about the health problems in HIV patients. We are inviting you to answer these questions because you have been diagnosed with HIV and have been admitted to our hospital.

In the questionnaire, we will ask you and your family about your health since your HIV diagnosis, your personal background and habits. The questions will take about 1 hour. We will also write information from your chart. The answers you provide for us will be private. We will perform the interview in a private location. We will not tell anyone that you provided us this information. Your answers will be part of a large group of other people's answers. You and your family are the only one to decide for or against participation in this survey. You may stop answering questions at any time. You may choose to skip any questions in the survey. We will not punish you if you decide not to participate or stop participating later on. People who do not participate in the survey get the same care and treatment at this hospital as patients who take part in the survey.

We will enter your information into a computer. We will keep all your information confidential. Surveys will be locked in a secure location. Information in the computer will only be accessible by special people with a password. Only HIV researchers will have access to this information. No one will publish your name with this information. Once information is collected in the computer, we may not be able to erase it. We may or may not contact you in the future to participate in future research studies. If you decline participation in these future studies, there will be no change in the quality of your treatment and you still will receive treatment when you need admission

There will be no associated physical examination with this survey. You will not receive any special treatment or special medications if you answer the survey. You will also not get money or any other type of benefit from participating in this survey. However, your participation would improve our knowledge about HIV in Bangladesh. This will help us provide better care, treatment and support in the future for all HIV patients in Bangladesh.

Please feel free to ask any questions about the survey and your health problems that you might have. If you have some questions later you can always ask the nurse or doctor who is in charge of you. You can also contact the hospital administrator of Dhaka Hospital. If you want to know more about your rights as a survey participant, you might contact M. A. Salam Khan, at the Research Administration office of ICDDR,B personally or at following telephone numbers: 9886498 (direct), mobile: 01711428989. You may also contact the principal investigator, Lars Henning, with any questions. Lars Henning and Salam Khan both can be contacted at this hospital. The address is ICDDR,B, 68 Shaheed Tajuddin Ahmed Sharani, Mohakhali, Dhaka 1212. If you voluntarily agree to participate in this survey please indicate that by putting your signature or left thumb impression at the specified space below.

Thank you very much for your cooperation.

Comments:

_____	_____	_____
Patient's signature/left thumbprint	Witness' signature	Date

Protocol Number: 2008-060
Protocol Title: Inpatient surveillance project for the ICDDR,B HIV Ward
Investigators: Henning L, Ohata B, Faruque ASG, Cobb B

INFORMED ASSENT: HIV SURVEILLANCE QUESTIONNAIRE
PEDIATRIC ASSENT

evsjv‡`‡ki wKQ wkk** HIV- **Øviv Avµvš Ges Zv‡`i msL¨v †e‡o Pj‡Q| HIV- **Avµvš †ivMxiv mvavib †jvK‡`i Zjbvq Am¯ n‡q c‡o|**

HIV- **Avµvš †ivMx‡`i ¯v¯¨ mgm¨v m¤ú‡K AwaKZi Ávb jv‡fi j‡¶¨, Avgiv AvB.wm.wW.wW.Avi.we- Gi XvKv nvmcvZv‡j (K‡jiv nvmcvZvj) †ivMx‡`i wKQ ck wR‡Ám KiwQ| Avgviv Avcbv‡K GB ckM‡jvi DËi ‡`qvi Rb¨ Avgšb Rvbw"Q, Kvib Avcwb** HIV- **Øviv AvKvš Ges Avgv‡`i nvmcvZv‡j wPwKrmvi Rb¨ fwZ n‡q‡Qb|**

hw` Avcwb m¤§Z nb, Avgiv Avcbv‡K Ges Avcbvi cwievi‡K Avcbvi ¯v¯¨ mgm¨v, e¨w³MZ cUfwg Ges AvPib m¤ú‡K wKQ ck wR‡Ám Ki‡ev| ckM‡jv Ki‡Z GK N›Uvi gZ mgq jvM‡e| Avgiv nvmcvZv‡j Avcbvi bw_ n‡Zl wKQ Z_¨ msMn Ki‡ev| Avgiv Avcbvi ‡`qv mKj Z‡_¨i DËiM‡jv †Mvcb ivL‡ev| Avcbvi m¶vrKviwU GKwU ‡Mvcb ¯v‡b ‡bqv n‡e| ‡KD G m¤c‡K AewnZ n‡e bv ‡h, Avcwb Z_¨M‡jv Avgv‡`i c`vb K‡i‡Qb| GB Rwi‡c AskMnb ev AskMnb bv Kivi wm×vš ïagvÎ Avcbvi Ges Avcbvi cwiev‡ii| Avcwb PvB‡j †h †Kvb mgq c‡ki DËi †`lqv †_‡K weiZ _vK‡Z cv‡ib| wKQ ck ms‡e`bkxj Ges e¨w³MZ, †m‡¶‡Î Rwi‡ci †h‡Kvb ck ev` w`‡q Ab¨ c‡k †h‡Z cv‡ib| Avcwb hw` Rwi‡c AskMnb bv K‡ib A_ev cieZx‡Z AskMn‡b Am¤§Z Rvbvb †m‡¶‡Îl Avgiv Avcbv‡K AskMn‡b eva¨ Ki‡ev bv| ‡h mKj ‡ivMx Rwi‡c AskMnb Ki‡eb Ges hviv AskMnb Ki‡eb bv Df‡qB GB nvmcvZvj n‡Z GKB †mev Ges wPwKrmv †c‡q hv‡eb|

