

PLANNING FOR FINANCIAL SUSTAINABILITY



A Guide for Research Ethics Committees in Africa

Developed by



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Planning for Financial Sustainability

A guide for Research Ethics Committees in Africa

This guide is meant for Research Ethics Committees (RECs) / Institutional Review Boards (IRBs) responsible for the ethical review of health research and for the organisations with which they are associated. This guide is appropriate to both public and private sector health research organisations.

Our main focus is to support RECs in Africa. However, RECs in any other country may also find this guide useful.

This guide aims to assist RECs to develop transparent and sustainable financing that is needed to improve the quality of ethics review, to digitize and accelerate the review of research proposals, to engage in continuing professional education, to interact with other relevant committees regulating research or research products, and to implement post-approval oversight.

Our ultimate aim is to ensure that all countries, regardless of the level of socio-economic development, have adequately resourced ethics review systems. This is essential for their research institutions to participate effectively in research needed to improve health, equity and development, not only nationally but also globally.

The specific objectives of this guide are to encourage RECs:

- *to quantify the financial resources needed to promote the conduct of ethical research, to be responsive (even in emergencies), to engage in continuing education, and to provide oversight of approved research;*
- *to implement a financial management plan to obtain these resources in a sustainable and transparent manner that does not affect its independence, reduces conflicts of interest; and*
- *to account for all finances and other resources received and used.*



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Who should read this Guide?

This guide serves as a resource for anyone responsible for the organisation, implementation and management of Research Ethics Committees (RECs) – and, in particular:

- i. REC Chair persons;
- ii. REC Administrators (RECA);¹
- iii. Administrators and Finance Managers of institutions that host RECs, including:
 - *Chancellors and Vice-Chancellors at Universities – especially those tasked with research management and -development;*
 - *CEOs and research development officers of research organisations in the private or public sectors;*
 - *Finance managers of these organisations;*
- iv. Administrators and Finance Managers of institutions regulating research, including:
 - *Ministry of Health (staff involved with regulation and supervision of research ethics review);*
 - *Ministry of Higher Education and Science (staff involved with regulation and supervision of research ethics review);*
 - *Ministry of Finance (in case of national policies related to charging for ethics review);*
- v. Research funders, sponsors and grant writers:
 - *Funders interested in building research system capacity in LMICs;*
 - *Grant writers and research partners in high income institutions to be able to make adequate provision for local ethics review costs and infrastructure support.*

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Layout: Holger Postulart

¹ https://www.healthresearchweb.org/en/togo/ethics_1132



Executive Summary

The last few decades have experienced a dramatic transformation in the regulation of health research ethics. Research involving human participants is no longer accepted without independent ethics review. Major, globally accepted, guidelines provide the basis for ethics review of health research (2-5) but many more national or regional guidelines, standard operating procedures (6,7) and topic-specific guides have been written to support RECs in their work. To reinforce the need for competent ethics review of health research, the editors of major journals agreed not to publish research that has not been approved by an established research ethics committee (8). Similarly, many funders of health, including the US NIH, will provide funding only after researchers have themselves completed a basic course in research ethics (9) and if grant proposals clearly indicate how ethics review will be done (10).

Research done in the context of international collaborative research involving Low- and Middle-Income Countries (LMICs) has increased in volume and complexity over the last few decades, driving an increased expectation of 'local' ethics review. (11,12) Increasingly, local RECs are expected to approve, reject or stop studies or require modifications to research protocols that have already been approved by international partners.(7) Substantial funding has been allocated by international research funders, such as the NIH / Fogarty International Center. (13,14) and others to provide high level educational programmes for ethics scholarship in Africa (<http://sareti.ukzn.ac.za/Homepage.aspx>) and for operational training and continuing education of REC members (<http://blogs.sun.ac.za/aresa/>). Ethics review in Africa is now well established and growing, both at institutional and at national levels. (11,12,15,16)

In short, competent and rapid ethics review is essential for all health research, including in LMICs. Without solid ethics review systems (17,18), Africa cannot fully participate in global health research needed to deal with its own health, equity and development challenges, let alone growing its health science infrastructure to drive innovation and become globally competitive.

RECs need basic funding for administration, equipment, communication and internet access, and to pay staff and rent. More than basic funding is required for ongoing training, consulting international experts, subscribing to digital ethics review platforms, for oversight activities, and more. As research is becoming more complex, as health emergencies require accelerated global review, and as the protection of research participants from harm related to research becomes more difficult to assure, RECs require more financial resources. And that is where Africa experiences a serious bottleneck. A case study conducted by the Johns Hopkins Bloomberg School of Public Health in 2004, reported financing as the biggest challenge that African RECs experienced. Three of the RECs that were interviewed reported that they had no operating funds whatsoever and nine reported that they received modest funds solely or in combination from government, foreign agencies and/or fees for review. (19)

There are some grants available for travel to conferences, and there are grants for individuals to enroll for Masters and Doctoral programmes, but once back in their REC, there are few sources of funding to optimize REC functioning. As best as we can determine, only two research sponsors (EDCTP, NIH Fogarty International Center) are systematically providing funding to RECs for 'capacity building', infrastructure, and ongoing development, at this time. (13,20)

On the other hand, there is a great scarcity of information on fees being asked for review in Africa. There is also a lack of transparency and standards for financing of RECs, and few, if any, published guidelines on maintenance of independence of ethics review from the interests of those paying 'review fees. (21-23, 36)

There is no doubt that adequate, transparent and sustainable finance is critical to the independence and efficient operation of RECs. This document aims to provide a start. This Guide enables RECs to estimate a reasonable operating budget, to identify reliable sources of revenue, and to account for their finances transparently. It outlines options making important decisions. Ultimately, this Guide encourages RECs to secure the finances needed to operate efficiently and to provide quality and independent ethics review and optimum research participants' protection. It is the ethical thing to do.

Glossary and Abbreviations

Glossary:

Research Ethics Committee (REC) / Institutional Review Board (IRB) = the structure responsible for ensuring the protection of human participants in health research. Usually associated with research or academic institutions. Some are private, using a 'fee for service' approach, while others are paid for by their institutions, sometimes in kind only. REC is the terminology commonly used in Africa, while IRB is the terminology commonly used in the United States of America. For purposes of this Guide, REC is used but implies IRBs as well where the latter is more commonly used.

