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Researchers

Research trips/experience will be < 90 days duration:

If you are coming to conduct collaborative research at KCMC, but will be staying < 90 days (including recurrent or frequent trips, all of which will be < 90 days in duration), please SKIP to **COSTECH research permit** requirements and **Business Visa**.

Research trips/experience will be >= 90 days consecutively:

such as students or fellows coming for an entire academic year or for a 2-year research fellowship.

As outlined in the Figures below, a considerable amount of lead time is needed to process all the required permits and licenses. Please allow at least 6 months prior for processing all the paperwork for all these requirements. **Ideally you should start 9 months prior to your arrival date or as soon as you know you will be coming to work on-site at KCMC for a period that extends beyond 90 consecutive days. arrival to start this process.**

We recognize that these application processes are A LOT to tackle; but please also remember that if you were a foreigner coming to provide clinical care and conduct research in the United States, you would face a similar amount of requirements.

Before traveling to Tanzania

Ensure you have:

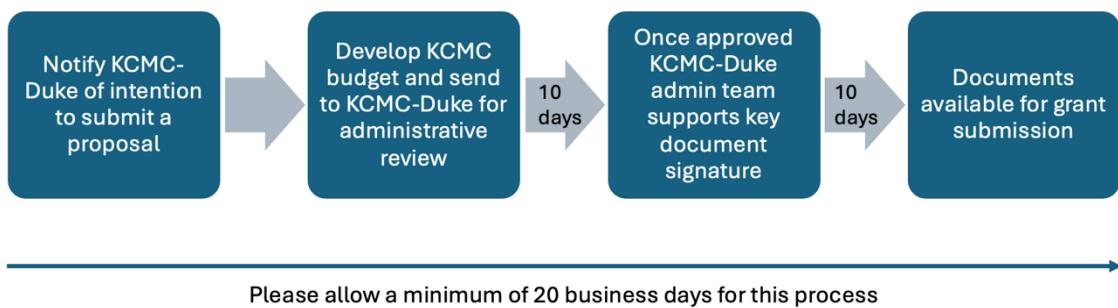
- 1) at least 6 months remaining on your passport from your final travel date before it expires.
- 2) at least 2-3 blank pages in your passport for VISA stamps.
- 3) VISA arrangements (either in advance or upon arrival)
 - Visa's may be obtained in advance
 - <https://visa.immigration.go.tz/guidelines>
 - Note without a Residency permit, your time in country is likely to be limited to 3 months at a time

If you are a non-US citizen please make sure to check the visa requirements for your country of citizenship

Building a research budget

Project budget/research budget

This is a budget that is prepared and submitted to the KCMC-Duke collaboration at least 20 business days prior to the institution's administrative deadline for the KCMC subcontract packet & signed Face Page. The project budget/research budget should cover the costs of all specific research activities.



Grant Budget development process

- Research idea is developed by the PIs/research team in collaboration with Tanzanian colleagues to confirm need and local buy in of the research.
- PI or designated member of the research team should alert the KCMC-Duke Collaboration administrative team (kcmc-duke-collaboration@duke.edu) of their intention to submit a proposal at least 20 business days in advance of the institution's administrative deadline or grant due date (whichever is sooner).
- The KCMC administration team should be provided at least 20 business days to review the proposed budget to provide input and to request signature on the institutional face page. **An administrative review of the budget details and justification is a requirement prior to processing a face page or institutional letter of support.**
- After the review is complete and the final budget is agreed between the PIs/research team and the KCMC-Duke financial administration, the KCMC-Duke administrative team will support the research team in submitting documents requiring institutional signatures (face page, institutional letter of support, etc.).
- The KCMC admin team will aim to provide all signed documents by the stipulated Duke Office of Research Administration deadline (typically 3 weeks prior to the funder's submission deadline). It should be noted that signature execution is dependent upon KCMC leadership travel and vacation days. Any anticipated delays will be communicated in advance to support efficient grant preparation

and submission. Submitting your budget 20 business days (i.e., approximately 4 weeks) prior to the Duke ORA deadline helps absorb any such unanticipated delays in finalizing the KCMC sub-contract.

It is the responsibility of principal investigators/budget developers to send the proposed budget to the KCMC-Duke collaboration finance administration team in compliance with the above timeline.

The structure of the budget depends on the donor/funder's guidelines and project activities. Budget templates and previous successful examples can be made available to you; and the Administrative Team can help link the PIs/Research Team to resources (e.g., Lab personnel to provide lab costings; trusted local vendors for supplies); salary benchmarks (see Appendix 1), etc.

Most project budgets contains the following categories:

1. Personnel/salary support including fringe benefits (at KCMC this includes PayE tax, Workers compensation,) at a level of 13.5% and inflation at a rate of 1.5% each year*
 - a. Research coordination and assistance
 - b. Consultants
 - c. Data management
 - d. KCMC-Duke administrative support: This includes four components of 1) financial accounting; 2) human resources to support hiring, navigating any personnel challenges, compliance; 3) regulatory support in ethical submissions
2. Supplies:
Note, for research projects in Tanzania to be successful, there are some supplies that will need to be purchased as direct costs to the project; these supplies would often be considered "indirect costs" at US institutions. Or in the case of laboratory tests, they would be budgeted under "Patient Care Costs." Typically, as long as these are specified in the grant submission budget and are accompanied by reasonable justifications, these other direct costs will be allowed.
 - a. Printing & clerical supplies: examples include file folders, file cabinets and box files for storing study forms; logbooks, pens, clipboards; printing labels
 - b. Clinical supplies: examples can include, as applicable to your project, swabs, needles, syringes, alcohol cleanser, hand sanitizer, gloves and other personal protective equipment, sharps containers, scales and height boards, automated blood pressure machines, pulse oximeters, thermometers
 - c. Laboratory supplies: these can be listed as a cost-per-test that you plan to perform or you can list the actual reagent supplies that the project will purchase. We suggest you liaise with the laboratory for specific needs (psakasaka@yahoo.com)
3. Equipment

4. Travel costs
5. Publication costs (if KCMC is the prime institution)
6. Ethics submission fees (see current fees in Appendix II)
7. Other costs:
 - a. Transportation of staff or study samples
 - b. Transportation reimbursement for study participants
 - c. Participant remuneration: can be cash transfer or phone voucher or similar
 - d. Document translation fees (for consent forms and other patient-facing study materials)
 - e. Shipments
 - f. Stakeholder meetings / Launch / Closeout/Dissemination Meetings
 - g. Facility fees for enrollment sites/clinics
 - h. Tables and chairs for placement at study enrollment site
 - i. Phone vouchers for study staff communications
 - j. Specimen archiving fees
 - k. Laboratory access and utilization fees
8. Overhead/indirect costs (NIH is capped at 8%; other foundations have varying rates)

Important items to consider in every budget

Suggested personnel salaries

The KCMC-Duke Collaboration embarked on a salary benchmarking exercise to ensure that salaries are equitable and fair market based on other similar research entities across the country. A suggested (not required) salary range depends on degree, experience, funding available within the project, and duration of the project. This information is included in Appendix I of this document. Further questions can be directed to the KCMC-Duke Collaboration administration (kcmc-duke-collaboration@duke.edu).

1. Administration support

During budget preparation, it is very important to consider the grant administration support for the team who will execute the grant on the ground at KCMC-Duke collaboration offices; the support will be extended to the HR, regulatory office, and finance team, so it is very important for the PIs/research team to allocate this important effort in their budget. We suggest approximately 5% effort for each of these three roles depending on the needs and capabilities of the project.