Avgiv Avcbvi Z_¨ GKwU Kw¤úDUv‡i ivL‡ev| Avgiv Avcbvi †`qv Z_¨mg‡ni †MvcbxqZv i¶v Ki‡ev| Z_¨mgn GKUv miw¶Z RvMvq Zvjve× K‡i ivLv n‡e| GB Z_¨mgn ïagvÎ wKQ we‡kl †jvKRbB cvmlqv‡Wi gva¨‡g Kw¤úDUv‡i e¨envi Ki‡Z cvi‡e| ïagvÎ GBPAvBwf M‡elKMY GB Z_¨mgn e¨envi Ki‡e| GB Z_¨mg‡ni mv‡_ †KD-B Avcbvi bvg cKvk Ki‡e bv| Avcbvi Z_¨ Kw¤úDUv‡i msi¶‡bi ci Avgiv Zv g‡Q bvl †dj‡Z cwi| fwel¨‡Zi bZb M‡elbvq AskMn‡bi Rb¨ Avgiv Avcbvi m‡½ cieZ‡Z †hvMv‡hvM Ki‡Zl cwi A_ev bvl Ki‡Z cwi| Avcwb hw` fwel¨‡Zi M‡elbv Kv‡h AskMn‡b A¯xKwZ Rvbvb †m‡¶‡Îl Avcbvi wPwKrmv Kv‡hi ¸bMZ gv‡bi †Kvb cwieZb n‡e bv Ges c‡qvR‡b Avcwb nvmcvZv‡j fwZ n‡q wPwKrmv †mev †c‡Z cvi‡eb|

Rwi‡c AskMn‡b †Kvb kwiixK SwK †bB | Gi m‡½ m¤ú³ †Kvb kwiixK cwi¶v †bB| Avcwb Rwi‡c Ask wb‡j †Kvb we‡kl ai‡bi wPwKrmv ev Jla cv‡eb bv| Avcwb Rwi‡c AskMnb Ki‡jl †Kvb A_ ev AY¨vb¨ m‡hvM mweav cv‡eb bv| wKš Avcbvi AskMnb Avgv‡`i Ávb weKv‡k, we‡klZt evsjv‡`‡ki gvbl wKfv‡e HIV- **Øviv AvKvš nq Zv Rvb‡Z mnvqZv Ki‡e| Bnv fwel¨‡Z Avgv‡`i‡K evsjv‡`‡ki mKj** HIV-**†ivMx‡`i DbZ †mev, wPwKrmv Ges mnvqZv c`v‡b mvnvh¨ Ki‡e|**

Rwic Ges Avcbvi ¯v¯¨ mgm¨v m¤úwKZ †h‡Kvb ck wb`avq Ki‡Z cv‡ib| cieZx‡Z wKQ Rvb‡Z PvB‡j Avcbvi `wq‡Z wb‡qwRZ _vKv bvm A_ev Ww³vi‡K wR‡Ám Ki‡Z cv‡ib| Avcwb XvKv nvmcvZ‡ji cav‡bi mv‡_l †hvMv‡hvM Ki‡Z cv‡ib| Avcwb Rwi‡c AskMnbKvix wn‡m‡e Avcbvi AwaKvi m¤ú‡K Av‡iv Rvb‡Z PvB‡j AvB.wm.wW.wW.Avi.we- Gi M‡elbv ckvlb Kvhvj‡qi Gg.G. mvjv‡gi m‡½ e¨w³MZ fv‡e A_ev wbæwjwLZ bv¤v‡i †hvMv‡hvM Ki‡Z cv‡ib| †dvbt 9886498 (mivmwi), †gvevBjt 01711428989| ‡h †Kvb c‡ki Rb¨ Avcwb wcwÝcvj Bb‡fwó‡MUi jvm †nwbs Gi mv‡_ †hvMv‡hvM Ki‡Z cv‡ib| jvm †nwbs Ges mvjvg Lvb-Gi mv‡_ GB nvmcvZv‡jB †hvMv‡hvM Ki‡Z cv‡ib| Zv‡`i wVKvbvUv n‡jv: AvBwmwWwWAvi,we, 68 kwn` ZvRDwÏb Avn‡g` ¯§iYx, gnvLwj, XvKv 1212| Avcwb hw` ¯ZtùZ fv‡e GB Rwi‡c AskMn‡bi B"QK nb, Z‡e AbMn K‡i Avcbvi ¯v¶i A_ev evg nv‡Zi e×v½‡ji Qvc wb‡Pi wb‡`wkZ ¯v‡b c`vb Ki"b|