Abbreviations:

AARECA:	Association of African Research Ethics Committee Administrators
AMANET:	African Malaria Network Trust. (Began as : African Malaria Vaccine Testing Network) (31)
CBRS – Togo:	Comité de bioéthique pour la recherche en santé du Togo (Bioethics Committee for Health Research of Togo)
COHRED:	Council on Health Research for Development
DHHS:	Department of Health and Human Services (USA)
EDCTP:	European and Developing Countries Clinical Trials Partnership
HIC:	High Income country
IRB:	Institutional Review Board
LMIC:	Low- and Middle-Income Country
MARC:	Mapping Africa's Research ethics review Capacity
NIH:	National Institutes of Health (US)
REC:	Research Ethics Committee
RECA:	Research Ethics Committee Administrator
USA:	United States of America
WHO:	World Health Organization

Background and Objectives

The number of Research Ethics Committees (RECs) in Africa has seen a steady increase over the last few decades. According to MARC Project (Mapping African Research Ethics Review) funded by the European and Developing Countries Clinical Trials Partnership (EDCTP) and conducted by COHRED, a total of 170 RECs in Africa were registered by the MARC Project by 2014. (15,16). It was expected that this number was already higher at the time of the survey and it will be even higher now as more and more countries continue to establish institutional and national REC. (24) The growing number of RECs is, clearly, a response to the increase in the volume of research being conducted in Africa over the last two decades, even though the increase in research is not homogenous across the continent. (14,25)

The increased volume and complexity of research has also come with an increased complexity and number of partnerships involved in research over the last few decades. Conducting complex clinical trials, including genomics and human challenge studies in Africa have become common. (26,27) All these changes have increased the workload of RECs and the need for more and diverse expertise to be able to conduct competent ethics review, in Africa like everywhere else. Health emergencies only add to the need for RECs to be equipped and ready. (28,29,30)

In spite of these developments, the resources available to RECs do not seem to have increased in line with increased workloads, increased needs for expertise, increased oversight requirements and more. (1,19) While budgets for international collaborative health research have increased massively over the last 20 years, financing for REC operations remains mostly undocumented but are presumed to be lagging. Other than training grants, notably from the Fogarty International Center of the NIH (NIH/FIC) (13), the main REC infrastructure building grants have come from the EDCTP. (20)

In November 1999, the African Malaria Vaccine Testing Network, later renamed into African Malaria Network Trust (AMANET) (31) sponsored a seminar on health research ethics in Africa in Arusha, Tanzania. The objectives were to identify health research needs and priorities in sub-Saharan Africa, and to study the mechanisms used for ethics review and monitoring of research in the region. Reports by country representatives revealed several problems with the review and monitoring of health research in the region, including the following: (11)

- *inadequately developed ethics review committees (erratic meetings, poor leadership);*
- *lack of resources (computers, office space);*
- *limited or outdated legislation;*
- *overworked and/or untrained committee members and REC administrators;*
- *low awareness of ethics guidelines, and*
- *lack of training in bioethics and research ethics.*

In 2007, AMANET conducted a survey with 31 RECs in Africa to identify institutional needs. The survey indicated insufficient ethical review expertise, insufficient institutional financial support and lack of independence as the main challenges facing REC's. (F Kombe, personal communication). Similar challenges were also reported by others working in Africa in 2005 (12) and in 2007 (19). To address these challenges, AMANET embarked on a program for strengthening RECs inclusive of training workshops and grants of \$50,000 for each of the 20 RECs.

The first survey of and workshop with Administrators of African Research Ethics Committees Administrators (AAREC), convened by COHRED in 2011 in Botswana, found the same or similar problems more than 10 years later. (1,32)

Underlying these problems is the lack of finance to support RECs sustainably and in ways that encourage building a competent, emergency ready, future facing research ethics system that can promote both African scholarship in research ethics and help Africa's research systems to become locally relevant and globally competitive.

In spite of this realisation, there is very little transparency, comparative analysis or standardization in terms of financing RECs, particularly in Africa. Studies done in the USA and Europe report dedicated federal and institutional budgets and the pre-set of charging of fees for ethics review as a key source of funding for RECs/IRB. Budgets of IRBs are typically included in institutional budgets, while private RECs charge substantial fees. (33,34).

A survey conducted in Africa in 2004, reported lack of institutional and government funding as a key challenge that all RECs that participated in the survey reported. (19) The majority of the participating RECs reported to be charging fees for reviewing protocols, and the study found that there were substantial differences in fees charged across RECs. For example, in the case study by Kass et al, one REC used a "sliding scale" charging US\$5 for proposals submitted by under-graduate students, US\$10 for studies submitted by post-graduate students and US\$20 for all other research proposals. Another REC did not charge for institutional applications but demanded a payment of US \$365 for external applications and US \$585 for industry-sponsored studies. Some used a "fixed fee" structure, such as US\$100 for all applications and 1% of the study's overall budget once it was funded. (19)

Similar disparities in the fees charged for protocol review by RECs across Africa were also noted by COHRED during the mapping of RECs in Africa (16,24) and in a baseline assessment of ethics review frameworks in health research undertaken with the East African Community (EAC) member states to improve harmonization of ethics review in the EAC. (35) There were large differences in the budgets and resources allocated to RECs in the EAC: 9 out of 22 RECs (41%) that were interviewed had no annual budget allocation at all, while the annual budgets for those with a budget ranged from US \$3,000 to US \$2.9M per year. The latter amount refers to the total income at national level received for 'ethics review' charged to external grants and sponsored research. The actual fees charged ranged from \$0 to 10% of total budget, for international clinical trials. RECs that depended on fees charged for ethics review as their only source of revenue had the smallest annual budget compared to those whose revenues included both institutional support and revenue from review fees. In this study group, no RECs received external financial support although 5 out of 13 RECs (38%) reported 'receiving some funding from external collaborators'. Budgeting was also largely absent: most RECs (12 out of 22 RECs (55%) did not have specific budgets for office operations. (35)

Financing of RECs in the Economic Community of West African States (ECOWAS) is another regional study available on REC financing. (Appendix 1) (36)

There is no doubt that adequate, transparent and sustainable finance is critical to the independence and efficient operation of RECs and to support LMICs in developing their research ethics systems. This document aims to provide a start. This Guide enables RECs to estimate a reasonable operating budget, identify reliable sources of revenue, and account for their finances transparently, and it outlines options for making important decisions.

The purpose of this Guide is to encourage RECs to develop adequate, transparent and sustainable revenue to optimize their work, accelerate review, increase ability to deal with complexity as their contribution to making Africa's science relevant, ethical and globally competitive.

This Guide addresses five key actions on the road to sustainable REC financing:

1. *Decide on measures to ensure that the REC can conduct independent ethics review at the same time as charging fees for review.*
2. *Establish a reasonable operational expenses budget for the REC.*
3. *Identify (sustainable) revenue sources to match the operational expenses budget.*
4. *Create a Revenue Generation plan – in line with the Operating Budget.*
5. *Provide transparent financial reporting.*



Appendix 2 provides the one-page overview of the process this Guide proposes.

ACTION 1: Ethics Review Fees and the Independence of Ethics Review

Decide on measures to ensure that the REC can conduct independent ethics review at the same time as charging fees for review

Charging fees for the ethics review of research – is it, or can it be, compatible with independence of ethics review? That is a core question to answer before continuing to establish a revenue stream based on a ‘fee for service’ approach.

