Research Authorization Processes: A Descriptive Comparison of Kenya and The United States of America

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Abstract

Obtaining research authorization to ensure compliance with ethics regulations is critical for those seeking to conduct research. Consequently, the primary objective of this study was to closely examine information regarding review boards and review processes that a researcher would encounter during the process of preparing and submitting a proposal. Information posted about the review process from two similar universities, one in the USA representing a localized review process and one in Kenya representing a centralized review process was analyzed to address two key questions, "How well does each system support the successful approval of the researcher in preparing a proposal," and, "How might the strengths of each system be used to improve the other to better support increased research for all?" Methodology focused on using key features related to five questions a new researcher might ask when preparing and submitting a proposal: What structure governs the review process? What is the composition of the review board? What does the research approval process involve? What information and documents are required for submitting a proposal? What evaluation criteria are used to ensure fair and consistent review of research proposals? Side by side comparative charts of key features related to each of these questions was used for the analysis. It was concluded that both systems supported the approval of ethical research and that both institutions adhered to their respective government's research ethics policies. The biggest differences in the two systems related to the actual information provided by the institution to guide proposal development and submission, ethics training provided to researchers, costs, and timelines. The most significant weakness for both institutions was lack of information regarding specific criteria used for evaluation of proposals. Consequently, four recommendations were made. First, a supportive and positive relationship needs to exist between the review board and researchers. Structural elements that create an adversarial rather than cooperative relationship need to be identified and eliminated in order to provide collaborative support. This is particularly important for novice researchers. Second, providing or developing ethics training for researchers has the potential of reducing frustration for those preparing a proposal and increasing the quality of submissions to the review board. Third, while there is cost associated with research review, placing the burden of this cost on individual researchers can be detrimental to promoting research. Governments and institutions need to consider the value of research and find ways to reduce or eliminate personal costs to the researcher. Finally, it is imperative that review boards provide current, accurate, and complete information regarding proposal preparation and develop rubrics that result in transparent evaluation and useable feedback for the researcher.

Keywords: **Research Authorization, Institutional Review Board, Research Permission, Research Regulation, Research Oversight, Localized Review Boards, Centralized Review Boards**

Introduction

International guidelines for human subject research approval processes required in countries around the world can be traced directly to the scientific community's reaction to instances where research harmed participants in the name of science (Miller, 2016; Faden, 1994). In an effort to prevent future abuses, an outline of ethical requirements was first codified in the 1947 Nuremburg Code and later modified in the 1964 Declaration of Helsinki (WMO, 1996; Anesthesiol, K.J., 2012). Because of the international and cooperative process employed in developing these documents, they have served as the basis for the laws which individual countries have passed regarding required research authorization. Consequently, the core content of policies governing research review are similar from country to country. However, despite these similarities, the experience of researchers who seek approval can be very different due to policy and procedural factors specific to each country.

For example, stringent research review measures have been put in place to protect human subjects in the East African Countries of Kenya, Rwanda, Uganda and Tanzania. However, excessive regulatory and legislative oversight has resulted in a "significant amount of red tape, frequent delays, increases in the cost of conducting research, lost opportunity costs, stale findings, and frustrated researchers" (Petrova & Barclay, 2019). While there is agreement on the need for independent oversight, much needs to be done to address system complexity, eliminate redundancies and inefficiencies that consume resources and delay research, and keep the review process focused on core ethical issues (Infectious Diseases, 2009). How these processes are carried out is critical for graduate students, their supervisors, faculty at institutions of higher learning, and others who are attempting to conduct research. Challenges in obtaining authorization can impact completion of graduate degrees, interfere with applications for grants to support research, restrict private sector involvement in scientific research and innovation, and delay lines of research that further knowledge exploration across fields of study.

In addressing the need for ethical yet efficient research review, one area of discussion has focused on examination of localized and centralized review systems (Moon, 2009). In countries, such as the United States, where local review boards are allowed, the review process takes place within the institution where the research is conducted. A single level of institutional approval is required before research may begin and researchers are accountable to their institution for any subsequent changes to the approved research protocol.