Avcbvi mn‡hwMZvi Rb¨ A‡kl ab¨ev`|

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ZwiL

APPENDIX 2: HIV Ward Surveillance Project-ABSTRACT

The purpose of the HIV surveillance project will be to assess future needs, plan future research initiatives, and evaluate trends within the newly opened HIV ward at ICDDR,B. This is done with the aim to improve the care, support and treatment for People Living with HIV/AIDS. ICDDR,B's HIV ward has been open since June 2008, and has seen a wide variety of medical conditions afflicting HIV-positive patients requiring admission. A surveillance project of current admitted patients is necessary to anticipate future needs and assure high-quality healthcare delivery to our patients. Our surveillance questionnaires will collect demographic information, past medical history, relevant laboratory investigations, final diagnoses, and patient outcomes at discharge in order to achieve these goals. The scope of the surveillance project will be limited to inpatients only.

The HIV surveillance project is essential for the delivery of high quality healthcare to our patients, and it would be unwise to establish this HIV ward without some form of surveillance monitoring. The surveillance project will establish a system of quality control in clinical care on our ward that should be universal, and will characterize problems that have never been described in this country, yet need to be illuminated for future planning purposes. We will ask every patient admitted to the HIV ward for informed consent, and then complete a survey on willing individuals. Patients will have the opportunity to decline participation at any time during the questioning with no adverse effects on the quality of their healthcare. Three questionnaires will be utilized. If the patient is new to the HIV ward, an "initial visit questionnaire" consisting of 26 questions will be completed on arrival. It will take approximately 1 hour to complete the questionnaire. This questionnaire will capture demographic information, socioeconomic status, past medical history, chief complaints, recent CD4 counts, and disease-transmitting risk factors. Every patient, both pediatric and adult, admitted to the HIV ward will be invited to participate in the surveillance project. We anticipate 100-150 patients will be admitted to the HIV ward per year. Children will be included because they form an integral part of our patient base and the problems they face will impact planning for the future. Only legal adults will be asked questions about disease-transmitting risk factors. If the patient has been admitted to the HIV ward in the past, they will complete a "follow-up visit questionnaire", which omits previously collected demographic information but is otherwise identical to the "initial visit questionnaire". The nurses and doctors on our ward will complete the "initial visit questionnaire" and "follow-up visit questionnaire" and will be trained to complete these forms. At discharge, doctors will complete a "discharge questionnaire", which captures final diagnoses, relevant investigation results from the patient's hospital chart, medications prescribed, and complications. Once the hospital medical record system has been digitalized, redundant sections of the questionnaires will be eliminated and data will be imported directly from the electronic hospital database.

We do not see any ethical dilemmas stemming from our methodology, since all patients will receive the same standard of care regardless of their participation in this study. Written informed consent will be obtained from all willing participants. Adult informed consent forms, parental informed consent forms and pediatric informed assent forms have been developed. Only patients who give their informed consent, or pediatric patients whose parents/guardians provide informed consent, will be enrolled in the project. The informed consent protects the right of patients to participate, not participate, or withdraw participation in the project. All risks and benefits are described clearly in the informed consent, and patients have the option to opt out of the project and specific questions in the questionnaires with no adverse effects on their standard of care. The informed consent explicitly notifies patients that information from their chart will be collected, in addition to the answers they provide in the questionnaires. The patients will have no additional medical risks from participating in this project, since no interventions are involved; the study itself is comprised of data collection exclusively, not any interventions. The data we will collect is identical to the data we would need to collect in order to provide comprehensive, state-of-the-art clinical care to the patients. We do not think our proposal presents any threat to patient safety, since all patients will receive the same standard of care regardless of their participation in this study, and no additional investigation will be ordered or medications administered above and beyond standard practice. Personal information collected is all of clinical relevance and an integral part of the standard medical interview for these

patients. Although the personal information and other medical data collected from these patients is sensitive and carries social stigma, any institution adhering to international standards would collect and document this data anyway as a part of routine patient care. We do not ask patients questions beyond the scope of a standard medical interview for patients of this disease burden. Therefore, the data collection poses no greater risk to the patient than they would face from standard hospital record-keeping and routine medical care. There are no societal risks incurred by this project. Patients will receive no immediate benefit from study participation, and have no incentives to persuade them into enrolling in a study in which they might otherwise not agree to enroll. However, their participation will benefit future patients by improving patient care and assisting in future planning. Patients can withdraw from this surveillance and will still receive the same care and treatments as before.