Research Ethics Committees need funding to support their operations. Therefore, it may not be inappropriate to charge research sponsors a fee for review. However, the fee mechanism should be designed to ensure that committees and their members have no financial incentive to approve or reject particular studies.

The first point to note is that charging for ethics review is common practice, also in Africa. (16,19,24,33,34,35) Perhaps this is not a justification in itself, but it is important to note that many countries and institutions have been charging fees for ethics review of research proposals for many years. In preparing this manual, we were able to find some information on actual fees charged in African countries, for example in Kenya (37), South Africa (38) and West Africa (ECOWAS) (36).

A second point to note is that if legitimate costs for the operations of a REC cannot be met from existing sources – such as institutional budgets and ‘in-kind’ support like office rentals (38) – then, effectively, the REC cannot operate competently but only ‘partially’. For example, if there are no means to validate that investigators are conducting their research in line with what the REC has approved (‘oversight of research’) (39), then the REC’s operations depend entirely on the goodwill of investigators. This does little to satisfy the requirement for RECs to protect research participants against potential harm. In fact, it can be considered unethical (and even unlawful in some jurisdictions where REC members are personally liable for REC/IRB negligence) to operate in this manner. Therefore, even if there is concern that charging fees for review may reduce the independence of the REC, this should be weighed against the ability of the REC to operate fully – or, at least, execute essential responsibilities. (6,10,12,23,39).

A third consideration is the increasing complexity of research designs and the need for larger international research collaborations. These developments mean that there are few, if any, RECs that have all the expertise available within the REC to provide comprehensive reviews. This applies anywhere in the world, not just in LMICs. One consequence of this is that in countries such as the USA, Canada and the United Kingdom, there has been a growth of both for-profit and non-profit RECs that are able to employ highly trained experts to conduct reviews against payment. This third point is listed here to indicate that where institutions intend to join globally competitive research efforts, then the RECs on which they rely for ethics review may also need to become more professionalized. (33) Private RECs can play a significant role in the overall ethics review process (33,38) but there is limited information on private RECs operating in Africa, except in South Africa (38) and in Zambia. (40)

To maximize the independence of research ethics review, it is important to create the maximum space between payer, payments and revenue, on the one hand, and the REC and ethics review process, on the other hand. This can be done in many ways, for example:

- *Support the REC from institutional overheads that are charged to every grant that the institution receives. That way RECs can be both independent and well-funded.*
- *Charge fixed fees or a percentage of a study budget for review (instead of charging for ‘successful review’); (37,38)*



- *Publish charges on the website (37) so that users, researchers and funders can comment if needed;*
- *Charges can be made to vary on reasonable grounds, for example, based on study type or work to be done by the REC; (37,39)*
- *Create a national/regional payment structure rather than an institutional one, so that individual RECs are not directly dependent on payers. This may also help in increasing financial transparency and accountability;*
- *And more – as appropriate to individual REC circumstances.*

It is NOT wise for RECs to receive funding directly, nor to make payments to members based on the type of studies reviewed, not to charge for approval – instead, charge for review irrespective of outcome. It is also not wise for the institutional CEO or Finance Manager to be a member of the REC as this is likely to pose a conflict of interest between independent review and the need for institutional income. Preventing or adequately dealing with potential financial conflicts of interest is important and the measures taken under ACTION 1 of this Guide can significantly help to eliminate or reduce such conflicts of interest. (41)

Where responsive and responsible institutional financial management exists, perhaps the best manner to ensure independence and appropriate funding is through institutional overhead fees charged against research grants. However, this is often not the case and, in such cases, ethics review by competent RECs cannot simply wait until institutional financial structures have been improved. Pandemics are a key issue in point. This Guide takes the point of view that RECs can responsibly include ‘fee charges for ethics review’ and remain independent at the same time, provided that they maximize transparency and maintain a clear separation between REC work and fees received.

The key message of this Guide is therefore that RECs should seriously consider including review fees to achieve sufficient and sustainable financing, i.e. if national legislation and institutional policy permits. If national (or other) legislation or regulation does not permit this, then it is probably time for RECs to begin discussions with their institution, or combine efforts to begin discussions with regional or national government. (42)

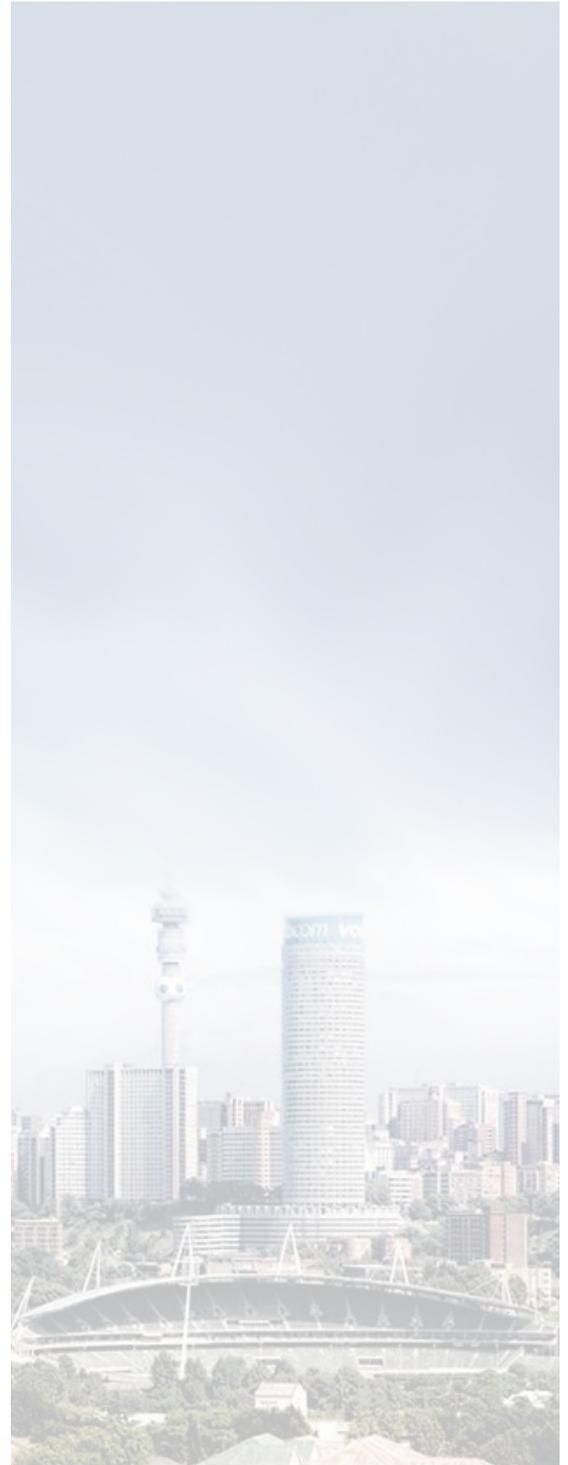
In summary: while charging for the ethics review of health research, can present obstacles to the independence of such reviews, it also enables RECs to develop the revenue needed to optimize review and to maintain their competence into the future. In addition, if charges are based on a reasonable operating budget (Action 2 of this Guide) and is transparently accounted for (ACTION 5 of this Guide) then RECs have established a best practice routine that will minimize, if not eliminate, conflicts of interest related to payment for review.