Suggested language to support these line items for your justification is as follows:

- Financial Officer/Accountant: This person will manage payroll, financial compliance and procurements.
- Human resources administrator: This person will ensure compliance with federal grants regulations, will provide human resource management for hiring

procedures, contract renewals or termination, and support administrative, financial and procurement logistics.

- Regulatory Officer will advise and support institutional and national ethics board submissions and district/regional approvals for research. These tasks include, among others, research protocol submission to the KCMC University Research Ethics Committee and the National Health Research Ethics Committee at the National Institute for Medical Research. This person will coordinate with the investigator team to respond to ethics review comments, follow-up on approval status, and submit protocol renewals, progress reports, and protocol amendments.

Data Manager will be responsible for oversight of data entry, data cleaning, data reports, and assist with maintenance of technology systems that support data collection and management (e.g., servers, computers, tablets, software).

2. Fringe benefits*

The PI/research team should communicate with the KCMC-Duke collaboration administration team during development of the grant budget so as to confirm the fringe percentage to include in the personnel budget; the current rate to include in the personnel basic salary is 13.5%, but this is subject to change dependent on changes in Tanzanian law. Similarly, inflation rates are subject to change. Currently we recommend 1.5% per year.

3. Overhead/indirect costs

This is another important area that should be included in the budget. The current rate for NIH indirects is 8% of the budget direct costs. Please note, this amount will be paid directly to KCMC to be used for expenses like water, electricity, security, office space, etc. These funds do not stay within the KCMC-Duke collaboration. Common costs incurred in Duke indirects (example purchase of computer, printing, internet, phone calls, should be budgeted as an independent direct costs for international sub awards).

Time framework for budget document review and signatures

As described in Figure 1, after budget development, it is critically important for the PI/research team to share the budget and justification to the KCMC-Duke administrative team within 20 business days prior to the institution's administrative deadline for the KCMC sub-contract packet & signed Face Page. This allows time for the KCMC-Duke administration to provide their inputs and/or approval to help you have a successful project. **This step is required prior to the KCMC-Duke admin team obtaining signatures for documents like the face page, letters of support, advance form, etc.**

Grant awarded/not awarded feedback

It is also very important for the KCMC-Duke administrative team to receive feedback on whether the grant was submitted, date of review, and outcome, whether awarded or not awarded and if a resubmission is planned. Please provide these updates throughout the life cycle of your grant submission so that the team at KCMC-Duke Collaboration is aware and well-positioned to provide the support you need (e.g., Just-In-Time paperwork, resubmission sub-contracts, etc.). Please note that the same timeline provided throughout this document applies to grant re-submissions: even if the budget may not have changed from the PIs/research team's standpoint, the administrative team may need to incorporate changes in HR policy or fringe rate, etc. and these necessary updates could have budgetary implications for your grant proposal.

APPENDIX I

Job Data and Market Range by Quartile (NGOs)

Job Code	Job Title	Qualification	Experience		Low	25th Percentile	50 th	75th Percentile	High	Employers Matching
KD101	Project Accountant	Bachelor Degree + CPA or ACCA /Masters Degree	5+		1,843.00	2,243.00	2,689.23	3,485.48	3,957.28	7
KD102	Project Administrator	Bachelor Degree/Masters Degree	4+		1,284.12	1,523.54	1,998.06	2,645.87	3,123.38	7
KD103	Social Welfare Officer	Bachelor Degree/Masters Degree	4+		1,233.48	1,508.07	1,802.34	2,597.38	3,005.26	7
KD104	Laboratory Supervisor	Bachelor Degree/Masters Degree	3+		1,878.95	2,031.01	2,565.13	2,986.50	3,601.78	4
KD105	Regulatory Officer	Bachelor Degree/Masters Degree	4+		1,134.56	1,398.47	1,695.42	1,967.56	2,656.50	4
KD106	Data Manager	Bachelor Degree/Masters Degree	4+		1,122.40	1,499.76	1,931.88	2,492.43	2,954.67	7
KD107	Study Coordinator	Bachelor /Masters Degree/Medical Degree	4+		1,367.54	1,746.97	2,275.23	2,694.58	3,208.63	7
KD108	Laboratory Technologist	Diploma/Bachelor/ Masters Degree	4+		914.21	1,374.5	1,698.43	2,072.45	2,797.05	4
KD109	Pharmacist	Masters Degree/Bachelor Degree	3+		898.26	1,222.11	1,697.65	1,945.97	2,269.82	4

Job Data and Market Range by Quartile(NGOs)

Job Code	Job Title	Qualification	Experience		Low	25th Percentile	50 th	75th Percentile	High	Employers Matching
KD110	Clinical Officer	Diploma/Bachelor/ Masters Degree	3+		589.32	789.55	997.35	1,123.16	1,350.13	7
KD111	Data Entry Clerk	Diploma/Bachelor Degree	2+		245.12	392.50	579.91	765.24	990.55	7
KD112	Research Assistant	Diploma/Bachelor Degree/Masters Degree	3+		520.45	745.71	1,010.46	1,327.72	1,857.23	7
KD113	Clerical Assistant	Bachelor Degree/Masters Degree	3+		403.23	699.54	950.72	1,356.93	1,540.37	4
KD114	Project Driver	Certificate/Diploma	4+		200.45	398.92	520.42	670.38	945.13	7
KD115	Histotechnologist	Bachelor Degree/Masters Degree	3+		648.09	949.32	1,442.40	1,962.67	2,376.52	4
KD116	Field Workers	Diploma/Bachelor Degree	2+		427.65	610.53	898.27	1,165.81	1,390.72	7

Appendix II: Ethics fees

KCMC

Table 1: CRERC fees

S/No.	Category	Locally funded research	Internationally funded research	Tanzanian students	International students
1.	Ordinary health research	300 USD	500USD	Masters 50 USD PhD 300 USD	Masters 300 USD PhD500 USD
2.	Clinical trial	500 USD	700 USD	Masters 50 USD PhD 300 USD	700 USD
4	Renewal of ethical approval	N/A	100 USD	100 USD	100 USD
5	Expedited review	400 USD	600 USD	N/A	Masters 400 USD PhD 600 USD
6	Expedited review clinical trial	600 USD	1000 USD	N/A	

NIMR



UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH



NATIONAL INSTITUTE FOR MEDICAL RESEARCH

PAYMENT FOR ETHICAL CLEARANCE FEES

NatHREC Payment Rates from 1st January 2025

Payment Category	Tanzanian Collaborators (TZS)	Tanzanian Students (TZS)	International Collaborators (USD)	International Students (USD)
Ordinary Proposal (Expedited Review)	1,375,000	312,500	1,375	438
Clinical Trial Proposal (Expedited Review)	3,875,000	390,625	5,125	548
Ordinary Proposal (Ordinary Review)	500,000	312,500	750	438
Clinical Trial Proposal (Ordinary Review)	2,625,000	390,625	2,625	548
Ordinary Proposal (Amendment)	300,000	250,000	450	375
Clinical Trial Proposal (Amendment)	750,000	250,000	750	375
Ordinary Proposal (Extension)	150,000	125,000	150	125
Clinical Trial Proposal (Extension)	300,000	125,000	300	125
Ordinary Proposal (Appeal fee)	150,000	150,000	100	75
Clinical Trial Proposal (Appeal fee)	300,000	150,000	150	75
* Penalties (Late Renewal)	100,000	50,000	100	50

Note: * The penalty cost will be imposed for each month that the PI fails to renew the protocol.