Additionally, we will collect patient data in a manner that ensures confidentiality. The data collection poses no greater risk to the patient than they would face from standard hospital record-keeping. We will conduct the questionnaire upon admission in a private location, and ensure that only investigators and data entry persons have access to the raw patient data. All persons involved in patient data will be informed of the importance of confidentiality. Original questionnaires will be kept locked as per international standards, and personal data stored on password-protected files in password-protected computers. Information on confidentiality safeguards is outlined in the informed consent, and patients who are uncomfortable with these measures may opt out of participation. After reviewing the literature on HIV surveillance systems, we have opted for a name-based surveillance system with security checks on par with those of other countries. Name-based HIV surveillance systems have been proven to capture superior data quality in at least 7 different published studies; conversely, no studies have proven name-based systems to suffer from more frequent confidentiality breaches. We intend to safeguard confidentiality as rigorously as other international institutions, and have no reason to believe that cultural norms are different in Bangladesh in such a way that would result in our staff behaving less professionally with confidential information than the rest of the world. Given the burden of proof demonstrating the superiority and non-inferiority of a name-based system, we see no reason to resort to a non-name-based system.

The data from the surveillance project will be analyzed by the investigators at least once per month and results will made be accessible to the scientific community inside and outside of Bangladesh. We are looking to assess who is coming to our ward, how many people are coming, what their health status is, what their outcome is on discharge, and if their disease-transmitting behaviors are changing. Although this is not an interventional trial we will analyze morbidity and mortality data monthly. Every complication or adverse outcome, including but not limited to death, will be examined in the Dhaka Hospital Setup. The data collected will be used to improve the quality of the healthcare delivered to our patients. We will use the data collected from the HIV surveillance project to identify the strengths and weaknesses of the healthcare we provide, thereby allowing us to design capacity-building trainings for our staff.

APPENDIX 3: Budget

Detailed Budget for the study titled: Inpatient surveillance project for HIV Ward of the Dhaka Hospital of ICDDR,B

Name of Principal Investigator: Lars Henning

Protocol Number: 2008-060

Division: Clinical Sciences Division

Funding Source: NIH, USA

Budget: Direct: 98,338 Indirect: 7,867 Total (US$): 106,205

Study period: Ongoing

Strategic Priority Code(s): 2.3, 4.1, 4.4, 5.5

Line Items	Budget										
Payroll and Benefits:	Name of personnel/position	Pay level	% Effort	# of posts	Monthly Rate	Year-1	Year-2	Year-3	Year-4	Year-5	Total amount (US$)
	Lars Henning, Principal Investigator		4%	1	5,502	2,641	2,826	3,024	3,235	3,462	15,187
	Brent Ohata, Co-principal Investigator		25%	1	1,500	4,500	4,815	5,152	5,513	5,899	25,878
	ASG Faruque, Co-investigator		10%	1	4,064	4,877	5,218	5,583	5,974	6,392	28,044
	Brian Cobb, Co-investigator		3%	1	5,855	2,108	2,255	2,413	2,582	2,763	12,121
	Data entry		10%	1	1,668	2,001	2,141	2,291	2,451	2,623	11,507
	Sub-total of Payroll and benefits:					**16,127**	**17,255**	**18,463**	**19,755**	**21,138**	**92,738**
Travel and transport											
	Sub-total of Travel and Transport:					-	-	-	-	-	-
Supply and materials	Computer, monitor, printer					1,500	-	-	-	1,500	3,000
	Paper, pens, pencils, printer cartridges, CD-R					450	450	450	450	450	2,250
	File cabinet					350	-	-	-	-	350
	Sub-total of supply and materials:					**2,300**	**450**	**450**	**450**	**1,950**	**5,600**
Other contractual											
	Sub-total of other contractual:					-	-	-	-	-	-
Total direct costs:						**18,427**	**17,705**	**18,913**	**20,205**	**23,088**	**98,338**
Total indirect cost:						**1,474**	**1,416**	**1,513**	**1,616**	**1,847**	**7,867**
Total costs:						**19,901**	**19,122**	**20,426**	**21,822**	**24,935**	**106,205**

APPENDIX 4: External Review and Response #1

Title: Inpatient HIV surveillance project for the ICDDR,B HIV Ward

Summary of Referee's Opinions: Please see the following table to evaluate the various aspects of the proposal by checking the appropriate boxes. Your detailed comments are sought on a separate, attached page.

	Rank Score		
	High	Medium	Low
Quality of project		X	
Adequacy of project design			X
Suitability of methodology		X	
Feasibility within time period	X		
Appropriateness of budget			X
Potential value of field of knowledge		X	

CONCLUSIONS

I support the application:

a) without qualification ☐

b) with qualification

- on technical grounds ☒
- on level of financial support ☐

I do not support the application ☐

Detailed Comments

Please briefly provide your opinions of this proposal, giving special attention to the originality and feasibility of the project, its potential for providing new knowledge and the justification of financial support sought; include suggestions for modifications (scientific or financial) where you feel they are justified. (Use additional pages if necessary)

Title: Inpatient surveillance project for HIV Ward of the Dhaka Hospital of ICDDR,B
PI: Lars Henning

Reviewer: The proposal deals with a very important emerging problem in Bangladesh. It might be very useful to set up a surveillance system for HIV positive patients admitted in HIV ward of ICDDR,B. However, the protocol needs to be more focused and the methodologies and processes need to be discussed in details.