ACTION 2: Establish a reasonable Operational Expenses Budget for the REC

In the page(s) below, we have provided a basic template that can be used to estimate the annual expenses budget for any REC. A 'first-time' budget can often be more 'guess' than 'estimate' but as it is done in subsequent years, its accuracy and validity will improve.

Although the template is self-explanatory, we want to emphasize the following points:

1. Allocate a 'priority score' to each item in the budget. Any item can be either 'essential / high priority' (1) or 'non-essential / can be delayed till next year / lower priority' (2). This will help to identify the core issues needed for a particular year. However – be careful: when resources are scarce, there is a tendency to never allocate funding to items that 'can be postponed'. For example, continuing professional development activities for REC members. Clearly, these are rarely 'acute' but if there is never any budget for keeping members at the cutting edge of ethics review, then the REC will lose its expert status – slowly but surely.
2. Transparency is key to fairness to all involved in research, including those providing ethics review of research proposals who usually do this at no cost. It is highly recommended that after the annual operating expenses budget has been prepared as a draft, that it be discussed and approved by the REC members themselves before submitting it to higher authorities.
3. If you are an REC that handles its own finances, we still recommend strongly that you ask your base- or host-institution to validate the budget and sign off on its fairness.
4. This budget should serve as input for the annual financial audit process (see ACTION 5 of this Guide).
5. Preparing a reasonable budget will also greatly help you to convince research partner institutions and funders of research with whom you work that your REC takes the review process seriously and requires adequate resources to be able to do so. Presenting this budget to them will help to motivate for financial support – even beyond fees for ethics review.
6. This template is just that – a template. You can modify this to suit the particular requirements of your own REC. If you do so, we would ask you to keep sending us copies of the changes you make, so we can keep improving this guide and this template for others to use as well! Thank you in advance! Our contact details are on the the outside back cover.



Determining the Annual Operating Budget for a Research Ethics Committee

[NAME of REC]

Year:

Prepared by:

Nr	Category & Item Names	Unit Costs [Currency]	Number Units	Total Costs [Currency]	Comments	Priority (1 or 2)*
Human Resources						
	REC Chair					
	REC Administrator / other staff					
	REC members					
	REC consultants / external reviewers					
					<i>Subtotal Human Resources : Priority 1</i>	
					<i>Subtotal Human Resources : Priority 2</i>	
					<i>Subtotal Human Resources - All</i>	
Operations						
	Oversight actions (specify)					
	Certification/Accreditation - national					
	Certification/Accreditation - international					
	Transport for Field Inspection Visits					
					<i>Subtotal Operations : Priority 1</i>	
					<i>Subtotal Operations : Priority 2</i>	
					<i>Subtotal Operations - All</i>	
Continuing Quality Improvement						
	Continuing Professional Development					
	Journal subscriptions					
	REC workshops, training					
	National / Regional workshops					
	Conference Attendance					
	Benchmarking					
					<i>Subtotal Continuing Quality Improvement: Priority 1</i>	
					<i>Subtotal Continuing Quality Improvement: Priority 2</i>	
					<i>Subtotal Continuing Quality Improvement: - All</i>	

Nr	Category & Item Names	Unit Costs [Currency]	Number Units	Total Costs [Currency]	Comments	Priority (1 or 2)*
	Facilities & Administration**					
	Office(s)					
	Computer(s)					
	Printer(s) / Scanner(s) / Copier(s) / Shredder(s)					
	Telephone connection(s)					
	Internet - Access					
	Internet - REC website maintenance					
	Internet - enabling e-submissions				Subscription(s) and/or Purchase(s) e.g. online review system	
	Consumables (paper, printer cartridges)					
	Mail / Parcel Services					
	Meeting costs (specify)					
	Electricity / Water / other routine costs					
					<i>Subtotal F&A: Priority 1</i>	
					<i>Subtotal F&A: Priority 2</i>	
					<i>Subtotal F&A: All</i>	
	Financial Audit: Annual costs					
					<i>Subtotal Financial Audit</i>	
	Other					
	Publications (annual report, journals)					
	Outreach & communication activities					
	Legal costs					
	REC Financial reserves					
	Other (specify)					
					<i>Subtotal Other: Priority 1</i>	
					<i>Subtotal Other: Priority 2</i>	
					<i>Subtotal Other: All</i>	
					Total Annual Operating Budget: Priority 1 items	
					Total Annual Operating Budget: Priority 2 items	
					Total Annual Operating Budget: all items	

* We recommend using a simple ranking for 'essential' (this year) and 'non-essential' (this year) – 1 or 2 respectively. This will help with establishing the 'minimum budget'

** If any F&A items are provided 'in kind' – list this in the 'Comments' column but include '0' in the 'Total Cost'



ACTION 3: Identify Sources of Revenue

Identify (sustainable) revenue sources to match the operational expenses budget.

Once there is an estimate for an annual operating expenses budget for the REC, it is time to identify the sources of revenue from which to obtain the finances needed to match expenses. Although there will be many variations in sources of revenue for different committees, the basic framework is simple. There are usually four possible sources of revenue:

- 1. Institutional / Governmental budget support**
- 2. Ethics Review Fees**
- 3. Charges to research grants and contracts, projects and programmes**
- 4. Grants & Donations made directly to RECs**

In ACTION 1 of this Guide, RECs are asked to decide how to remain independent while charging for ethics review. In fact, as this basic 'revenue framework' will show, all sources of revenue that RECs use will bring their own challenges to acting independently. Each of these 4 possible revenue sources has their own potential conflicts of interest.

For example, while 'institutional budget support' may seem to provide most 'independence' to RECs, this may not be the case. In fact, there can be subtle hints from top-management and principal investigators about the need for continued income for the institution on which the REC relies. (NB. There are ways of managing this pressure, for example, by ensuring that there is at least one REC member not affiliated with institution). Similarly, deriving income from 'charging to research grants and contracts' may create a dynamic system in which RECs may be more lenient if large grants are concerned. And, finally, who wants to upset a donor who funds both the REC directly with an infrastructure grant, and then sponsors research that is reviewed by the same REC ?