Required Permits

Overview

The following document applies to researchers from Duke University (Faculty, Fellows/Research Associates, Residents, or Students) who will be conducting collaborative research with KCMC.

Your main contacts for navigating this process is

- 1) The KCMC-Duke Collaboration Welfare Officer, Gwamaka William Nselela (gwamakawilliam14@gmail.com / +255 713 883 058)
- 2) Your Duke faculty mentor or champion
- 3) Your KCMC co-investigator/collaborator

RESIDENCE PERMIT

To stay in Tanzania beyond 90 days, you need a **Residence Permit**. (Note: entering on a Business Visa then leaving at Day 89 and re-entering on a new Business Visa is generally not allowable or appropriate.)

All persons applying for a Residence Permit will need a certificate from the Tanzanian Commission for Universities (TCU). This **TCU Certificate** process validates/verifies your educational degrees, and it requires original transcripts from high school through your highest degree as well as original diplomas and passport to all be presented in-person by you or a representative designated by KCMC-Duke Collaboration.

There are generally two paths to obtain a Residence Permit:

A) Research Permit: as a Researcher via a COSTECH Permit

This is the most common option. It typically provides a 1-year approval to reside in Tanzania, and it requires 3 steps: TCU Certificate, COSTECH research permit, Residence Permit.

B) Work Permit: as Volunteer Doctor via a Work Permit

For researchers who are also medical doctors (MD / DO) who plan to care for patients while working at KCMC, entering as a Volunteer Doctor with KCMC and applying for a Work Permit is another option.

This option typically provides a 2-year approval to reside in Tanzania, but it requires 4 steps: TCU Certificate, Medical Council of Tanganyika Registration (i.e., Medical License), Work Permit, Residence Permit. COSTECH Research Permit still required for your research activities (5th Step).

Figure 1 below provides common scenarios for trainees coming to conduct/participate in collaborative research with KCMC. And the **Table** provides some timeline estimates and high-level requirements for these various steps.

Medical Students	Residents or Fellows (MD/DO) Not Doing Clinical Work (Research Only)	Post-Doctoral Research Fellows (Non-Clinicians, Research Only)	Residents or Fellows (MD/DO) Research AND Clinical Work
<ul style="list-style-type: none"> TCU Certificate COSTECH Research Permit Residence Permit & NIDA 	<ul style="list-style-type: none"> TCU Certificate COSTECH Research Permit Residence Permit & NIDA 	<ul style="list-style-type: none"> TCU Certificate COSTECH Research Permit Residence Permit & NIDA 	<ul style="list-style-type: none"> TCU Certificate COSTECH Research Permit Residence Permit & NIDA Medical License

Figure 1. Common scenarios regarding requirements for research and clinical experiences at KCMC

Table 1. Overview of costs, typical turn-around times (once submitted) and requirements for the various application processes required for obtaining a Residence Permit.

Process	Cost	Typical Turn-Around Time	Requirements
TCU Certificate	300,000 TZS	1-2 months	<ul style="list-style-type: none"> Online application After approval of online application, original versions of transcripts, diplomas and passport need to be presented in-person
COSTECH Research Permit	\$350 USD	3-4 months	<ul style="list-style-type: none"> Online application NIMR Ethics approval certificate
Medical Council of Tanganyika (MCT) Registration	\$500	1-2 months	<ul style="list-style-type: none"> Online application TCU certificate
Work Permit	\$500	1-2 months	<ul style="list-style-type: none"> Online application MCT Registration (i.e., Medical License) Volunteer doctor signed contract with KCMC
Residence Permit	\$550	1-2 months	<ul style="list-style-type: none"> Online application TCU Certificate [COSTECH Research Permit] OR [Work Permit]

Payment Process for Application Fees

Payment of the fees listed in the Table above can be made on your behalf by the KCMC-Duke Collaboration administrative team once a Control Number has been provided by the agency/entity. In this way, out-of-pocket expenses can be minimized. These payments can either be charged to a Duke “Fund Code” or, in special

circumstances, they can be charged to your project (i.e., KCMC-Duke Collaboration will make the payment up front and then your project will reimburse the Collaboration once research funds arrive.

Note that Residence Permit cost listed in the Table is for one person. If you are coming to Tanzania with dependents, there will be additional costs for them to be included on your Residence Permit (i.e., to obtain their “dependent’s pass”).

COSTECH Research Permit

Website: <https://www.costech.or.tz/>
Cost: \$350 USD

IMPORTANT NOTES

1) Method of Submission

Before initiating your COSTECH Research Permit application, it is best to confirm with the KCMC-Duke Collaboration Welfare Officer, Gwamaka Nselela (gwamakawilliam14@gmail.com), whether COSTECH applications are being submitted through the online portal versus being submitted via email. This can change year-on-year, month-on-month.

2) Existing examples

Your Duke faculty mentor/champion, KCMC collaborator/co-investigator, or Gwamaka should be able to provide you with successful examples. Do not re-invent the wheel.

3) Obtaining a Research Permit via an already approved protocol

If your research entails a *de novo* stand-alone IRB/ethics protocol (i.e., it is NOT an amendment to an already-approved study protocol), you will need to apply for a COSTECH for that study protocol once it has been approved by the National Institute for Medical Research (NIMR).

But since the NIMR ethics approval process can take 6-9 months and because many of the research trainees are often contributing to or working on existing projects in one way or another → trainees typically apply for a COSTECH research permit linked to the mentor's study protocol already approved by NIMR. In this way, a trainee does not have to wait until his/her research protocol has been approved by NIMR in order to move forward with a Residence Permit application.

Required Documents:

To be submitted through the online application portal or to be sent to rclerarance@costech.or.tz

- Please apply at least 3 months before arriving in the country.
- Bank copy of application fee \$350 for the new applicant and \$300 for renewal (cash deposited) Note: **do not pay until you get the control number.**
Contact Costech or Gwamaka
As noted in the Summary on Page 3, payment can be made on your behalf by the KCMC-Duke Collaboration Administrative Team.
- Completed application form (download from above link)
- Completed curriculum vitae form (download from above link)
- One passport size photo (Blue or white background – any of the two colors)
- A letter from local contact/collaborator (academic / research institute or host institution)
- **Comprehensive Research proposal** which should contain an **abstract, introduction; literature review; research problem; objectives; methodologies, research beneficiaries and bibliography.**

Note if a renewal this should be a progress report as opposed to the proposal

- Actual CV
- NIMR Ethical Clearance (NIMR Ethics approval certificate)
- Implementation Plan

During application, make sure you submit the following

✓ Full Research Proposal
✓ Ethical clearance/Supporting letter from Institution(PI Country)
✓ Funding covering letter
✓ Research ethical clearance/Letter of Approval from relevant institution(if applicable) (e.g. TAWIRI, NIMR, TAFORI, TAFIRI)
✓ Supporting letter from Local Collaborator(For foreigner)
✓ Other supporting documents

TANZANIA COMISSION FOR UNIVERSITIES (TCU) CERTIFICATE

Application link www.tcu.go.tz then go to **foreign award assessment system (FAAS)**.

Note that your passport and original diplomas may be required.

Are you in Tanzania and hold a Foreign Academic Award?