In contrast, a centralized review process requires approval from an entity outside the institution before a study can begin. In East African countries, a government agency, such as Kenya's National Commission for Science, Technology & Innovation (NACOSTI), holds this authority. In an effort to capture some of the advantages of a localized review process, they may delegate part of the review process to research institutions. However, doing so results in a stepwise process for researchers to navigate as they must then seek approval at different levels before gaining final approval from the centralized authority to begin their study.

In undergoing the process of obtaining approval to conduct a study, researchers require a significant amount of information. They need to have a good understanding of the structures that govern the review process and have confidence in the ability of the review board to fairly evaluate their proposal. Procedurally, they need to understand the research approval process that they must go through and specifically what information and documents are required for submitting a proposal. Furthermore, they need to understand

the criteria that will be used to determine whether they will obtain approval so that their proposal has a strong chance of being approved. Universities who host a review board should communicate this information to potential researchers effectively and efficiently if the scientific community and individual governments wish to support and promote research.

The purpose of this paper is to examine these elements in the context of information provided by review boards to researchers seeking approval for their proposals. The perspective of a new researcher is used to analyze the guidance provided to researchers as they seek approval for proposed studies under each system in an effort to address the core questions, "How well does each system support the successful approval of the researcher in preparing a proposal," and, "How might the strengths of each system be used to improve the other to better support increased research for all?"

Methodology

Subjects

Two similar sized universities offering undergraduate and graduate programs in a range of areas, one in the United States of America (Shepherd University) and one in Kenya (Daystar University), were selected as representative of their respective systems. United States policy allows for localized review and Shepherd University is an accredited university conducting research approved through this process. In contrast, Kenya requires a two-step centralized review. Daystar University has been a leader in the country with a well-established government-approved review board that supports researchers throughout the country. In addition to their respective ability to represent localized and centralized review processes, these two universities were selected for comparison in this study because they share many characteristics thus providing validity for a comparison of the two research approval systems.

Both universities rely on student tuition for a significant portion of their budget and neither relies heavily on funded research grants to remain fiscally solvent. Both institutions expect teaching faculty to be actively engaged in scholarship (research, publishing, and professional presentations) for promotion, but faculty have heavy teaching loads of at least 12 credits per semester leaving little time for research. At both institutions, student researchers are linked to a supervising faculty member. Daystar has significantly more graduate students engaged in research. However, all Shepherd undergraduate students are required to complete a capstone project for graduation. For many majors, this project involves research requiring review and approval. No undergraduate majors at Daystar require research. Consequently, the potential total faculty and student research being conducted at each institution is similar.

Data Examined for Comparison

Researchers rely on information provided from the review committee to prepare and submit research proposals. Consequently, each university's review board webpage was accessed as a new researcher would do under each system (Shepherd, 2022a; DU-SERC, 2022). All links provided on the review board webpage were opened and, where applicable, additional links were followed so that all posted information related to the review board and procedures governing the submission of a new proposal was included as data to be described for each system. In addition, a single email was sent to a member of each university's review board requesting any additional relevant materials the institution had available that might not be posted.

The contacted committee member from each review board responded and the content of their response along with attached documents and links were also included in the data analyzed to describe each and compare factors involved in the two research review processes.

Analysis

The analysis of data was organized around guiding questions proposed prior to examination of posted information. Features relevant to each question were identified and information available on each feature was extracted for direct comparison. Charts identifying each feature were prepared and as information available was analyzed, information relative to each feature for each university was entered into the chart. This process provided support for both describing characteristics of each feature for each university as well as for comparing features between the two universities. In some cases, the analysis of available data brought new information to the attention of the researchers. Where this occurred, additional features were added to the charts to promote consideration of these factors. The following discussion is organized around the five key questions asked regarding each university's review process.

Results

What Structure Governs the Review Process?

Each university represented one of the primary types of review boards, localized or centralized. Other aspects of the board structure include who has oversight, who is served, cost, and who is required to obtain a review. Each country provided a different context on these factors as shown in Figure 2.