The key message of this short introduction is that there are potential conflicts of interest with all of these, and other, sources of revenue for RECs. Short of taking no money from anyone and meeting in the open air, it seems difficult to not have 'potential' conflicts of interest. For that reason, it is important to consider each source carefully for possible influence, to try to maximize the 'distance' between the source of income and REC operations, to relate any income to an approved operational budget, to generate revenue from more than one source, and to provide for transparent accounting. Jointly, these measures will minimize undue influence of REC deliberations and actions.

1. Institutional Budget Support

Most RECs globally receive a budget allocation from the institution that established and 'hosts' the REC. Allocations can be 'in kind' or as a financial budget or, usually, both of these. (38) These allocations derive often from institutional charges made against research grants and contracts RECs then receive a proportion of this. This is also the case for most African RECs – which is not a very satisfactory situation as most African RECs state that financial allocations are inadequate (19). Ironically, in Africa it seems that RECs are often used by institutions to obtain income from research grants, but then do not receive an appropriate allocation afterwards.

While institutional budget support offers stability and creates a distance between research funding and ethics review, it can also have major drawbacks, including:

- *Budget support is likely to depend more on the finances that can be 'spared' from regular institutional budget for ethics review rather than on the actual needs and workloads of RECs. Certain REC activities that are essential to become more able to conduct rapid and expert review, such as those related to continuing professional education, to quality improvement or to digitizing REC operations (for example, by installing RHInnO Ethics (43-46), are least likely to be funded especially where budgets are constrained and institutional support consists mostly of allocating offices, printers and administrative time of existing personnel as an 'in kind' contribution. (18,38)*
- *There may be subtle pressure to approving studies that receive (large) external grants. This can be even more pronounced if members of an institution's top management are also a member of the REC which should, ideally, not be the case. (47)*
- *REC membership is likely to remain a 'volunteer' effort that may only attract staff unable to get their own grants or those leaving active research life. Lack of resourcing may make RECs set themselves up for perceived or actual mediocrity rather than excellence and relevance. (1,48)*

Institutional budget support – issues to consider:

The REC Annual Operating Expenses Budget should be an integral part of the host institution's budget. RECs have a major role to play in this and cannot expect that their own budget allocation will be done routinely and adequately without their explicit inputs from the REC to the host institution. Some of the key actions that RECs can take to create more understanding of their importance and get more reasonable financial and 'in kind' allocations from their host institution are the following:

1. **Ensure RECs are mandated by institutional policies and national legislation / regulations** – so they become an integral part of the institutions and institutional budgets.
2. **Educate institutional management** – provide briefs, organise an annual 'ethics review day', send interesting stories to institutional newsletters, be present on the institutional website. Design your own ways to improve communication.
3. **Produce a reasonable and timely Annual Operating Expenses Budget** – use the template produced in ACTION 2 of this Guide, or your own version that is compatible with your host institution. Make sure it reaches the Finance Office before the budget decisions for the next cycle are made.
4. **Write an annual activity report** – so everyone gets to understand workload, see what issues the REC deals with, which problems were prevented, what key issues were highlighted to national authorities, and more. Even a short, on-line document is more than most RECs currently provide!



5. **Ensure financial transparency and accountability** – in whichever way you do it, with whatever support from the institution, but make sure to generate annual financial statements that are clear, comprehensive and cover all income and expenditures. Ideally, this should be publicly available for inspection and interested parties should be able to download it from the REC's website. Send the first copy to the institution's leadership and Finance Office to build trust that money sent to the REC is well spent.

2. Ethics Review Fees

ACTION 1 of this Guide will assist RECs to decide whether or not to charge fees for the review of research projects. Once it has been decided by the REC (and approved by the host institution), the type and magnitude of review fees should be decided upon.

There are the following issues to consider when determining review fees in non-profit RECs:

1. **The amount of work to be done by the REC related to the types of study** (for example, oversight and complex studies may be more expensive than student research, continuations or amendments);
2. **The workload of the REC** – in terms of numbers of studies reviewed;
3. **Other REC activities included in Annual Operating Expenses Budget** –(for example, payments for connection to digital platforms, equipment, appointing external experts, and more); and
4. **The ability to pay by the investigator or sponsor** – in view of building up REC financial reserves that can be used for activities for which there is no institutional support (for example, cross-subsidizing low-and no-budget research, continuing education and training, and more).

Ethics Review Fees – issues to consider:

1. **Perceptions** – 'lack of altruism', 'getting rich on the research of others', 'biased reviews', and more are arguments we have heard when discussing the topic of charging for ethics review – especially when RECs begin charging. Charging for ethics review is only recently taking hold in Africa and many misconceptions and misperceptions occur without there being empirical data that any of these are true or more than anecdotal. In fact, in most settings that enable charging fees for ethics review, including USA, Europe and more recently some African countries, such as Kenya, Uganda, South Africa, Malawi and Swaziland have done so successfully without any reports of compromised ethics review – at least, as far as we are aware. (17,35,38,39,49,50) Transparency in budgeting and financial accounting, and continuing education through websites, 'ethics symposia' and other means are essential to demonstrate the increased efficiencies and competencies in ethics review.
2. **Value for money** – charging fees is likely to lead to increased expectations for accelerated review, high quality comments (not just 'approved' or 'not approved'), digital submission and review platforms that also provide guidance for submissions to make the process easier, expedited review tracks, training courses for researchers – and more. It is good practice for RECs to introduce new and better ethics services at the same time they start charging for reviews.

3. Charges to research grants and contracts

This is slightly different from charging for ethics review of individual research proposals as grants and contracts deal not only with single research projects but may be provided for programmes and projects that comprise more than one study and possibly non-research-based interventions. There are national organisations and institutions that charge a percentage – up to 10% or more of total grant value. (50) This is done sometimes under the heading of ‘ethics review fees’ or ‘research and ethics administration’ or, simply, ‘administrative fees’. This is done mostly in the context of large donor-funded programmes, industry-sponsored research and ‘external’ grants. Beware that if all RECs in a multi-site study build in capacity building support, this may make studies prohibitively expensive ! (54)

Yet, in spite of these potentially large financial charges against research grants and contracts, the RECs that are actually responsible for the ethics review of individual research studies that are part of these large programmes often do not see their budgets increased to reflect an increased work workload. This is clearly problematic, and it may lead to perceptions of abuse of funding. (35,50,51,52).

Institutions may charge more for industry sponsored research, usually as in ‘clinical trials’ (36) or by ‘waiver of research administration fee (50). As far as we are aware, none of these institutions publish annual financial statements on the funding received.

On the positive side, charging against large grants and contracts provides an opportunity to diversify REC revenue and plan for medium-term activities rather than on a ‘year-by-year’ basis. Where external funding for research is available, charges for ethics review should definitely be included as an essential part of any REC revenue plan.

Charging to research grants and contracts – issues to consider:

1. **Prepare reasonable REC budgets and publish these on the REC website** – to optimize transparency of REC finances (ACTION 2 of this Guide)
2. **Publish charges to grants and contracts on the REC website** – as mentioned in ACTION 1 of this Guide, charge for reviews not for ‘successful reviews’ and justify differences in charges, such as differences in charges for student research, sponsored research, clinical trials – each of which may require more intensive REC engagement. Include a justification for charges and differences in charges.

In general, such charges are handled in two ways:

- Usually, the charge is made by a national² or individual institution, and income received becomes part of institutional budget process. If this is the case, RECs can make legitimate claims to adequate allocations from these funds – especially when they are listed as ‘ethics review’. RECs should also insist that all funds received for ‘ethics review’ are publicly accounted for by the institution.
- Less frequently, at least for RECs in public institutions, funding is received directly by the REC. Especially in these cases, RECs should concentrate on proper budgeting and public financial accounting to help minimize undue influence from grant-holders or research sponsors.

2 A key problem with national charges are that any funds become part of national finances, government allocations and decisions – which may not support research nor research ethics. Several readers of this booklet recommend to steer away from national charges for ethics review for this reason.

4. Grants made directly to RECs

There are some grant mechanisms that specifically target capacity building of RECs in LMICs. Most provide support for short-courses, degree education of members of RECs (13) and conference participation (53). There are only very few grants in support of REC infrastructure and operations. EDCTP is one mechanism that provided infrastructure grants directly to institutional RECs about 10 years ago, but has since moved on to providing funding to national RECs only (20). The NIH still provides some grants (G11). At this time, we are not aware of other funding available to provide direct operational grants to institutional RECs in LMICs in spite of need and lack of resources, as was outlined in the introduction to this Guide.

On the other hand, pro-active RECs can engage principal investigators in their institutions to include REC capacity building and operations in a grant. This could make eminent sense, for example, in complex trials, long-term studies, international collaborative projects – as efficient and competent ethics review is essential for these studies to succeed. Many research funders and industry research sponsors can (easily) be convinced to allow inclusion of reasonable costs for REC operations as part of their grants. For example, an annual subscription fee for a web-based research ethics review platform (43-46) can easily be justified as part of any clinical trial or multi-center study. It will help all parties involved, after all. In terms of the costs of conducting clinical trials, and in terms of unnecessary costs prevented because the digital platform can substantially reduce the time between submission and approval (43,44), the costs of an annual subscription is negligible.

Direct grants to RECs – issues to consider:

- **Competitive grant-making** – is, unfortunately, also used for capacity-building and infrastructure support grants. (20) This is almost a ‘contradiction in terms’ because those without review capacity are also likely to lack grant-writing skills, may not have access to internet, or are not sufficiently able to produce a proposal in English – and are therefore likely not to end in the top few proposals that receive awards. There are some modifications to this – by reserving certain grants for certain countries, for example – but the essence of ‘competitiveness’ remains. If a REC wishes to access such grant mechanisms, and if it has not had ‘won’ grants before, it is wise to team up with people, RECs or institutions that have been successful in the past. If the REC is not sufficiently Anglophone – make sure to get a native English speaker on the writing team, even virtually, because most grants for research ethics are available in English language only.
- **Grants tend to be ‘once-off’** – so ensure that you use such grants for ‘once-off’ activities or infrastructure improvements only. There is an exception possible – for example, subscription costs for digital review platforms can be included in many grants so when one ends, the other can take over. In short, plan for sustaining any ongoing expenditures from the moment the grant has been awarded!
- **Grants may come with ‘strings attached’** – requiring the REC to undertake certain activities. This can pose risks. For example, an industry grant or even a REC allocation of a larger grant received by a principal investigator in the host institution may create undue influence on the independence of review. Even grants from bilateral, multi-lateral and philanthropic research funders may come with the same problem. While there can be legitimate expectation that funding will accelerate and improve ethics review, there should never be an expectation that review changes because of a grant. These risks should be clearly declared and reviewed during REC meetings (‘disclosure’), and appropriate measures taken (and even published on the REC website). RECs should clarify what they consider ‘(potential) conflicts of interest’ and state how these will be handled.

ACTION 4: Generating Revenue to match Operating Expenses

A simple Revenue Plan consists of listing the possible sources of revenue and making a realistic estimate of how much income can be reasonably / legitimately be generated from each source.

When the revenue plan begins to exceed the Operating Expenses Budget for the year, care is required: RECs are not profit-making bodies (unless it is a 'for profit company', of course). If there is more revenue than there are operating expenses, it is possible to re-budget the Operational Expenses Budget to include costs that were lower priorities. You can also reduce revenue. Or, as we suggest, you consult within the REC and with the finance administration of the host institution on what to do. Of course, this would be a nice problem to have ... too much rather than too little ... but it does happen!

The easiest way to prepare the revenue plan for the year or for multi-years is to use the same framework as the REC Operating Expenses Budget (ACTION 2 of this Guide). When using a spreadsheet, one can simply have "sheet 1" as the Operating Expenses Budget and "sheet 2" as the Revenue Plan.

Determining the (Annual) Revenue Plan for a Research Ethics Committee

[NAME of REC]

Year / Years:

Prepared by:

1. Summary of Revenue Requirements

	Annual Operating Expenses Budget : Priority 1 items
	Annual Operating Expenses Budget : Priority 2 items
	Annual Operating Expenses Budget : All

NB 1. You can provide more detail by listing the 'Priority 1' and '2' items for each of the budget categories (such as 'human resources', 'Facilities and Administration', etc). In this way, you can possibly find specific sources for specific costs ... instead of just trying to get one total budget.

NB 2. For the Revenue Plan, ignore 'in-kind' contributions as it is not needed to raise actual income to pay for these. (Should you want to calculate REC costs 'comprehensively' – then you will need to include the 'in-kind' contributions as well and add this to the Revenue Plan).

2. Potential Sources and Amount of Revenue - See the table on the next page – as a simple template to estimate revenue for the year or for a longer period.



Preparing the (Annual) Revenue Plan for a Research Ethics Committee

[NAME of REC]

Year / Years:

Prepared by:

Nr	Category	Total Amount [Currency]	Year 1	Year 2	Year 3+	Comments
	Institutional REC Budget Support					
	National REC Budget Support					
	<i>Sub-total</i>					
	Ethics Review Fees					
	Fee level 1 x Nr of Reviews					
	Fee level 1 x Nr of Reviews					
	Fee level 1 x Nr of Reviews					
	etc					
	<i>Sub-total</i>					
	Charges to Grants and Contracts					
	<i>Sub-total</i>					
	Direct REC Grants					
	<i>Sub-total</i>					
	Other revenue sources					
	Donations					
	Direct Support from Other Entities					
	<i>Sub-total</i>					
	Total Revenue Expected					
	Total Budget Required					
	Excess / Shortfall					

ACTION 5: Transparent Financial Reporting for RECs

Transparency builds trust, mutual understanding and respect, and makes people feel that they are working for an organisation with high ethical standards. Lack of transparency, on the other hand, can result into mistrust and encourage misappropriation of funds. That is why transparent financial reporting is a “must” for public and private sector in general, and for RECs in particular. If there is anything that can be expected from a REC is that its own conduct is ‘ethical’. Transparent financial reporting is key to achieving this.

Transparent financial reporting for RECs – issues to consider:

- *How to set up for ‘transparent financial reporting’?*

RECs usually do not have (extensive) financial management skills, they were not set up for this, unless they are private sector RECs (for-profit or not-for-profit) which are probably subject to national tax reporting. They may produce their own ‘annual financial statements’ and require ‘external financial audits’ of these statements.

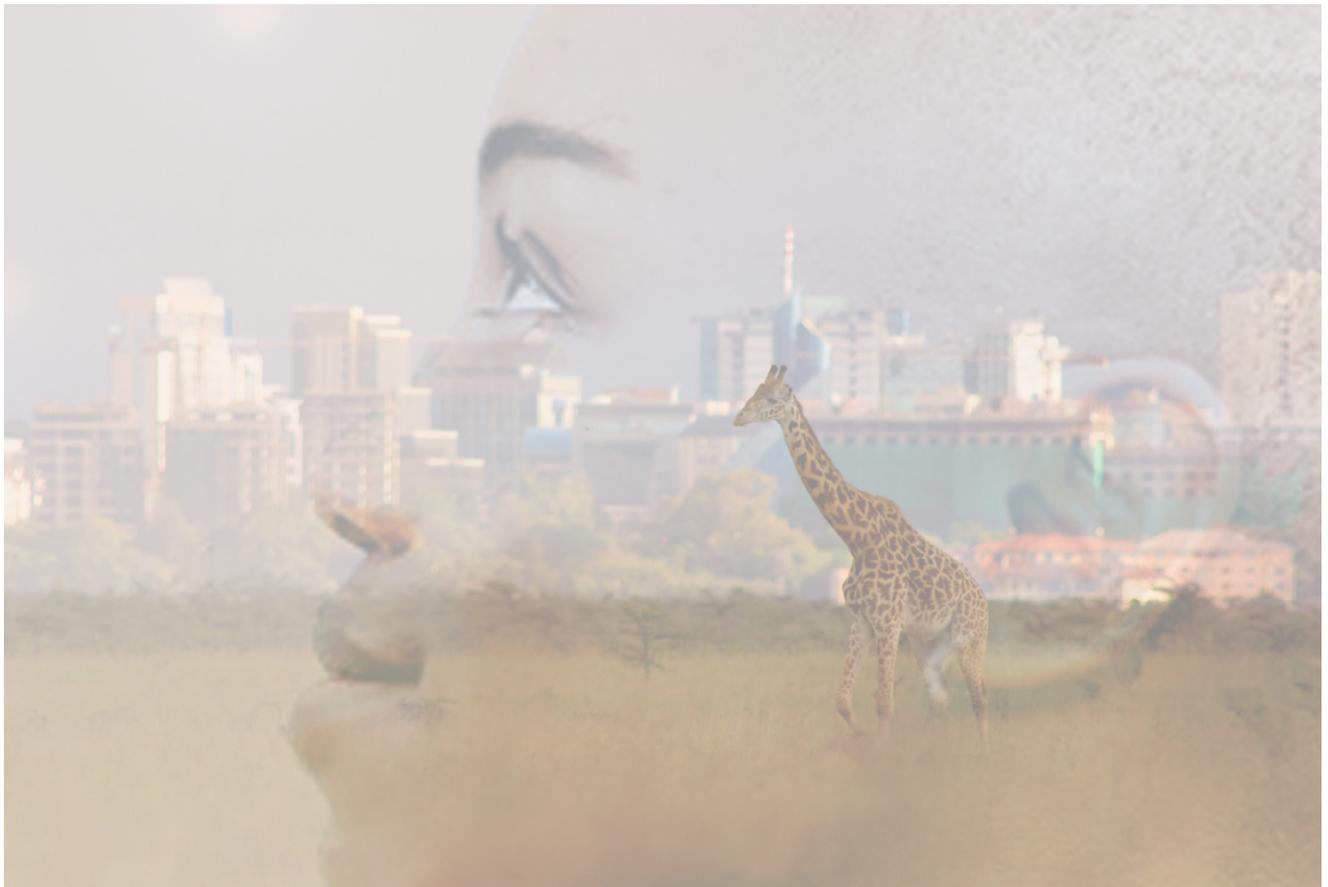
RECs that are hosted in research or academic institutions or organisations do not normally have their own financial officers nor do they have access to and support from the finance officer of the institution, certainly not in the public sector. Institutional RECs are not usually considered as ‘cost-centers’ and rarely, if at all, produce financial reports.

One key message of this Guide is to encourage all RECs to provide basic financial reporting – even if they only receive revenue from the institution which they serve. The case for financial reporting becomes much stronger if RECs also receive grants, allocations of grants, review fees, or other sources of income – and especially if payments are made directly to the REC. For those situations, preparing annual financial statements should be considered an essential and routine activity of the REC.

This Guide is not a financial management tool, therefore we limit the discussion to pointing out three levels of ‘financial reporting that can be used by RECs:

1. *A ‘basic financial report’ contains income and expenditure information, and explains where the ‘excess income’ comes from and how ‘shortfalls’ will be covered by reducing activities. This can usually be done by the Research Ethics Committee Administrator (RECA).*
2. *A more comprehensive ‘annual financial statement’ follows the format of an accepted “good accounting practice standard” and prepares an appropriate balance sheet to which management comments are added by the REC Chair. To prepare this requires someone with training in bookkeeping or accounting. All institutions receiving grants have financially trained personnel – and their services should be available to the REC, especially if institutions have charged ‘ethics and administration fees’ against these grants. RECs should insist on getting support to prepare annual financial statements.*
3. *At the highest level, these ‘annual financial statements’ are audited for accuracy and comprehensiveness by an ‘external auditor’. Especially RECs receiving grants directly, charging fee for reviews and handling their own finances should be required to get such external financial audits. External financial audit is usually done at the institutional or project / programme level, and it needs to be budgeted for because it is a legitimate operational expense. RECs that charge against research grants and contracts can also ask and budget for a sub-audit of their REC accounts so the annual financial report and external audit can be produced automatically every year.*

- *Who should see the financial reports?*
 1. *The primary target for the financial reporting is the REC itself – so it can understand progress, point out new budget requirements, place emphasis on certain activities, and see that resources are well spent and fairly distributed.*
 2. *The second “audience” for the report is top management and the financial management of the institution in which the REC is hosted. This will ensure continuing oversight, improved understanding of the REC work and its relevance for the institution, and may help convince the institution to provide more sustainable institutional support.*
 3. *Thirdly, users of the REC services are also the ‘payers’ if the REC’s revenue includes not only institutional contributions but also fees, charges and grants. For that reason, it is good practice to publish the REC financial report and make it available to users who wish to see it, for example through the REC website. It is also important for external stakeholders to check for potential conflicts of interest. Although still rarely done, this Guide encourages RECs to make annual financial reports available to anyone requesting it to maximize transparency, accountability and to engender trust.*
 4. *There may be other reasons for reporting and other interested parties depending on the specific REC. For example, Ministries of Health may require annual reporting to trace potential undue influence at national levels; other Ministries may require institutions that receive external funding to keep track of income and expenditures; or in private RECs, the directors may wish to see annual reports, including externally audited financial statements.*



Appendices

Appendix 1.