Follow these six simple steps to get your qualification recognized:

1. Go to <http://faas.tcu.go.tz/login.php> click and read "**Guidelines**"
2. Go to <http://faas.tcu.go.tz/login.php> and click "**Register New Account**"
3. Gather all hardcopies of documents** that are relevant to your application, Scan and save the hardcopies to obtain softcopies of the same
4. Pay the processing fee* by visiting the TCU website www.tcu.go.tz and click "**To pay for TCU services through Government Electronics Payment Gateway (GePG)**" and generate **Control number**. Visit any Branch or Bank agent of CRDB or BOT. Use provided **Payment Control Number** as the Account Number and the Account Name is **Tanzania Commission for Universities**.
5. Fill the online application forms and upload or attach the softcopies in relevant sections (Step 1-5)
6. Only click "**Declaration and Acceptance**" at step 5 when you are ready to submit your application

***What is the processing fee**

- i) A sum of TShs. 150,000/= for postgraduate qualifications (PhD,Master degree, Postgraduate Diploma, and Postgraduate Certificate) and TShs. 100,000/= for undergraduate qualifications(Bachelor degree,Diploma and Certificate), per qualification

****Which documents will I need:**

- ii. An official translation of the qualification into English (if applicable)
- iii. Certified photocopy of transcript/mark sheets/list of subjects passed in original language
- iv. An official translation of transcript/mark sheets/list of subjects passed into English (if applicable)
- v. Documentation in support of name change (if applicable), e.g. marriage certificate or deed poll
- vi. Parchment in relation to the undergraduate qualification (if applicable)
- vii. Certified photocopy of ordinary level secondary education certificate
- viii. Certified photocopy of advanced level secondary education certificate
- ix. Thesis/dissertation or Abstract and Declarartion Page (**For masters and PhD holders**)
- x. Certified copy of the Bachelor degree certificate in its original language (**For masters and PhD holders**)
- xi. Certified official translation of the Bachelor degree certificate into English (if applicable)-(**For masters and PhD holders**)
- xii. Certified copy of the Bachelor transcript in its original language (**For masters and PhD holders**)
- xiii. Certified official translation of the Bachelor transcript into English (if applicable)- (**For masters and PhD holders**)
- xiv. Certified copy of the Master degree certificate in its original language (**For PhD holders**)
- xv. Certified official translation of the Master degree certificate into English (if applicable)-(**For PhD holders**)
- xvi. Certified copy of the Master degree transcript in its original language –
- xvii. Certified official translation of the Master degree transcript into English (if applicable)-(**For PhD holders**)
- xviii. Certified copy of the Passport page containing your details
- xix. Certified copy of the Entry visa/stamp in the country where studies were undertaken (**For Tanzanian**) or Employment contract/Letter of Employment offer (**For Foreigners**)
- xx. Certified copy of the FAAS application fee payment slip

How do I get feedback?

Outcomes of evaluation are collected in person at TCU offices. Appointments for collecting the outcome of evaluation will be set and communicated to you through your user account within Fourteen working days (14) from the date your application was submitted into online system. During your appointment, you will be required to bring with you all original documents used to make an online application.

MEDICAL COUNCIL OF TANGANYIKA (MCT) REGISTRATION

Website: <http://www.mct.go.tz/>
Cost: \$500

IMPORTANT NOTES:

Existing Examples

As with any of these application processes, you should avail yourself of existing examples, especially for any required documents that you are uncertain about the correct content and formatting. Examples can be provided by your Faculty Mentor/Champion, KCMC Co-Investigator or Gwamaka William.

Soft Copies & Hard Copies

You will start with the online application and once you “SUBMIT” please save a pdf for future print the forms for hard copies so we can submit to the Medical Council.

Timing of Registration

People applying online, should register online before arrival, but note the license registration date starts the day you register online and not the day you receive the certificate. In other words, if you start a year in advance, your license could expire before you arrive! Please confirm with Gwamaka ideal timing as guidance may change.

Steps:

Please begin the registration process online by going to “REGISTER NOW” as a foreign practitioner

On website, SCROLL OVER Registration & Licensing drop down menu → then SELECT “Limited Registrations (Foreigners)”

Needed documents are;-

1. Certified copy of qualifying diploma/degree (MD/MB.BS/MB.,ChB/DDS/BDS: **(Certified)**)
2. Certificate of verification of diploma /degree by the Tanzania Commission for Universities.

Note: If you have Bachelor Degree, Masters Degree and PHD will have to pay **450,000/=**

Do not pay until you get the control Number from the system or contact Gwamaka.

Again, the KCMC-Duke Collaboration Administrative Team can make this payment on your behalf.

3. One passport size photograph.
4. Certificate of registration from the registering authority of the last jurisdiction of practice.
(Certified)
5. Original Certificate of Good Standing from the registering authority of the last jurisdiction
Of practice. (Only acceptable within six months from the date of issue).
6. Curriculum Vitae.
7. Certified copy of passport.
8. A non-refundable fee of US\$ 500/= (payable to Medical Council of Tanganyika, Tanzania)
Postal Bank (TPB) do not pay until you get the control number. Contact MCT or Gwamaka
As mentioned above, the KCMC-Duke Collaboration Administrative staff can make the payment on your behalf, charging your project/Duke Fund code for the expense.
9. Introductory /Covering letter from Host Institution/ Hospital in Tanzania.
10. Letter from Duke addressed to;
**Medical Council of Tanganyika,
P.O. Box 9083,
Dar es salaam,
Tanzania**

RESIDENCE PERMIT

Website: <https://eservices.immigration.go.tz/online/web/permit>
Cost: \$500, subject to change

REMINDER ABOUT BUSINESS VISA OPTION:

For researchers who will not be staying beyond 90 days any given research trip, you can obtain a Business Visa (see Page 3 above).

For the applicants staying more than three months, should apply online. Create your application account then fill your details. In **applying entity section** select **organization/institution**, registration no **10264**

Region – **Kilimanjaro**, District – **Moshi urban**, Area - **Longuo**, Street - **Longuo B**

Please see the application link below

<https://eservices.immigration.go.tz>

You will have to upload the following documents

- 1 passport size photos please send either white background (1) Or Blue background (1)
- Certificate of verification of diploma /degree by the Tanzania Commission for Universities
- 2 filled Resident Permit data sheets. **Please print and send the forms to me for the signature and stamp then I will scan the form to you for submission**
- 3 filled TIF 1 forms for resident permit Class C (last form in the bullets list). **Please print and send the form to me for the signature and stamp then i will scan the form to you for submission**
- Work testimonials/letter(s) of reference from Duke/Sent University addressed to; For the new applicant only, Not renewal
**The Executive Director,
Kilimanjaro Christian Medical Centre,
P.O.Box 3010,
Moshi,
Tanzania.**
- Copies of all relevant academic certificates, diplomas, degrees (refer on your CV)
- Copies of passport pages showing validity, nationality and all of your status
- Volunteer contract with KCMC (For those who are not doing research. This is made after we have opened you a personal file at KCMC, Gwamaka will have you sign in person or via email before it is signed by KCMC Executive Director). It doesn't apply to students. Not for researchers