Specific comments regarding the protocol

Face sheet:

Title: "Inpatient HIV surveillance project for the ICDDR,B HIV Ward". This is not actually a HIV surveillance rather it is surveillance of patients admitted in HIV Ward of ICDDR,B hospital. It might be useful to reward the title.

PI: *Title changed on pages 1, 7, 23, 24, 26, 27, 29, 30 to "Inpatient surveillance project for HIV Ward of the Dhaka Hospital of ICDDR,B" to reflect the fact that it is not a surveillance for HIV, but rather for the myriad complications associated with HIV requiring admission, including, but not limited to, drug-drug interactions, drug intolerance, immune reconstitution syndrome, co-infections, and opportunistic infections.*

Page 3: Although the activities will be conducted at ICDDR,B, HIV ward other arrears of Bangladesh *is* marked.

PI: *"Other areas in Bangladesh" is marked because our patient population comes from the entire country, not only Dhaka, even though they are all seen at Dhaka hospital. If our understanding of this question is incorrect, we have no problem unchecking that box.*

Page 4: **"Do you consider this research":** I will consider it as Greater than minimal risk.

PI: *The definition of greater than minimal risk in this question is, "a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical, psychological examinations or tests." According to the definition stated in this question, participation in this research intrinsically does not pose a greater than minimal risk to the patient. Patients will come to the hospital of their own accord, and will be treated exactly the same as all patients with similar disease burden. Patients will be exposed to a standard amount of risk only as a result of their standard patient care, and the study itself does not require risky experimental treatments/investigations beyond what would be needed to treat them at an international standard of care. Therefore, we believe the risk to our patients should be classified as "only part of the diagnostic test." The study itself is comprised of data*

collection exclusively, not any experimental interventions. Although the personal information and other medical data collected from these patients is sensitive and carries social stigma, any institution adhering to international standards would collect and document this data anyway as a part of routine patient care. We do not ask patients questions beyond the scope of a standard medical interview for patients of this disease burden. Therefore, the data collection poses no greater risk to the patient than they would face from standard hospital record-keeping and routine medical care.

Project summary:
It might be useful to add some baseline HIV *I* AIDS information in the background. Current patient load of the HIV ward and future patient load estimates etc. It might be important to elaborate the rationale of the study such as "information collected might be useful to characterize the opportunistic infection pattern in this population" etc.

PI: *Baseline HIV/AIDS information can be found in the background section on pages 8-10. Additionally, the following sentences have been added to address the reviewer's concerns, "Current patient load is highly variable, and ranges from 0-9 patients per day. We have no method to quantify current patient load, or to estimate future load, which is why we are creating a surveillance project. In order to assess future needs, plan future research initiatives, evaluate trends within our patient base, characterize opportunistic infection patterns in our population, identify the frequencies of drug-drug interactions, identify the frequency of drug intolerances, and plan accordingly for the necessity of alternative drug regimens, a surveillance project examining HIV patients admitted to the ward is necessary. "*

Hypothesis:
"Survey participants might be asked to participate in others research studies, This will require the corresponding additional informed consent" should be deleted from hypothesis

PI: *These sentences have been deleted.*

Specific aims:
"Assess and analyze trends over time regarding the care, support" The study tool does not support the measurement of care and support. This should be removed.

PI: *Vis-à-vis the initial visit questionnaire, follow-up visit questionnaire, and discharge questionnaire, we will be able to identify all patients' health status on arrival, the investigations and treatments ordered/administered, and the patient's outcome. Thus, we will be able to quantify the level and standard of care provided to our patients, its appropriateness, and if we are improving.*

"In order to achieve..... discharge from hospital" this is a description of method and should be removed from specific aim section.

PI: *"In order to achieve…discharge from hospital" has not been removed because the instructions in this section state, "State the specific parameters, biological functions/ rates/ processes that will be assessed by specific methods." Everything listed in this section describes the parameters that will be assessed.*

Introduction:

Page 9 Para two, it might be useful to have some more information regarding the available hospital services for HIV positive patients in Bangladesh, previous attempts to provide inpatients services to HIV

positive patients and their limitation. The general description and patient load of the ICDDR,B HIV inpatient ward, services offered by this ward and source of patients or referral linkage of VCT sites, PLWHA organization to this ward.
The Background section needs further expansion and clearly explain the social context, current HIV diseases burden, HIV care and support information, available data on AIDS patients in the country, future projections of patient load based on limited access to ARV treatment.