Figure 2 Research Approval Structure

	SHEPHERD - IRB	**DAYSTAR - ISERC**
Locus of Approval	Shepherd Administered*	Accredited by NACOSTI
Oversight	Reports Provided Annually from the University to Federal Agencies Showing Adherence to Policy. Violation is Linked to Potential Fines, Loss of Government Funding, and/or Overall Institutional Accreditation	NACOSTI Delegates Responsibility to the ISERC Housed at Daystar – Annual Report to NACOSTI is Required and Accreditation Must be Renewed Every 3 Years
Who is Served	Only Shepherd Faculty and Students	Any Kenyan Researcher
Cost	Free to the Researcher	1,000 KSh Undergraduate to 37,500 KSh Institution
Who Must Seek Review	Faculty or Students doing any Research that Involves Humans or Vertebrates Can apply for review exemption under some circumstances.	Anyone Conducting Research of Any Type No one is exempt from applying.

** Shepherd has separate committees reviewing human research and invertebrate research. Because their functions were parallel and similar processes established under Federal policy were in place, this study focused on an in-depth analysis of the human subjects committee alone.*

As with all localized review boards, the Shepherd Institutional Review Board (IRB) is accountable to Shepherd University. However, the university is accountable to the federal government for ensuring that all research-related regulations and policies are adhered to in research conducted by its faculty and students. A lengthy document was provided on the university website which included links to federal policy and federal offices that the university reports to annually (Shepherd, 2022b). While the IRB chair was responsible for maintaining records that the university could use in their reports, the IRB had no direct responsibility for preparing or submitting reports to the federal government thus maintaining a level of independence in their approval decisions. However, this independence was balanced with a substantial level of pressure to reject any proposed research that could negatively impact the university's standing and lead to serious outcomes for the institution. Any proposed research being done collaboratively with another institution was only accepted for review if the other institution's review board also approved the research, holding both institutions equally responsible for adhering to federal regulations (Shepherd, 2022b).

Shepherd considers the review process as an essential service provided to faculty and student researchers who contribute to the reputation of the university through their scholarly activities. Consequently, there is no cost to these researchers for submitting a proposal; the IRB relies on individuals who volunteer their professional service to the institution. For faculty serving on the IRB, membership contributes towards meeting employment expectations for professional service.

The centralized system is quite different. In Kenya, all research institutions are expected to set up an Institutional Scientific and Ethics Review Committee (ISERC) that is accredited by NACOSTI (NACOSTI, 2017). However, not all institutions have their own ISERC and policy allows a host ISERC to serve multiple institutions. Furthermore, researchers may apply for ethical clearance from any accredited review board. Thus, responsibility for fulfilling NACOSTI's mandate for assuring quality research is delegated to accredited committees like the Daystar ISERC with responsibility for final licensing of the research remaining with NACOSTI. No links to NACOSTI and no information regarding the country's policy was available on the Daystar ISERC website. Furthermore, the NACOSTI website was under construction at the time of the review which required an internet search for an older document that could provide necessary information about government policy.

The Daystar ISERC must renew its accreditation every three years and submit an annual report to NACOSTI. Daystar recovers expenses associated with maintaining accreditation, generating reports, and reviewing research through charges assessed to applicants. The fee schedule is adjusted depending on the status of the researcher as student/non-student and member/nonmember or the status of the institution. Beyond a statement addressing "areas of review, which caused difficulty for the committee in making a decision" (NACOSTI, 2017), no direct monitoring of ISERC decisions was noted by either NACOSTI or Daystar in published information.

From the perspective of a novice researcher seeking review, being in-house is an advantage because it is easier to establish dialog regarding questions with known associates who serve on the review board/committee. However, the localized system of Shepherd restricts access to anyone who is not faculty and staff leaving independent researchers without recourse. The localized system is also more fiscally supportive. As has been noted by many researchers in Kenya, the fees assessed by both ISERC and

NACOSTI can repress potential research due to lack of funds. This is especially true when approval is needed to apply for research funding, but funding is needed for the review fees.