- In addition you will need at least one of the below or both (This is not applicable for students please see a short summary at the bottom)
 - Temporary Medical certificate from the Tanganyika Medical Council (if you will deal with patients). This is the certificate you get from your application of Medical licence—see A
 - Costech permit (All the researchers). It is the certificate you get from COSTECH—see B
 - Work permit for those not doing research of which he/she gets from Ministry of Labour—see C
- Job description (List of things you will be working on while you are in Tanzania). **This doesn't apply to researchers and students.**
- Fees \$ 550 for Medical doctors and Researchers. **Do not pay until you get the control number from immigration. (Contact Gwamaka)**
- FEE \$ 250 for students and East African citizens. **Do not pay until you get the control number from immigration. (Contact Gwamaka)**
- If you may have any dependent you pay extra fee of \$50(**Only if this dependent is not working/studying/involved in any official business**) then add the following documents (Note that the husband can not be dependent to the wife)
 - Introduction letter from you introducing your depends
 - Marriage certificate copy
 - Passport copy
 - Birth certificate copy (Sometimes they ask for this, sometime they do not)

Work Permit (rarely needed) (Ministry Of Labor)

Website: <http://www.kazi.go.tz/> <https://epermit.kazi.go.tz/web/main/guidelines>

Cost: \$500

IMPORTANT NOTES:

As mentioned on page 2 of this document, as of October 2024, the Work Permit option is a relatively rare option for trainee researchers to pursue for the purposes of obtaining a Residence Permit. If you think this is a pathway that makes sense for you to pursue, we recommend you talk with your Duke Faculty Mentor/Champion first.

You start with the online application and once you “SUBMIT” please print the forms for hard copies so we can submit to the Ministry.

Documents you will to submit include the following;

- Justification Letter (Covering Letter) From Kcmc Hospital
- Certificate of verification of diploma /degree by the Tanzania Commission for Universities
- Application Form TFN 901 (2Forms)
- Contract of employment or engagement , as the case may be duly signed by relevant parties
- Job or engagement description
- Curriculum Vitae
- Two recent passport size photographs of the application
- Accreditation certificate, if any , from respective professional entities
- Academic/professional certificates
- Certified translation of certificates/documents by competent Authority or Embassy or Consular office (If they are in a languages other than English and Swahili)
- Photocopy of a valid passport)
- Previous work permit (for renewal application)
- Industrial/Operating /Business license
- Certificate of Incorporation, Business name and Extraction from the Registrar of Companies, **I have these documents**
- Memorandum & Article of Association
- Succession plan (for renewals) **I have it**
- Letter of no objection (if any) from previous employer
- Sectoral approval (where applicable)
- Certificate of Incentives **(if any)**
- Certificate of verification of diploma /degree by the Tanzania Commission for Universities. Application link www.tcu.go.tz then go to **foreign award assessment system (FAAS)**.

These are the cost for the evaluation

Bachelor Degree Postgraduate **150,000/=**

Master's Degree **150,000/=**

PHD Holder - **150,000/=**

Do not pay until you get the control Number from the system or contact Gwamaka.

As mentioned elsewhere (page 2) the KCMC-Duke Collaboration Administrative staff can make the fee payment on your behalf.

National Identification Card (NIDA)

NIDA: <https://eonline.nida.go.tz/>

Cost: \$

Once you have completed your Residence Permit process, an additional step for researchers residing in Tanzania for >6 months consecutively is to apply for a National Identification Card, known as a NIDA card.

If you plan to stay in Tanzania long term you are expected to apply for NIDA.

Please confer with Gwamaka William about this process.

BUSINESS VISA

Only Researchers Whose Research Trips / Experience Will Be Less Than 90 days

REQUIREMENTS:

- COSTECH Permit (see Page 6)
- Business Visa (DO NOT EVER ENTER ON A TOURIST VISA—if you enter on a Tourist Visa, you will have to pay a \$600 fee to process your tourist visa into a Business Visa).

Business Visa Instructions

Business visas can either be applied for online in advance of your travel (10 business days or more in advance of your travel) or they can be applied for upon arrival at the airport, typically Kilimanjaro International Airport (Moshi/Arusha) or Julius Nyerere International Airport (if you are first de-planing and entering the country via Dar es Salaam).

Note, there are some nationalities that are not allowed to apply and pay for the Business Visa upon arrival. Please check with Gwamaka William if you are uncertain about your eligibility for a Business Visa upon arrival.

Instructions for Business Visa Upon Arrival

Cost: \$250 (in cash) for US Citizens (\$100 for Eastern African citizens; other countries will be \$200-\$250)

Steps:

- 1) Request a Letter of Introduction from KCMC 3-4 weeks in advance of your travel
 - Email the KCMC-Duke Welfare Officer, Gwamaka Nselela, copying your KCMC co-investigator / collaborator on the email
 - Gwamaka will provide you the Letter of Introduction template with some drafted boiler-plate language on the purpose of your visit → you and your KCMC collaborator can then edit the letter so that it describes the purpose of your time at KCMC. Usually only light edits are required.
 - Print the final version (signed by Gwamaka) of the KCMC Letter of Introduction and bring it in your carry-on items so that you can present the letter to Immigration upon arrival
- 2) Prepare your cash in advance of your travel to Tanzania: Bring correct change in the form of \$100 bills and \$50 bills) and make sure that the bills you bring were NOT printed prior to 2003.
- 3) Present yourself to Immigration at the Airport (filling the entry forms that you are instructed to fill while on your flight or upon entering the Immigration Galley).

Instructions for Business Visa Online Application

Cost: \$250 or for US Citizens there is a multi-entry visa option costing \$100

Steps:

Note: web addresses and website content can often change, so if the steps below do not square with what you see on the website, please consult with Gwamaka

1) Go to the Tanzania Immigration Services Department website: <https://immigration.go.tz/>

2) Ensure that you have sufficient days in advance of your arrival date to apply (typically 10 business days but DOUBLE CHECK the guidance on the Tanzanian Immigration Services Department's website as this guidance could change).

3) Obtain a letter of introduction from KCMC. As state above, it is best to request this letter 3-4 weeks in advance of your travel:

- Email the KCMC-Duke Welfare Officer, Gwamaka Nselela, copying your KCMC co-investigator / collaborator on the email
- Gwamaka will provide you the Letter of Introduction template with some drafted boiler-plate language on the purpose of your visit → you and your KCMC collaborator can then edit the letter so that it describes the purpose of your time at KCMC. Usually only light edits are required.

4) Fill out the online application:

- From the Main page select the **E-Services** Dropdown menu → Select **Online Visa Application** → on this page select **New Application**
- Completing the business visa application generally only requires your passport details, contact information in US/country of residence, your flight details (typically arrival and departure details) and then contact information for your time in Tanzania.

- For Local Host you can select **Company/Organization** (rather than selecting Citizen or Resident with pass, etc.) and provide the following as applicable:
Name: Gwamaka William
Telephone/E-mail: +255 713 883 058 / gwamakawilliam14@gmail.com
Relationship: Administrator
Company Name: Kilimanjaro Christian Medical Centre
Address: Sokoine Road, Moshi, Kilimanjaro

For place of stay: provide hotel information or if you are staying at the Doctors Compound state
“KCMC Doctors Compound, House #___”

5) Await disposition: you will typically receive an email notification of approval, but it is also wise to check your visa status by logging in to the application portal <https://visa.immigration.go.tz/checkapplicationstatus>. Typically, the approval is granted within 5-7 business days.

Additional Notes for the Multi-Entry E4 Business Visa

- This visa is for 1 year duration
- It allows multiple entries into Tanzania, and all trips to Tanzania must be < 90 days in duration
- The application instructions generally follow the steps as listed above for the regular online Business Visa Application. A few differences to note:
 - The Letter of Introduction will need to be modified to suit the purposes of a Multi-Entry E4 Business Visa application: Gwamaka has templates for this so the main task here is to communicate clearly with Gwamaka if you are proceeding with a multi-entry E4 business visa
 - KCMC's Certificate of Registration is required: Gwamaka can provide a PDF of this document
 - Purpose of Travel: you would select Option #9 "Other" (Consultancy with registered companies, NGO's & Other Institutions)
 - When completing the application, there can often be some required fields to upload documents that appear to be Not Applicable to your situation → in these instances you can upload a PDF letter signed by you stating something to the effect of "This document is not required for the specific visa type I am applying for"
 - For this, we suggest you confer with Gwamaka A) to check that he agrees that a given field is Not Applicable and B) Gwamaka can provide an example letter for you to upload for these required fields.
Example: Application might Request "Passport or National ID of a host citizen / Resident Permit Tanzanian resident"
Response: "I did not upload such a document as I do not believe it is required for this type of visa application. If I have misunderstood the requirements, please contact the KCMC-Duke Health Collaboration administrator, Gwamaka Nselela (+255 713 883 058) to communicate about this matter."

Ethics Submissions

ETHICS APPROVALS FOR RESEARCH FOR RESEARCHERS CONDUCTING COLLABORATIVE RESEARCH WITH KCMC VERSION: OCTOBER 2024

PURPOSE: To provide description and instructions for the ethical approval process to conduct collaborative research with KCMC.

- Timeline: allot 7-9 months of lead time!
Ethical approval to conduct research in Tanzania with KCMC is a multi-step process that typically takes **7-9 months** to obtain all requisite approvals for a de novo “new protocol” submission.
 - An amendment to an existing protocol typically takes 4-6 months
 - Researchers and trainees should work with their collaborators and mentors with this timeline in mind: as many researchers come in June/July **→ this means starting this process by October/November** with a goal of study protocol or protocol amendment **submission by January** (i.e., 5-6 months before arrival)
- Steps:
 - Submission to Duke IRB
 - Submission to the Kilimanjaro Christian Medical University College Research Ethics Review Committee (CRERC)
 - Submission to the National Institute for Medical Research (NIMR) National Health Research Ethics Committee
 - Transfer Agreements (between KCMC and Duke, counter-signed/approved by NIMR):
 - NIMR templated Data Transfer Agreement (DTA) is required for all protocols.
 - NIMR templated Material Transfer Agreement is required for any protocol where study specimens are intended to be shared by KCMC to Duke or other collaborating institutions are required for all protocols,
 - Once approved by NIMR
 - A counter approval is needed from the President’s Office (TAMISEMI)
 - Local approvals from the Regional Medical Officer of Kilimanjaro Region and the relevant District Medical Officers
 - (If your study is a clinical trial, it will also require approval by the Tanzania Medicines & Medical Devices Authority [TMDA])
- Support:
KCMC-Duke Collaboration has a Regulatory Coordinator, Ms Caroline Allen Samboko (lorynsimon@gmail.com). Caroline can assist with your study protocol submissions in Tanzania.

Please be mindful that she manages the regulatory aspects of HIV Clinical Trials at KCMC in addition to supporting Duke faculty and trainee researchers with their in-country ethical approvals.

Your mentor/faculty champion and collaborator at KCMC can and should also provide support and guidance, including existing examples of approved protocol documents.

- Costs: Typically \$1,100 for non-clinical trial protocols. Fee schedules are provided below on page 2.

Ethics Submission Fee Schedules (subject to change)

Fees schedules are provided below.

Payment process:

As noted in the PERMIT REQUIREMENTS document, the KCMC-Duke Collaboration Administrative Team can make these payments on your behalf. These payments can either be charged to a Duke “Fund Code” or they can be charged to your project’s sub-contract at KCMC. It is common that at the stage of study protocol ethics submissions, sub-contracts between KCMC and Duke University may still be pending. In this case, KCMC-Duke Collaboration can still make these submission fee payments up front and then your project will reimburse the Collaboration once contracting has been executed.

KCMC University Ethics Committee Fees

S/No.	Category	Locally funded research	Internationally funded research	Tanzanian students	International students
3.	Ordinary health research	300 USD	500USD	Masters USD PhD USD	Masters 300 USD PhD 500 USD
4.	Clinical trial	500 USD	700 USD	Masters USD PhD USD	700 USD
4	Renewal of ethical approval	N/A	100 USD	100 USD	100 USD
5	Expedited review	400 USD	600 USD		Masters 400 USD PhD 600 USD
6	Expedited review clinical trial	600 USD	1000 USD		

The Table above is provided by the KCMU College Ethics Committee.

The Take-Home message has been bolded / highlighted by the KCMC-Duke Collaboration:

- \$500 USD for a new protocol submission (non-clinical trial)
- \$100 USD for the annual renewal submission fee

Amendments to Study Protocols: may soon require a fee

NIMR National Health Research Ethics Committee Fees

NIMR <http://www.nimr.or.tz/ethical-guidelines/>

- Application should be accompanied by a KCMC IRB approval and your costech permit



UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

NATIONAL INSTITUTE FOR MEDICAL RESEARCH



PAYMENT FOR ETHICAL CLEARANCE FEES

NatHREC Payment Rates from 1st January 2025

Payment Category	Tanzanian Collaborators (TZS)	Tanzanian Students (TZS)	International Collaborators (USD)	International Students (USD)
Ordinary Proposal (Expedited Review)	1,375,000	312,500	1,375	438
Clinical Trial Proposal (Expedited Review)	3,875,000	390,625	5,125	548
Ordinary Proposal (Ordinary Review)	500,000	312,500	750	438
Clinical Trial Proposal (Ordinary Review)	2,625,000	390,625	2,625	548
Ordinary Proposal (Amendment)	300,000	250,000	450	375
Clinical Trial Proposal (Amendment)	750,000	250,000	750	375
Ordinary Proposal (Extension)	150,000	125,000	150	125
Clinical Trial Proposal (Extension)	300,000	125,000	300	125
Ordinary Proposal (Appeal fee)	150,000	150,000	100	75
Clinical Trial Proposal (Appeal fee)	300,000	150,000	150	75
* Penalties (Late Renewal)	100,000	50,000	100	50

Note: * The penalty cost will be imposed for each month that the PI fails to renew the protocol.

TMDA CHARGES

Clinical trial application fee: \$3000 USD (double the cost, \$6000 USD, for a “fast track” application).

For the detailed fee schedule, please consult the TMDA website and you can also confer with Caroline Allen in the KCMC-Duke Regulatory Office.

The full details are not provided in this document, as most researchers from Duke are submitting ethics submissions for observational studies and not for clinical trials.

Formatting & Application Instructions

KCMC University Ethics Committee & NIMR National Health Research Ethics Committee provide guidance on formatting. Their respective guidance is shown in the Table below.

