

IDI Use Only; Please Do Not Write Here:

Date Received \_\_\_\_\_ Summary Score \_\_\_\_\_ Date Approved by SRC \_\_\_\_\_ Date Returned by SRC for Revisions \_\_\_\_\_

Date Forwarded to Ethics Committee \_\_\_\_\_ Date Approved by Ethics Committee \_\_\_\_\_

Date of Final Implementation Agreement with IDI \_\_\_\_\_

## INFECTIOUS DISEASES INSTITUTE Research Project Proposal Form

### Section A: Project Cover Sheet

Research Project Title: \_\_\_\_\_

IDI Research Number: \_\_\_\_\_

Project Abstract (200 words or less):

#### *Approvals (for official use only)*

<i>Requirement</i>	<i>Date</i>	<i>Verification Signature (or attach a confirmation letter)</i>
Implementation Plan and Budget agreed with Head of Operations and Finance		
Scientific Review Committee Approval		
Ethics Committee Approval		
Materials Transfer Agreement Finalized (if applicable)		
UNCST Research Permit Secured (if applicable)		
Necessary Funding Secured		
Funding agreement finalized with Head of Operations and Finance (if applicable)		

#### **Resubmission History**

<i>Submitted to:</i>	<i>Date:</i>	<i>Version #:</i>

## Section B: Project Description

*(Please insert the following information into this form; the complete set of responses to Section B should not exceed 5 pages)*

### Investigators (Principal Investigators first)

*Please list all investigators and collaborators (Note: The PI should be a fully credentialed professional and if still in training, work under the authority of the one. A Uganda-based co-PI is required)*

Name	Institution	PI/Co-PI/Co-Investigator

Please indicate the name and contact information of the person who will present the proposal at the Scientific Review Committee.

### Hypothesis and/or Specific Aims

### Background

**Preliminary or Supportive Data (if any)**

**Research Methods** *State the overall design of the study (i.e. observational study, clinical trial, case control, prospective cohort, randomized control trial, etc.); for questionnaires, state how they will be administered; for clinical trials state treatment, duration, who will be administering drugs, commonly occurring side effects and plans for addressing problems that arise.*

**Justification for proposed study size** *(please consult with a bio-statistician if you are not familiar with how to do these computations)*

**Studies involving human subjects:**

- 1) How and where will the study subjects (cases, controls, etc.) be selected? Has it been confirmed that they are not already involved in other studies?

- 2) What inclusion/exclusion criteria will be applied?

- 3) What samples (blood, urine, cells, DNA, etc.), if any, will be taken and what investigations will be conducted? Please justify volumes to be taken.

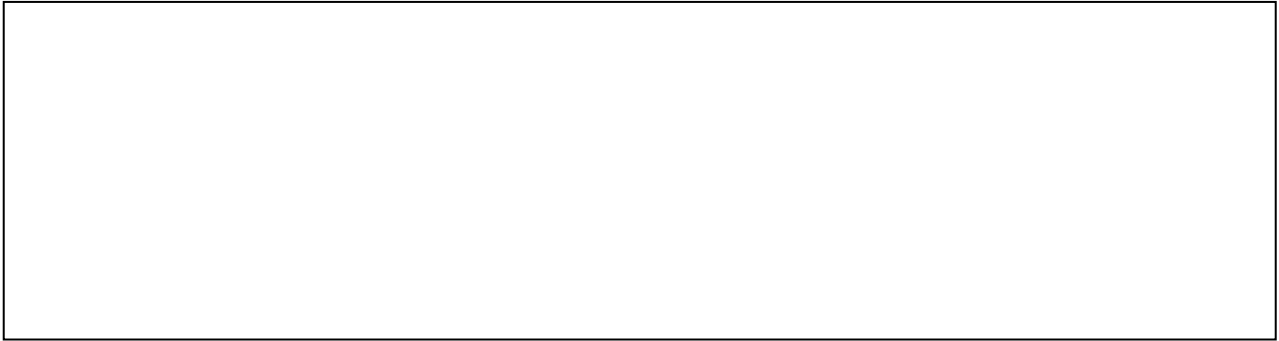
#### Expected Outputs and Dissemination of Results

- 1) What are the expected outputs (publications) from this project?

- 2) What other arrangements will there be to disseminate the findings?

#### Capacity Building: How will this project build capacity at IDI and/or Makerere University?

## References

A large, empty rectangular box with a thin black border, occupying the upper half of the page. It is intended for the user to enter a list of references.

## Section C: Methodology and Physical Inputs

Location(s) of Research

1	
2	
3	
4	

Proposed Start Date and Duration \_\_\_\_\_

Important Dates:

Date	Why Important?

Please give a brief overview of how the project will be staffed.

Please give a brief overview of key facilities and equipment requirements for this study.

Please give a brief overview of data management requirements; please indicate who will be responsible for data management activities.

Please outline the most important steps in the implementation of this project:

<i>Activity</i>	<i>Person Responsible</i>	<i>Target Date of Completion</i>

## Section D: Ethical issues

*In addition to reviewing the answers to these questions, the committee will evaluate the consent form and patient information sheets to ensure that they are simple enough to be understood by study participants. Please indicate on your consent form/patient information sheet which language(s) they will be translated into and whether they will be cross-translated to check for accuracy.*

Please outline how the study will contribute to improving the health of people in Uganda.

Summarize the potential risks and benefits to individuals and communities.

How will informed consent be obtained?

How will confidentiality of the data gathered be ensured?

Please attach your consent form, subject information sheet, and questionnaire (if applicable). If you are unable to attach any of these please use the box below to explain why not.