Information on revenues for RECs in West Africa. (36)

Countries	Support from government or national structures	Billing from protocols analyses	Support (projects, donor)
Bénin	Registration of a line of 20 million Fcfa, difficult to mobilize	<ul style="list-style-type: none"> • <i>Student: Free</i> • <i>Project with a budget from 0 to 18 182 USD: 545USD</i> • <i>Project with a budget higher than 18 182 USD: 900 USD</i> 	<ul style="list-style-type: none"> • <i>EDCTP Funds</i> • <i>Project Canadian funding</i>
Burkina Faso	Budget line of 20 Million Fcfa by the ministry of health	Payment directly to the public treasury: <ul style="list-style-type: none"> • <i>National Centers: 364 US\$</i> • <i>International organizations: 900 US\$</i> 	
Cap Vert	State-presence fee of -50 Euros (approx. 32 798 Fcfa) for each members of the secretariat	No payment for the revision of a protocol	Funders-Institute of Bioethics of Porto (UNESCO Chair) -Trainings
Côte d'Ivoire	No direct support from the government	<ul style="list-style-type: none"> • <i>Student: 100 US\$</i> • <i>NGOs and National Investigators: 545 US\$</i> • <i>NGOs and international institutions: 900 US\$</i> 	<ul style="list-style-type: none"> • <i>Approach to equip committee</i> • <i>Supervision visit financed by the project teams</i>
Gambie	MRC Gambia provides support for the functioning of the secretariat and gives transport costs to the members of the committee.	No payment for the revision of a protocol	Existence of financing of European commission
Ghana	Ghana health services finance the administrative costs	<ul style="list-style-type: none"> • <i>Clinical trials: 821 US\$/ Protocol</i> • <i>Biomedical, epidemiological research: 136 US\$</i> • <i>International students: (PHD: 82 US\$, international master: 54 US\$)</i> • <i>Local Master: 13 US\$</i> 	Support for partner training
Guinée	No direct support from the government	<ul style="list-style-type: none"> • <i>Protocol: 364 US\$</i> 	<ul style="list-style-type: none"> • <i>WHO Support</i> • <i>EDCTP Financing</i>

Countries	Support from government or national structures	Billing from protocols analyses	Support (projects, donor)
Guinée Bissau	No direct support from the government	<ul style="list-style-type: none"> Urgent review: 450 US\$ Normal review: 364 US\$ Re-Submission: 131 US\$ 	WATENAM, OOAS Support
Mali	Government (Amount received in 2014):83,156 million Fcfa for the CNESS	<ul style="list-style-type: none"> 900 US\$/ Project 	<ul style="list-style-type: none"> AMANET Project CE/ FMPOS: 25 000 euros NIH/NIAID workshop: 30 000 US\$ Tree for Africa/EDCTP workshop: 10 000 euros
Niger	Existence of a research support line that supports the committee's activities	<ul style="list-style-type: none"> Student: 0 US\$ Others: 220 US\$ 	Existence of support from certain partners
Nigeria	Existence of a budget line	<ul style="list-style-type: none"> Existence of protocol review fees 	<ul style="list-style-type: none"> NHERC received CDC USA funding in 2012, 2013, 2014 NIH Support 2012 and 2013 EDCTP support 2008/2009
Sénégal	No direct support received from the government	<ul style="list-style-type: none"> Local Students: 0 US\$ International students and independent researcher: 131 US\$ Institutions: 450 US\$ 	<ul style="list-style-type: none"> EDCTP Funds COHRED project
Sierra Leone	No direct support received from the government	<ul style="list-style-type: none"> Ministry Projects: 0 US\$ Local Student: 20 US\$ External Student: 200 US\$ Others bidders: 500 US\$ International institutions: 1500 US\$ 	
Togo	No direct support received from the government	<ul style="list-style-type: none"> Students: 0 to 100 US\$ Pharmaceutical firms: 1173 US\$ NGOs: 900 US\$ Research institutions: 450 US\$ Physical researchers: 364 US\$ 	EDCTP Financing

Source:

Appendix 2.

Instituting or Changing Fees for Ethics Review – Check list

Instituting a fee-for-review charge, or changing existing fees or fee schedules, can meet with resistance if it is not well thought through and is not done transparently and with inclusion of future users and other stakeholders. It is advisable that the REC first decides on the need for revenue, on the affordability of the new fees for users and on institutional and national legislation or policies related to charging fees for review – and only then prepare a reasonable budget and revenue plan.

Here is a checklist of Actions to take:

1. **Confirm that the REC may charge fees for review, decide to begin the process, and publish this process well in advance** on the REC website (or via other means of communication available). (ACTION 1 of this Guide)
2. **Prepare an Annual Operating Expenses Budget** (ACTION 2 of this Guide) – and present this for review, comments and approval to the institution and on the REC website.
 - Consult widely to identify which budget costs are deemed critical for optimal operation of the REC.
3. **Identify potential sources of revenue** (ACTION 3 of this Guide)
 1. Institutional budget support
 2. Ethics Review Fees
 3. Charges to research grants and contracts
 4. Grants made directly to RECs
4. **Prepare a Revenue Plan** (ACTION 4 of this Guide)
 1. Decide on fee schedule to implement – based on:
 1. The amount of work to be done by the REC related to the types of study
 2. The workload of the REC – in terms of numbers of studies reviewed
 3. Other REC activities included in Annual Operating Expenses Budget
 4. The ability to pay by the investigator or sponsor
 2. Consult widely again: present proposed fees and fee schedule for comments, make appropriate changes, and inform stakeholders about these changes –using the REC website.
 3. Clearly communicate the fees and fee schedule (on the REC website) and any changes that are made in future.
5. **Provide and publish an annual financial report** (ACTION 5 of this Guide) to maintain transparency and accountability and to promote public trust and integrity.



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Reviewing fees should provide financial sustainability!

"The key message of this Guide is therefore that RECs should seriously consider including review fees to achieve sufficient and sustainable financing (...).

If national (or other) legislation or regulation does not permit this, then it is probably time for RECs to begin discussions with their institution, or combine efforts to begin discussions with regional or national government."

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