KCMU CRERC	NIMR NatHREC	Combined Format Recommended by KCMC-Duke Collaboration
	Institutional Logos	Title Page: Study Title List PIs & Co-Investigators Include Institutional Logos
0. Abbreviations		Abbreviations
1. Abstract	Summary	Abstract / Summary
2. Introduction	Background	Background: Introduction
3. Literature Review		Background: Literature Review
4. Problem statement		Problem Statement
5. Study rationale	Rationale	Study Rationale
6. Broad objectives & specific objectives	Objectives	Broad Objectives & Specific Objectives
7. Methodology: study design, study area, study population, inclusion/exclusion criteria, sample size & sample size techniques, data collection methods & tools, study variables	Methodology: include recruitment procedures	Methodology: include and address all the sub-headings listed in the KCMU Co column; include recruitment procedures
8. Limitations of the study		Study Limitations
	Ethical Considerations	Ethical Considerations
9. Investigators Roles*	Composition of Research Team	Composition of Research Team & Investigator Roles
10. Dissemination of Results		Dissemination of Results
11. Budget & Justification	Budget & Justifications	Budget & Budget Justification
12. Investigators CVs in CRERC format (form 14)		Investigator CVs (state "Enclosed with Application")
13. References	References	References

	Appendices	Appendices (if applicable, otherwise state "Appendices: N/A")
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****KEY POINT**: ONE SINGLE PROTOCOL DOCUMENT**

- We highly recommend that you produce a single study protocol document (e.g., a Word file) which encompasses NIMR formatting and KCMU College formatting.
- This same document can then be submitted to Duke IRB, NIMR and KCMU College.
 - For the Duke submission, you or your regulatory coordinator at Duke will almost certainly need to piece-mail (i.e., copy & paste) the elements of this single document into the on-line application fields for IRIS.
 - The same can be said for NIMR's MRCC form.
 - But nevertheless, in our experience, it is best to have one single source document file from which all 3 ethics committee applications were derived and a single source document that all 3 ethics committees receive.
- We recommend AGAINST producing 3 separate protocol documents for each of the 3 ethics committees
 - This approach is not time-effective
 - This approach can lead to dizzying version control problems

If you have questions about this recommendation, please confer with your Duke faculty mentor/champion, your KCMC collaborator/co-investigator or Caroline Allen.

Similarly, for further details on the content specifications for any of the protocol sections listed below, the single best approach is to request a successful example of a study protocol ethics committee submission from your Duke faculty mentor/champion, your KCMC collaborator/co-investigator or, as a last resort, Caroline Allen.

*The Principal Investigator listed on the protocol document should be the Tanzanian collaborator on the project. It is acceptable to list BOTH the Duke lead researcher/Duke PI and the KCMC lead researcher/KCMC PI as Principal Investigators

Additional Instructions: KCMU College Ethics Review Committee (CRERC)

The following must also be submitted with your study protocol document

- Cover Letter
- Application Form CRERC Form 2
- Informed Consent Forms in English & Kiswahili
- Investigator CVs (CRERC Form 14)
 - Of course use existing versions as able of Form 14 CV's that your mentors, collaborators & co-investigators already have on file

Timing & Timelines: KCMU CRERC meets the first Friday of most months and their target turn-around time for responding to submissions is 4-6 weeks.

There is typically at least 1 round of initial comments, which the investigator team then responds to and re-submits to the KCMU CRERC for further review.

Additional Instructions: National Institute for Medical Research National Health Research Ethics Committee (NatHREC) <https://www.nimr.or.tz/>

The following must also be submitted with your study protocol document

- Cover Letter (include institutional logos)
 - This can be the same letter as the Cover Letter submitted to KCMU CRERC
- Commitment Letter from affiliated institution (KCMC) and local government officials (letter from Kilimanjaro Regional Medical Officer)
- Application form for ethics approval (from NIMR Website)
- Informed Consent Forms in English & Kiswahili (with institutional logo)
- Ethics committee approvals (from KCMU Co and Duke or other relevant collaborating institutions)
- Data Collection Tools in English & Kiswahili
- Any written information that will be provided to participants (English & Kiswahili)
- CVs of research team (composition of research team is addressed in the study protocol document)
- Submission fee proof of payment
- Data Transfer Agreement and, if applicable, Material Transfer Agreement (from NIMR website)
 - See Page 7 below regarding instructions for Transfer Agreements
- If clinical trial:
 - Investigator's Brochure & Case Report Forms
 - Proof of insurance coverage
 - List of DSMB members (must include at least one Tanzanian)

For all of the above, of course work with your Duke faculty mentor/champion or KCMC collaborators to obtain successful examples for any of the above documents.

Submission mechanics:

- Online submission process through the Research Ethics Information Management System (REIMS)
 - Caroline Allen can support your submission: please confer with your Duke faculty mentor/champion, KCMC investigators/collaborators or KCMC-Duke Collaboration Site Leaders on whether Caroline is positioned to perform this upload & online submission
 - A hard copy of the entire submission will be sent by Caroline through the Tanzanian secure post (known as EMS)

Turn-around time for NIMR NatHREC: ~8 weeks.

As stated above with the KCMU CRERC, there is likewise typically at least one round of comments from the NIMR NatHREC to which the investigator team will then respond and re-submit for further review.

TMDA Application Formatting & instructions

**RECALL: TMDA submissions are only required for clinical trials.

See TMDA website (<https://www.tmda.go.tz/>) and confer with Caroline Allen.

Further instructions on the TMDA submission process is not covered within this document as most Duke researchers new to the KCMC-Duke Collaboration are not conducting a clinical trial.

Some additional TMDA notes to be aware of:

- Note that trials of complex interventions may or may not require a TMDA submission. You should confer with your KCMC Collaborators and the KCMC Regulatory Officer, Caroline Allen.
- If your trial involves assessment of medical devices or medicines that are already available on the market (e.g., amoxicillin or a POC test), such trials typically still require TMDA approval and regulatory oversight. (In other words, TMDA approval and oversight is not restricted to new therapeutic agents, but can include agents or devices that are already in common use.)

DATA TRANSFER AGREEMENT (DTA) AND MATERIAL TRANSFER AGREEMENTS (MTA)

Background

- These agreements protect the interests and outline the rights and responsibilities for the collaborating institutions, in this case KCMC and Duke University
- By definition, any research project will include transfer of data between KCMC and Duke, and therefore a DTA is always required
- Many projects will also entail the transfer of study specimens. Technically (i.e., contractually, juridically), these specimens are collected by the KCMC work package for a given project, and therefore agreements are needed for the proper transfer to Duke University or to other collaborating institutions or reference laboratories.
- To obtain NIMR NatHREC approval certificate, NIMR typically (almost always with rare exception) requires that the partner institutions sign and submit a DTA and, if applicable, an MTA
- **IMPORTANT:** the DTA & MTA templates provided by NIMR cannot be altered. See further guidance in instructions below.