**Section E: Budget** *This section will be filled out during your initial meeting with the Head of Operations and Finance. Please add as many rows as necessary to give a comprehensive picture of the study budget.*

<b>Item</b>	<b>Unit Cost</b>	<b>Multiplied by</b> (# of days, # of people, quantity required, etc.)	<b>Multiplied by</b> (# of days, # of people, quantity required, etc.)	<b>Overall Cost</b>	<b>Notes</b>
<i>Contracted project staff</i>					<i>Indicate position title, rate, effort, duration, and overall cost</i>
<i>IDI Staff</i>					<i>Indicate position title, rate, effort, duration, and overall cost</i>
<i>Office, lab, clinical space</i>					<i>Indicate location, rate, duration, and overall cost</i>
<i>Research costs</i>					<i>Indicate individual costs for drugs, lab tests, and supplies</i>
<i>IDI equipment</i>					<i>Indicate all clinical equipment, CIT and laboratory equipment; calculate costs based on level of use</i>
<i>Administrative supplies, communications, transport</i>					<i>Indicate general categories of costs (i.e. photocopies, phone calls, etc.)</i>
<i>Travel and conferences</i>					<i>Indicate descriptions of meetings/conferences, cost per participant, frequency, and overall cost per</i>

					<i>meeting/conference</i>
<i>Capital procurement</i>					<i>Indicate major and minor equipment, and note who will procure equipment</i>
<i>Field expenses</i>					<i>Indicate all field activities including participant recruitment, home visits, etc.</i>
<b>Total Budget:</b>					

**Plans for Funding Study:**

<b>Grantor</b>	<b>Amount Requested</b>	<b>Amount Committed</b>	<b>Amount Received</b>

## Section F: Declarations

**Confidentiality:** *Applications will normally be made accessible to all IDI senior staff. If for reasons of commercial, ethical or scientific sensitivity you wish to restrict access/circulation to Scientific Review Committee members, please indicate here.*

Restrict access to Scientific Review Committee members? Yes  No

Please sign the following statements:

*The principal investigator undertakes to leave with the Data Management team at the IDI, a complete copy of the data set at the following two time points:*

1. *After data entry and verification (raw data sets)*
2. *At the point of submission for publication of final report (analysis data sets)*

Signature of Principal Investigator .....

*The principal investigator undertakes to leave with the IDI appropriate aliquots of the biological material being taken out of the country as applicable.*

Signature of Principal Investigator .....

*The principal investigator undertakes to leave with the IDI all equipment procured for the purpose of this project.*

Signature of Principal Investigator .....

Please verify that projects taking place at the IDI facility have been discussed with the following staff members as appropriate.

<i>Staff Member Consulted</i>	<i>Situations in which consultation is necessary</i>	<i>Date Discussed</i>	<i>Comments or Concerns; if fully endorsed, please indicate</i>
<i>Head of Clinical Services, Dr. Andrew Kambu; 031-307237 <a href="mailto:akambu@idi.co.ug">akambu@idi.co.ug</a></i>	<i>Projects taking place in the IDI clinic</i>		
<i>Head of Lab (Ali Elbireer; 041-307260; <a href="mailto:aelbireer@idi.co.ug">aelbireer@idi.co.ug</a>)</i>	<i>Projects utilizing MU-JHU laboratory facilities and/or storage space</i>		
<i>Head of Research (Yuka Manabe); 031-307227; <a href="mailto:peasterbrook@idi.co.ug">peasterbrook@idi.co.ug</a> )</i>	<i>All projects</i>		

<i>Head of Finance and Operations (Art Mooney; 031-307232; <a href="mailto:amooney@idi.co.ug">amooney@idi.co.ug</a>)</i>	<i>All projects; this consultation will cover use of IDI staff.</i>		
<i>Head, Information Services Peter Okwi; 031-307225 <a href="mailto:pokwi@idi.co.ug">pokwi@idi.co.ug</a></i>	<i>All projects; will handle data management capacities</i>		
<i>IDI Cohort Coordinator (Barbara Castelnuovo); 0312-307226; <a href="mailto:bcastelnuovo@idi.co.ug">bcastelnuovo@idi.co.ug</a></i>	<i>All projects; will handle data sharing policy</i>		
<i>Clinical Trials Coordinator (Gavin Robertson); 0312 – 307226; <a href="mailto:grobertson@idi.co.ug">grobertson@idi.co.ug</a></i>	<i>GCP compliance</i>		

### Status of Relevant Approvals from Other Participating Institutions

Participating Institution	Role (e.g. site, funding source, etc.)	Institutional Approval Status		
		Approved	Pending	Other (explain)

*I declare that all information contained in this form is correct to the best of my knowledge.*

Signature of principal investigator:

Date:

---

## IDI Research Project Score Sheet

Project Name: \_\_\_\_\_

Project Number: \_\_\_\_\_

Please rate the following:

<i>Area</i>	<i>Score (worst) 0 – (best) 5</i>
Scientific Aims (clear important scientific questions)	
Adherence with IDI Mission (i.e. advance the health of Ugandans and advance the careers of young investigators)	
Feasibility (can it be done with available resources in the available time)	
Resource Consumption/Provision (use of resources vs. giving equipment/materials/desired expertise)	
Does the study design answer the questions posed?	
Bonus (intangible benefits) <span style="float: right;"><i>(2 points only)</i></span>	
<b><i>Total Score</i></b>	

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

Do you have any ethical concerns?

Yes

No

If yes, please explain: