

INFECTIOUS DISEASES INSTITUTE – Research Approval Process (Committees)

COMMITTEE	RESPONSIBILITIES	REQUIREMENTS FROM RESEARCHER	OUTPUT	MEETING DATES
Infectious Diseases Institute Scientific Review Committee	<u>Reviews</u> <ul style="list-style-type: none"> • Scientific quality • Research feasibility • Research design • Operational procedures • Provisional ethical considerations 	<ul style="list-style-type: none"> • Project Proposal in IDI format, submitted 10 days before SRC meeting • Proposal presentation by the researcher suggested 	<ul style="list-style-type: none"> • IDI disposition letter 	<ul style="list-style-type: none"> • 2nd Friday of each month
National AIDS Research Committee (NARC)	<u>Reviews</u> <ul style="list-style-type: none"> • Ethical issues pertaining to the research 	<ul style="list-style-type: none"> • IDI approval letter • Letter from Study PI indicating issues raised by the SRC and how they were addressed • Consent form with the luganda translation • Full research proposal (10 copies) with IDI approval stamp, signed and submitted by the PI 2 weeks before the NARC meeting • Proposal presentation by the researcher (if proposal is being reviewed for the 1st time and at NARC's invitation) • NARC processing fees (\$300) 	<ul style="list-style-type: none"> • NARC approval letter 	<ul style="list-style-type: none"> • Last Thursday of each month
Uganda National Council for Science and Technology (UNCST)	<ul style="list-style-type: none"> • Issuance of research clearance 	<ul style="list-style-type: none"> • IDI approval letter • NARC approval letter • 2 copies of the approved research proposal • UNCST research approval forms (UNCST/RC 1 & R6) • 4 passport photographs from investigators • Other relevant Institutional and ethical approvals (for research collaborations) • Research administration and clearance fee (\$300) 	<ul style="list-style-type: none"> • Approval/clearance letter • Research identity card • Introductory letter to the Resident District Commissioner 	Every week

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National Drug Authority (NDA)	<ul style="list-style-type: none"> • Authorization for import and/or use of new investigational drugs/products---i.e. if study involves administration of INDs 	<ul style="list-style-type: none"> • UNCST approval • NDA forms (obtained from NDA) • Approved protocol • \$300 application fee 	<ul style="list-style-type: none"> • Authorization Certificate 	Every week

N.B:

- Principal Investigators conducting research in Uganda for the first time are required to present their bio sketches
- Research approvals are only valid for one year and researchers are required to submit progress reports to the different committees before approval can be renewed.
- A letter of renewal from the NARC is required by the UNCST before issuance of their renewal approval.
- The research administration and clearance fee is paid once for the UNCST and annually for the NARC.
- Researchers whose studies necessitate transfer of samples outside the country need a materials transfer agreement signed between the supplier and recipient institutions, and issued by the Uganda National Council for Science and Technology. UNCST requires a copy of the cover letter from the supplying institution and/or investigator before issuing clearance for the transfer.
- If a researcher intends to store patient samples for future testing, not specified in the consent form, they are encouraged to have a separate sample storage consent form.
- Investigators are responsible for providing copies of yearly ethical approvals to the IDI and to ensure validated consent forms
- It is the duty of the investigators to follow up on the acquisition of each of the approvals above.