Steps & Instructions

- Download agreements: from the NIMR website (<https://www.nimr.or.tz/>) the extant PDF versions of the DTA or MTA.
If you have trouble finding these links (e.g., website can be down, browsers can often refuse to navigate to NIMR website due to “unsecure” status, links can be broken, etc.), then reach out to the KCMC-Duke Regulatory Officer, Caroline Allen, to request the most recent version in her files.
- Score a successful example: Obtain a successful prior example from your Duke faculty mentor/champion, KCMC collaborator/co-investigator or, as a last resort, the KCMC-Duke Regulatory Officer. As with anything in this mind-numbing document, a successful example is worth 1000 hours of re-inventing the wheel.
- Populate the transfer agreement: Use the successful example you have to populate
 - KCMC address, Duke address, Duke investigator, KCMC investigator, investigator contact information
 - Description of data or material to be transferred
 - Provide study protocol numbers or grant information numbers as applicable
 - Leave blank the name and contact information for the KCMC authorized signatory and the Duke authorized signatory

- Send to Office of Research Contracts: Once you and your team have reviewed → send to Duke's Office of Research Contracts (ORC) for their review and signature
 - As of October 2024, there is NOT an online submission system for this. Instead, the agreement would be emailed to known contacts at ORC. As of October 2024, these include: David Kordys, Katie Factor, Dan Anacker. Check with your Regulatory Coordinator or Duke faculty mentor/champion for their recommended contacts.
 - Updates/amendments: as mentioned above, these DTA & MTA templates from NIMR cannot be altered. So the functional way to address any content in the agreement that Duke is NOT AGREEABLE to is by way of an addendum memo.
 - Duke ORC will take the lead on this and provide an addendum letter which outlines updates that Duke would like to propose to KCMC
 - This amendment letter can then be shared with the KCMC-Duke Collaboration Regulatory Officer, Caroline Allen, and it is best to include the KCMC PI on the project and other KCMC leadership as applicable (e.g., Blandina Mmbaga, Director of Research at KCMC)
- Duke ORC signature: Once KCMC and Duke have agreed to any needed changes outlined in the addendum letter → ORC will sign and the Duke PI will also sign
 - IMPORTANT: STAMP/SEAL. These signatures need to be accompanied by an Institutional Stamp/Seal which certifies validity. ORC has such a stamp, but if it is not available for any reason, then a notarized signature can suffice.
- Send to KCMC: ORC or you/your team then share the signed documents (agreement and addendum) with KCMC by emailing to Caroline Allen.
 - Caroline will let you and ORC know whether hard copy “wet ink” signatures are needed vs. whether the emailed “soft copy” suffices
 - Historically, 2013-2021, 3 print-outs all having wet ink signatures were needed and these would be sent DHL/FedEx to the KCMC-Duke Collaboration
 - More recently, 2022 onward, Duke ORC sending a scanned “soft copy” of the signed documents are allowable. This is subject to change, and Caroline Allen can let you know.
- KCMC signatures: KCMC PI and Authorized Signature will sign
- Forward to NIMR: then KCMC will submit this to NIMR for review and approval signature by NIMR

- Fully executed agreement: Caroline Allen and/or the KCMC PI will receive notification of the fully executed MTA and once it is shared back to KCMC by NIMR, Caroline will circulate to the Duke researchers and (ideally) ORC.
 - ORC will want a copy of the fully executed agreement, so if Caroline does not share with ORC, the Duke investigator team should close the loop.

Consent Form Translation

Translation of consent forms can be a rate-limiting step in the ethical review submission process. You should allot 2-4 weeks turn-around time to get translations from English to Kiswahili.

Translators: Translators are typically seasoned, bi-lingual team members from your Duke faculty mentor/champion's research team at KCMC (e.g., Study Coordinators), but if you are not able to identify a translator through your faculty mentor or KCMC collaboratory/co-investigator, then the KCMC-Duke Collaboration Regulatory Office or KCMC-Duke Site Leaders.

Certification: the requirements for vouching the translations have varied over the years. Duke IRB has required back-translations (Kiswahili back to English by an independent translator), but more recently, a letter certifying the validity has sufficed. This letter would come from a bi-lingual representative at KCMC who can attest that the Kiswahili consent forms are an accurate translation of the English consent forms.

Animal Welfare

KCMC does not have an IACUC animal welfare ethics committee. If your research involves animals, you will need to work with your Regulatory Coordinator at Duke and the Duke IACUC to navigate the ethical requirements. Generally, the Duke IACUC has been willing to work with researchers conducting research that involves recruitment of animals; but the required documentation the Duke IACUC will need may depend on the nature of the project.

Sequence of Events & Timing

This guidance on when to submit what to where can change. As with anything, it is always a good idea to confer with your Duke faculty mentor/champion, KCMC collaborators, or the KCMC-Duke Regulatory Coordinator.

As mentioned in the OVERVIEW on page 1 of this document, you should plan on 7-9 months turn-around time to see this entire process through.

This of course means that for a project that you and your team are hoping to initiate enrollment in October → you should aim to submit to KCMU College Ethics and NIMR NatHREC in January so as to avoid delays.

It is best practice to account for this timeline in your grant applications as well in your project Gantt charts and timelines.

Process	Typical Turn-Around Time for Approval	Comments
1a. Duke IRB	0.5-1 month	Duke IRB might not provide full approval until you have KCMU CRERC approval. Plan for an amendment to this protocol once you have received full approval from KCMC & NIMR (see Step 6 below)
1b. KCMU CRERC	3-4 months	This typically entails at least 1 round of critiques by EC & response by investigator team.
1c. Initiate Transfer Agreements	3-6 months	See instructions on page 9. A signed data transfer agreement between Duke & KCMC is often required by NIMR before they will provide their approval. If specimens are to be shared by KCMC to other institutions (including Duke), then likewise, a material transfer agreement will be needed and your study protocol approval could be contingent upon you providing an agreement signed by KCMC & Duke.
1d./2.* NIMR NatHREC	6-8 months	This typically entails at least 1 round of critiques by EC & response by investigator team. Often NIMR approval notification is received by email / REIMS notification, but then it can take another 1-2 months to receive the actual certificate.

		<p>*1d./2: NIMR will not provide approval until KCMU CRERC approval certificate is provided. This notation “1d./2” denotes that you and your team can either elect to submit to NIMR as Step 1d: submit at the same time that you are submitting to Duke IRB (Step 1a) and KCMUCo (Step 1b)</p> <p>OR you can opt to make the NIMR submission Step 2: submit to NIMR once you have obtained KCMU CRERC ethical approval.</p> <p>Your costech permit may be required to receive NIMR approval</p> <p>There are pros/cons to either approach. Suggest you seek updated guidance from your team and the Regulatory Office.</p>
3. TAMISEMI/President's Office	1-2 months	<p>This is presented after NIMR approval certificate has been received.</p> <p>There are not additional application steps: the Regulatory Office will provide a letter and share the NIMR approval certificate.</p>
4. Regional Medical Officer (RMO)	0.5 months	<p>This is a notification to the RMO that this study (which RMO office should already be aware of) has been fully approved by NIMR and TAMISEMI. The RMO's acknowledgement of this is essential to proceeding with the study.</p> <p>If your project involves recruitment in Regions other than Kilimanjaro, those respective RMO's must also be informed.</p>
5. District Medical Officer (DMO) and Beyond	0.5 months	<p>After obtaining RMO approval, the next requirement is to notify the DMO and receive acknowledgement by the DMO of the district(s) where you will conduct the research.</p> <p>Beyond: for hospital-based work, you and your team will work with Heads of Hospitals.</p> <p>For field work, you may need approval of the District Council and/or the subsidiary community leaders: Ward Officers, Village Chairpersons/Street Leaders.</p> <p>Confer with your KCMC collaborators and the KCMC-Duke Regulatory Officer.</p>

6. Amendment for Consolidation of Protocol	N/A	<p>After you have received full approval from KCMC and NIMR and Duke, it is often then necessary to proceed with a “catch-up” or “consolidation” of the protocol, as the feedback from NIMR or from KCMU CRERC will render changes (major or minor) from the protocol that was approved by Duke IRB. Work with your team, especially your Regulatory Coordinator at Duke, to navigate through Version name changes to the protocol version and consent forms, as applicable.</p>
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