PI: *The paragraph has been changed to read as follows, "As of 2007, it has been estimated that 12,000 Bangladeshis are living with HIV/AIDS. Major population subgroups include prostitutes, injection drug users, and overseas workers. Of these infected persons, less than 200 are thought to be on anti-retroviral therapy, equal to 10% of the population requiring these drugs at best. 500 people are thought to have died of AIDS in 2007, and the rate of death is increasing steadily (UNAIDS). Therefore, we can assume our patient load will increase with time. For the few HIV-positive Bangladeshis who receive ART, only first-line drug combinations exist, the most common being zidovudine + lamivudine + nevirapine, with one substitution drug (efavirenz) available; no second-line regimens exist in the country for patients with virological failure, drug intolerance, or contraindicative drug-drug interactions. In view of the limited availability and selection of antiretroviral drugs, we speculate that a significant number of HIV-positive patients will require inpatient treatment for co-infections, opportunistic infections, and drug-related complications. However, a systematic characterization of HIV-related health complications in Bangladesh has never been undertaken. To our knowledge, ICDDR,B's HIV ward is the only hospital in Bangladesh dedicated to the inpatient treatment of complicated HIV patients where patients are guaranteed adequate and comprehensive care. AITEM is the only hospital we are aware of that provides surgical care to HIV-positive patients. Anecdotally, many hospitals in Bangladesh are known to refuse treatment to HIV-positive patients, but a comprehensive study has never been performed. We are not aware of any previous attempts within the country to provide inpatient care to HIV-positive patients. Therefore ICDDR,B's HIV ward is well-positioned to examine HIV-associated complications in Bangladesh. The patient load in the HIV ward is highly variable, and ranges from 0-9 patients per day. The problems encountered is equally variable, including all manner of drug-drug interactions, drug intolerances, coinfections, opportunistic infections, and immune reconstitution syndrome, with multiple problems often occurring at the same time. We have successfully treated all of these classes of problems. Patients have been referred to our center from hospitals throughout the country and every NGO in Bangladesh offering ART."*

Advantage and disadvantage of name and non name based surveillance as well as possible safeguards to protect the subject needs elaborate discussion.

PI: *The following sentences have been modified, "Non-name-based identifiers have not been proven to provide a comparable level of data quality as name-based systems and often double-count patients (Buehler et al, Jara et al, Klevens et al, Marsh et al, Meyer et al, Rosenblum et al). The advantage of non-name-based systems is that they guarantee anonymity; however, in regions that practice name-based surveillance systems, breaches in confidentiality have been infrequent and can be avoided with reasonable safeguards (Torres et al). Therefore, name-based systems are often preferred since they provide better data quality and rarely compromise patient confidentiality."*

Materials and methods:

This section needs some more reorganization. Inclusion or exclusion criteria if necessary should be added.

Sampling method or "take all" sampling strategy should be defined. Information about interviewer training, qualification etc should be mentioned. There is no description on how the data will be stored, editing or data entry and analysis. There is no description on how the identity of the individual will be safeguarded.

PI: *The following sentences have been added, "We will adopt a "take all" strategy and ask every patient admitted to the HIV ward for informed consent, and then complete a survey on willing individuals. We feel this is feasible since we only have a 10-bed unit. There are no inclusion or exclusion criteria." "The nurses and doctors on our ward will complete the "initial visit questionnaire" and "follow-up visit questionnaire" and will be trained to complete these forms." Details regarding data entry, storage, analysis, and confidentiality can be found on pages 11-12.*

Sample size:

The author should review literature to identify the strategy and the minimum sample size needed for surveillance, based on assumption of different number of patients admitted to the ward. The number or proportion of patients on ARV or without ARV might be useful. Current estimate is 100-150 patients and it might not be essential to enroll all of them in the surveillance. Even if the number of patient increases, it might be important to enroll all selected and previously visited patients and a few newly admitted patients.

PI: *The following sentences have been added: "We anticipate the variety of presenting complaints to change in Bangladesh as patients are diagnosed with HIV earlier, patients begin ART earlier, and patients have a wider variety of antiretroviral drugs to choose from. Anecdotally, nearly all the patients on our ward are on one of two ART regimens, and most have critically low CD4 counts as a result of late diagnosis/treatment initiation. We predict that this will change, and would like to capture data on these changing trends. Therefore, it will be necessary to continuously enroll first-time patients in order to compare their problems to those of previous patients. A systematic review of the literature revealed no previous surveillance systems examining HIV-related complaints on which to base sample size calculations. As many patients as possible will be enrolled in order to capture the most accurate information pertaining to our patient population. We anticipate 100-150 patients to be admitted to the HIV ward within its first year of inception. Given the size of our patient base, we will have the capacity to interview all patients admitted. We believe it is essential to interview all patients that come to our ward, since it is feasible and since they present with an extreme heterogeneity of complaints. If our patient base expands, we might not interview all patients. In that case we will notify the RRC and ERC accordingly."*

Data analysis:

Any surveillance program should be well planned in terms of data collection, cleaning, editing, entry and analysis. Unfortunately the current proposal lacks most of these elements. The investigators suggested HIVS EXCEL for data analysis. I would recommend that the investigators should revisit this section and describe the clear plan.
There is no analysis plan enclosed. Even if frequency is analyzed it should be mentioned. I would recommend establishing an analysis plan based on the questionnaire. If trend analysis is planned then there should be details description of the methods.

PI: *The data analysis section has been revised as follows: "Relevant data will be directly entered into SPSS, and analyzed with that software. The investigators will not be blinded. Data collection will begin as soon as ERC/RRC approval has been granted. 2 databases will be maintained: 1 password-protected database containing identifying information of patients only and 1 password-protected database containing all other data. A data entry specialist will be responsible for entering data into the databases, and this data will be examined on a regular basis by the database manager to ensure that a high standard of data quality is met. Similarly, the principal investigator will examine questionnaires regularly to ensure questionnaires are properly filled out; the senior physician on the HIV ward will be responsible for resolving any issues surrounding improperly completed questionnaires. Data will be analyzed at least monthly and access restricted to qualified researchers. Frequency of patient visits, in addition to age, sex, demographic information, diagnoses, risk factors, presenting complaints, past medical history, ART regimen, and outcome will be examined serially. Frequencies alone of patient visits, presenting complaints, drug regimens, etc. will be analyzed at least on a monthly basis in order to adequately characterize our patient population and predict future needs. At least once every quarter year more rigorous statistical analyses will be performed to assess trends, clarify significant differences between patient subpopulations, and scrutinize patient outcomes. D'Agostino's K-squared test and Pearson's chi-square test will be utilized to determine the normality of various parameters' distributions. Differences between continuous parameters of Gaussian distribution will be detected by the Student's T-test, Fisher's analysis of variance, and the Wilcoxon signed rank test; differences between categorical variables will be analyzed by the Pearson's chi-square test; correlations including trends over time will be analyzed by Spearman rank correlation, Pearson correlation, least-squares fit, and multivariable linear regression analysis; assuming the continuity of this project in the long-term, Kaplan-Meier estimates can be used to compare mortality in specific subpopulations. When found to be relevant and significant, all models will be adjusted for age, gender and other parameters."*

Ethical Assurance for Protection of Human Rights:

This section needs rewriting. The investigator should mention the possible risk of the participant and then describe what precautions are taken to safeguard the participant. A risk benefit assessment should be described.

Considering the stigma associated with HIV / AIDS in Bangladesh it might be necessary to think about non name based surveillance. Fingerprint based biometric identifications system reliable, easy to use and vet}' cheap now a day and may only cost a few thousand US $. I strongly recommend that the investigators should adopt those systems instead of name and address for identification of the patients.

PI: *The following paragraph has been revised to address the reviewer's concerns: "The HIV surveillance project is essential for the delivery of high quality healthcare to our patients, and it would be unwise to establish this HIV ward without some form of surveillance monitoring. The surveillance project will establish a system of quality control in clinical care on our ward that should be universal, and will characterize problems that have never been described in this country, yet need to be illuminated for future planning purposes. The informed consent protects the right of patients to participate, not participate, or withdraw participation in the project. All risks and benefits are described clearly in the*

informed consent, and patients have the option to opt out of the project with no adverse effects on their standard of care. The patients will have no additional medical risks from participating in this project, since no interventions are involved; the study itself is comprised of data collection exclusively, not any interventions. Additionally, we will collect patient data in a manner that ensures confidentiality. The data collection poses no greater risk to the patient than they would face from standard hospital record-keeping. Access to personal patient data will be limited, and original questionnaires will be kept locked as per international standards. Information on confidentiality safeguards is outlined in the informed consent, and patients who are uncomfortable with these measures may opt out of participation. The patients themselves will receive no immediate benefit from study participation, and have no incentives to persuade them into enrolling in a study in which they might otherwise not agree to enroll. However, their participation will benefit future patients by improving patient care and assisting in future planning. Patients can withdraw from this surveillance and will still receive the same care and treatments as before." As described previously in the background section, name-based HIV surveillance systems have been proven to capture superior data quality in at least 7 different published studies; conversely, no studies have proven name-based systems to suffer from more frequent confidentiality breaches. We intend to safeguard confidentiality as rigorously as other international institutions, and have no reason to believe that cultural norms are different in Bangladesh in such a way that would result in our staff behaving less professionally with confidential information than the rest of the world. Given the burden of proof demonstrating the superiority and non-inferiority of a name-based system, we see no reason to resort to a non-name-based system or fingerprint-based system.

Dissemination and Use of Findings:

Data generated by the surveillance system will be very important for future planning and this is probably the only data source of this kind in the country. I would recommend that the investigators should mention internal and external dissemination, publication, report and source data for planning etc.

PI: *We agree with the reviewer that the information generated by this project will be invaluable to both the center and the country. To our knowledge, we also are not aware of any similar data source in the country. To address the reviewer's comment, the following sentences have been added, "We aim to make quarter-yearly presentations on surveillance findings to all clinical staff of the hospital. Additionally, we will make our findings available to the Government of Bangladesh, all HIV-related NGOs in the country, and any interested donor organizations".*

Consent form:

The English and bangle consent forms are not the same. I could not find the translation of the sentence "We mayor may not contact you in the future to participate in future research studies" as mentioned in adult English consent form.

PI: *We strongly believe that a well-designed informed consent is the most crucial aspect to any clinical project, as it is the primary tool for protecting patients' rights. As such, we took special care to translate the English consent to Bangla blindly, reverse translate the Bangla version back to English blindly, and made the necessary revisions. We appreciate the external reviewer's concern over the informed consent.*

The sentence mentioned by the external reviewer was already present in the adult Bangla consent form. After reviewing all the consent forms again, we could find no other examples of the English and Bangla

consent forms being different. However, we have modified the translation of the sentence cited by the reviewer in all three versions of the consent form to make it more clear. The new sentence reads, **"fwel¨‡Zi bZb M‡elYvq AskMn‡Yi Rb¨ Avgiv Avcbvi m‡½ cieZ‡Z †hvMv‡hvM Ki‡ZI cwi A_ev bvI Ki‡Z cwi|"**

Budget:

It is not clear from the budget how the project will be operated. There is no budget for data base development, interviewer, data transcription personnel and data editing. It is not clear who will conduct the interview and there is no budget for interviewer or person who will transcribe the data from patient file. It might be necessary to revisit the budget and accommodate those expenses.

PI: *Please see the "Budget Justification" section (p. 21) for an explanation of how the project will be operated. Much of the database infrastructure required for this project already exists within the diarrhea surveillance project. As mentioned in the "Budget Justification" section (p. 21), ASG Faruque will be responsible for incorporating HIV ward's surveillance project into the preexisting diarrhea surveillance, including database development, data transcription and data editing. He will supervise a data analyst's performance of all these duties and has stated that only 1 data analyst will need his salary covered under our budget. As stated on p. 10, counselors, nurses and doctors will conduct the interviews, which capture all the data these healthcare workers would normally collect for any hospital admission; therefore they do not require additional salary allocations. As mentioned on p. 21, Brian Cobb, the senior physician on the HIV ward, will supervise data collection.*

APPENDIX 5: External Review and Response #2

Title: Inpatient HIV surveillance project for the ICDDR,B HIV Ward

Summary of Referee's Opinions: Please see the following table to evaluate the various aspects of the proposal by checking the appropriate boxes. Your detailed comments are sought on a separate, attached page.

	Rank Score		
	High	Medium	Low
Quality of project	X		
Adequacy of project design	X		
Suitability of methodology	X		
Feasibility within time period	X		
Appropriateness of budget	X		
Potential value of field of knowledge	X		

CONCLUSIONS

I support the application:

a) without qualification X ☐

b) with qualification

- on technical grounds ☐
- on level of financial support ☐

I do not support the application ☐

Name of Referee:
Signature: Date:
Position:
Institution:
Address:

Detailed Comments

Please briefly provide your opinions of this proposal, giving special attention to the originality and feasibility of the project, its potential for providing new knowledge and the justification of financial support sought; include suggestions for modifications (scientific or financial) where you feel they are justified. (Use additional pages if necessary)

Title: Inpatient HIV surveillance project for the ICDDR,B HIV Ward

Reviewer:

The proposal is not a research project, but rather a surveillance project for all HIV positive inpatients admitted to J-Ward at ICDDR'B. For a specialized ward like J-ward it is mandatory to have such a system. It should meet 2 goals:
1. Monitoring of performance of the ward
2. Analyze data of the patients retrospectively (as described in the proposal)

Comments:

Ad 1.) Monitoring of the J-Ward is important to assess and continuously improve its performance in terms of quality and efficacy. If there is no parallel system of monitoring (within ICDDR'B), I think it could be useful to integrate it into above proposal and collect not only data of patients who sign the informed consent, but data of all HIV positive patients who are admitted.

PI: *We agree with the reviewer and believe that a system of oversight such as a surveillance system can be useful for improving healthcare services. As mentioned in the "Specific Aims" section (p. 8), one of the goals of this project is to establish a structure for analyzing the quality of healthcare delivered to the patients on the HIV ward. The decision to seek informed consent from participants was made after consultation with the Clinical Sciences Division Director. Given the sensitivity of the data and the precedent established by the diarrhea surveillance project, it was decided that written informed consent should be obtained from all patients' whose data would examined.*

Ad 2.) The proposal is a kind of "ICDDR'B-Cohort-Study of HIV". If Bangladesh wants to understand the actual state and future dynamics of its HIV epidemic, it needs to have a kind of "Bangladesh-Cohort-Study of HIV".
This means, that data collection (as mentioned in the proposal) should be done not only at J-Ward, but in all institutions which provide outpatient treatment for PLHIV in Bangladesh.
I think, the ICDDR'B would have the expertise and capacity to expand this kind of "internal surveillance system" into a National Cohort Study.

PI: *A national cohort study examining all HIV-positive patients followed by NGOs would be a worthy undertaking. Since ICDDR,B is a major national referral center for HIV-related*

complications, receiving referrals from all the NGOs in the country and all corners of the country, our center will be an ideal starting-point for examining HIV-related morbidities. Once a system that generates high-quality data and maintains confidentiality is established at our center, we can look to collaborate with other NGOs and the Government of Bangladesh and expand this project to a national scale.