A final point was exemption from review. In Kenya, all research must undergo review. However, at Shepherd only human and invertebrate research requires review. No information about review for other types of research was available on Shepherd's website which explicitly lists criteria for research eligible for exemption. For example, "Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content" (Shepherd 2022b). Such exemptions are based on Federal policy. IRB approval of exemption from review does not remove the requirement for informed consent and protection of participants. No information regarding possible exemption from review in Kenya was available on the Daystar ISERC webpage.

What is the Composition of the Review Board/Committee?

Board/committee membership was easily found for both institutions. The name and background of each member was listed on the respective websites. Likewise, the policy dictating the make-up of each group was easily found. Shepherd's policy manual outlined both federal and institutional policy regarding membership. Daystar did not provide information or links regarding government policy dictating the make-up of the review committee. The NACOSTI website was temporarily unavailable at the time of this study because guidelines were being revised, but previous guidelines were easily found through an internet search. The current composition of each group is shown in Figure 3.

Figure 3 Composition of the Review Board/Committee

	SHEPHERD IRB	DAYSTAR
Review Board Composition	Human Subjects Committee Federal Minimum of 5 Voting Members from Following 4 Categories: • Scientific Researcher • Non-Scientific Researcher • Psychology or Counseling Expert • External Individual Appointed by University President Shepherd Requires 8 Minimum • Representative from Each University College Voted on by colleges. Committee May Invite Expert as Nonvoting Advisor to Review Complex Issues Members Must Complete Ethics Training Course.	Chairperson with Basic Training and/or Experience in Research Ethics At Least 7 Members (If more, must be Odd Number). • 1 Member Must Know Kenyan Law • 1/3 of Either Gender • At least 1 External Member • At Least 2 Research Experts • At Least 1 Lay Person • Reflect Regional and Ethnic Diversity of Kenya Daystar has Representatives from the Following Bodies: • Religious • Medical • Clinical Daystar has Both: • Internal Members External Members

Current Number	8	19
Current Number	8	19
Length of Appointment	3 Year Terms Staggered to Ensure Continuity of Committee	3 Year Term

The composition of the board/committees were remarkably similar in both systems showing concerted effort to take advantage of the background, expertise, and experiences of a wide range of professionals. It was notable that both institutions went beyond minimum requirements for membership. Shepherd required at least three more members than required by federal regulations and Daystar had 19 members, well beyond the required seven. Shepherd requires IRB members to complete human subject research training from an independent organization. No specific training was indicated for Daystar ISERC members.
Inclusion of reviewers independent from the institutions was required by both countries as a check against institutional bias and Shepherd policy explicitly required board members to recuse themselves from review of their own research.

From a researcher's perspective, one fear is whether the individuals reviewing proposed research will have the specific background knowledge necessary to fairly evaluate their submission. Knowing the background and, in the case of Shepherd, the additional training of members provided confidence that members had necessary expertise.

What Does the Research Approval Process Involve?

Understanding the approval process is of key interest to researchers because review is based on successful application. Figure 4 provides information available from each institution regarding this process.

Figure 4 Research Approval Processes

	SHEPHERD - IRB	**DAYSTAR - ISERC**
When Submitted	Before Beginning Research.	Before Beginning Research
Initiation Step(s)	Access Instructions and Download Fillable pdf From Institution Website. Complete Online Ethics and Regulations Course: CITI Training	Access Submission Portal on Institution Website
Submission Method	Submit Cover Sheet and Application (Fillable pdfs) and Accompanying Materials via Email to IRB Chair.	Complete required fields on 5 tabs within the Thesis Management System which includes uploaded Application form (word) and Accompanying Materials Reference Number of Application Receipt provided "within reasonable time"
Submission Process Details	Submit 10 Days Before the Meeting.	*Submit by 15th Day of Preceding Month.

	IRB Meets Once a Month Excluding May-August	ISERC Meets Frist Friday of every Month except January
Member Reviews	Chair Sends Proposals to Committee Members for Review as Received	Plagiarism Check is Run
Board Meeting	Committee Meets to Discuss/Vote on Proposals Clarification May be Sought	Committee May Seek Clarification PI Responds Within 14 Days After Reminder File is Closed at 21 days
Notification	Chair Sends Letter in a "Timely Manner" of Decision Concerns to Resolve Provided for Reapplication if Needed	Typically, 21 Days from time Reviewers are allocated Protocols
Next Steps - Approved	Researcher Free to Begin	*Submit Proposal to NACOSTI at Extra Cost for Research Permit and Authorization

**Information not posted online but received upon request to a committee member.*

Both institutions clearly indicated that research could not begin until approval was received. While frustrating for researchers, retroactive approval is understandably not allowed by either system. The means for submission was clearly specified on both websites but very different. Shepherd simply directed researchers to email all required documents to the Shepherd IRB chair resulting in a somewhat informal submission process that did not ensure that all requirements for submission had been met. In contrast, Daystar had a well-designed submission portal with advancing pages, fillable fields, and an upload button for each required document. However, this system did not contain procedural information regarding the actual review process following submission and much of the information indicated in figure 4 was found in a policy document provided by the IRB member contacted rather than posted on the website. This document preceded the development of the submission portal which caused some confusion as the document contained outdated information and formatting impacted comprehensibility in some places.

Additionally, neither system provided a means for a researcher to track the progress of a submitted application. Shepherd's documentation indicated that each application is reviewed by every member of the IRB. How an application is allocated to ISERC members and how many members review each proposal was not provided on the Daystar website making the actual review process relatively vague.

Shepherd's process supported researchers on a tight timeline during the academic year with submissions due 10 days before a scheduled review meeting. However, the lack of meetings from May to August was problematic as there is little time to conduct research during the academic year for faculty with heavy teaching loads.

While the Daystar website indicated that review typically took 21 days after a proposal was allocated to board members, no information was provided regarding how much time would typically pass between submission and allocation. Additionally, no information was provided regarding how many board members reviewed a submission or what role the monthly committee meeting played in approval decisions.
Timelines are often critical for researchers and expedited review was addressed by both institutions. At Shepherd expedited review takes 14 days and is only possible for proposals deemed by the chair to pose minimal risk. For expedited review only three of the eight committee members review the proposal and

submit their votes independently without discussion to the chair. If any member has concerns, then the proposal reverts to a full committee review at the next board meeting. At Daystar, posted prices were given for an expedited review with the information that such review would be appropriate for emergency circumstances or when a deadline necessitated an answer in less than 21 days. Thus it could be inferred that a researcher would have an answer within 21 days if they paid the extra fee.

Prior to review, Daystar's ISERC runs a plagiarism check before beginning evaluation of the proposal. Shepherd has no similar mechanism for determining whether the writing of the proposal is the unique work of the researcher(s). Other than the plagiarism check, no information was provided by Daystar regarding the actual review process.

If questions arose during review, both institutions had a process for seeking clarification. Shepherd's process appeared to be very flexible. Daystar, however, would close the file at 21 days if the researcher did not respond to the query or a reminder. It was understandable that a file could not be left open indefinitely, but the strict timeline for response left little recourse other than paying for resubmission after this deadline. One unique element at Shepherd was the requirement for the researcher to complete the same ethics training required of IRB members. A number of organizations offer this training; Shepherd pays a flat fee of $4,000 per year for all employees to do the CITI training program (CITI, 2022). Consequently, there is no cost to researchers. The course involves 15 self-paced asynchronous modules on subjects including the history of ethical principles, federal regulations, informed consent, confidentiality, specific subject populations, and conflicts of interest. Certification rests on achieving acceptable scores on embedded quizzes about video vignettes demonstrating correct and incorrect application of each module's content. Such training ensures that researchers resolve potential problems in their research that might prevent approval. Training was not required by government policy, so it was commendable that Shepherd was committed to developing well-informed researchers by requiring the training at no personal cost to them.

Once approved, Daystar researchers had an additional mandatory step, submission of approved research to NACOSTI for a research permit. This requirement was clearly indicated in the submission portal. In contrast, Shepherd researchers could begin immediately with one caveat involving a proposal linked to a grant requiring university resources. In these cases, a separate university committee had to approve use of resources in the approved research before a grant proposal could be submitted.
While not part of the initial review process, it should be noted that researchers at Shepherd must have ongoing research reviewed by the IRB each year and file a final closure report with the IRB when an approved study has been concluded. The ISERC did not appear to have responsibility to ensure that approved protocols were followed once research began. Such monitoring rested with NACOSTI.

What information and documents are required for submitting a proposal?

At the heart of a submission is the information provided so that an informed decision regarding approval can be made. Information and documents required for submission to each institution are shown in Figure 5.

Figure 5: Contents of the Submission

SHEPHERD	DAYSTAR
Cover Sheet • PI Contact Information • Project Title • Type of Application • Funding Agency • Subject Description and Degree of Risks Application • PI Name • Project Title • Statement of Purpose • Subject Selection Criteria • Experimental Procedures • Risks and Benefits • Subject Confidentiality Procedures Consent Forms Measurement Instruments Participant Recruiting Ads (If Used) Forms Shared with Participants (Copy of Each) Valid CITI Training Course Certificate for EACH Investigator (or Faculty Sponsor for Students) School System Approval (if Applicable)	Personal Information • PI Contact Information Institutional Affiliation Payment: MPESA Code or Bank Slip Attachments • ID/Passport • Proposal (Contents not Specified online) • ERB Application Form ○ Administrative Information ○ Project Description which included a summary of the research, the research question, recruitment, informed consent processes, methods and analysis, confidentiality and a number of potentially applicable elements. ○ Appendices which may include: 2 copies of research proposal, payment receipt, Copy of ID/Passport, Recruitment Documents, Screening Devices, Consent Documents, Research Instruments, Debriefing Forms, Permission Letters, Support Letters, Informed Consent Forms • Supervisor Approval

Both systems required researchers to provide a significant amount of information regarding the proposed study. For Shepherd, guidelines for this information were included in the application cover sheet and the 28-page IRB Policy Manual linked directly to the IRB webpage. The one area of information not immediately available was the link to the required CITI training. Researchers were directed to email the IRB chair for this link.

For Daystar, the submission portal provided fields to be completed and upload tabs for specific required documents. Two of these documents were of particular interest. First, the ISERC required upload of the research proposal, however, no information regarding proposal requirements was provided. However, the ISERC committee member asked to provide any additional information not posted provided an 18-page document that predated the upload portal. This document indicated that it should include the following sections: Scientific Design, Conduct of the Study, Problem, Justification and Objectives, Methodology, Predicted Risks, Use of Controls, Withdrawal and Termination, Monitoring and Evaluation of Research Conduct, Site Specifics and How Results will be Disseminated, Recruitment and Training of Research

Assistants, Recruitment of Research Participants, and information on the Care and Protection of Participants.

The second ISERC document of interest was the application, a word document linked to the submission instructions, to be downloaded, completed, and uploaded to the 'attachments' section of the portal. This form consisted of three sections. The administrative information section required information on the research team, degree programs, supervisors, other reviews, and funding. The project description section required a summary of the proposed study, the research question, information about recruitment of participants, how informed consent would be obtained, study methods and data analysis, provisions for ensuring the privacy and confidentiality of participants, a risk/benefit analysis, and other areas that may or may not be applicable to the proposed study. It also required a signed declaration of the truthfulness of the information provided. The final section was for appendices which included a checklist of potential items to include and the direction to append all relevant materials to the application document.

It was noted that information and documents in both systems had a significant number of redundancies. For example, both systems required principle investigator contact information in multiple places. The most significant redundancy occurred in relationship to the Daystar ISERC application. Some of the overlap appeared to be a leftover artifact from a previous hardcopy submission process. For example, the application suggested that the appendix section include '2 copies of the research proposal.' With an electronic submission, especially one that included a tab for a required upload of the research proposal, directions to include 2 copies did not make sense. A potentially more significant redundancy exists regarding the overlap between the project description section of the application and the required proposal. Almost all proposal sections indicated in the outdated policy document were included in the application making one wonder about the need for both documents.

Aside from redundancy of information, the use of a standard form with specific questions on the ISERC's application provided significant support for ensuring that a researcher included all information necessary for the committee to fairly evaluate the proposed research for approval. While not quite as prescriptive, the Shepherd IRB guidelines provided similar guidance for ensuring that the board had the information necessary to make a decision.

While there were many similarities in the information requested, there were also some key differences. The Shepherd IRB did not address research design or overall quality of the proposed research. Its webpage indicated that it is, "established to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the institution" (Shepherd, 2022a). Consequently, required documents focused on subject selection criteria, experimental procedures subjects would undergo, risks and benefits, and measures for protecting confidentiality. Likewise particular emphasis for the submission was on inclusion of all consent forms and other materials to be used with the subjects.
While these elements were also included in the submission package for Daystar's ISERC, additional information about the design, objectives, and conduct of the study, along with specific methodology, information about the study site, and training/supervision of research assistants was included. In many ways, the committee played a similar role to a dissertation committee in ensuring that the researcher had done the level of planning necessary for quality results. It was noted that the demands on the ISERC members were substantial given the greater scope of the submission. Demands on researchers were also

substantial, however, the process had the potential of providing valuable insight into the research that could eliminate issues the researcher may not have considered. However, the guiding document did not specify whether this type of feedback was provided.

What Evaluation Criteria Are Used to Ensure Fair and Consistent Review of Research Proposals?

The positive relationship between the use of rubrics that establish consistent criteria for evaluation in a higher education setting and quality products has been consistently found (Bookhart, 2018). Therefore, one would expect that review of a product as important as a research proposal would be based on clearly defined criteria and descriptions of performance levels that could guide researchers in their proposed study's design and application for review. With this expectation, we reviewed information provided by the two institutions regarding evaluation criteria with results shown in Figure 6.

Figure 6: Evaluation Criteria

SHEPHERD	DAYSTAR
Benefits Have to Outweigh Potential Risk.	*Benefits Have to Outweigh Potential Risk.
Informed Consent	*Informed Consent
Protection of Participant Confidentiality	*Protection of Participant Confidentiality
Participation is Voluntary and Right to Withdraw	*Recruitment of Research Participants •Characteristics of Population Sample Drawn From. •Means of Contact, Recruitment, and Selection •Means of Conveying Information to Potential Participants •Inclusion Criteria for Participants •Exclusion Criteria for Participants.
Understandability of Consent Forms with Full Disclosure of Discomforts/Risks and Possible Benefits *Very specific outline of information that must be included on consent forms, scope, aims, and purposes of the research, description of the experimental procedures, expected duration…*	*Care and Protection of Research participants *For Animals: Investigator's Credentials, *Experience, and Capacity for Care *For Humans: Unclear because Section on Animals begins to refer to Humans and there is No Separate Section for Humans
Separate Processes for Obtaining Additional Consent of Participants Under Age 18	*Recruitment and Training of Research Assistants
	*Community Considerations

**Evaluation Criteria taken from the evaluation section of the policy document that governed review prior to the institution of the online submission portal.*

Neither institution has an established rubric for evaluation. However, both provided some indications of the criteria that would be evaluated. At no point did Shepherd refer explicitly to evaluation criteria, but a series of directives regarding what needed to be included in the proposal functioned as a checklist for evaluators to use to determine if each thing was included. The only area where a more qualitative approach appeared

to take place was in examining the proposed benefit of the research compared to the potential risk to subjects.

If attending only to posted information, Daystar's evaluation criteria would also be inferred based on the questions required on the application. However, the policy document that predated the online portal had a designated section covering evaluation criteria. While not including specific evaluation 'levels,' these criteria went well-beyond being viewed as a simple checklist for inclusion and addressed a number of qualitative elements of the proposed study. That being said, there was a problem with this section of the guidelines. A subheading for animal research included many elements that were only applicable to human research, and it was unclear where a missing subheading for human research may have been left out leaving many items ambiguous as to what type of research they applied to. It was also noted that there were no guidelines for other types of research that did not specifically use animals or humans as subjects. Additionally, the evaluation criteria did not seem to apply well to qualitative or single-subject research designs or for studies that used secondary data such as anonymized tissue samples from an established database.

Conclusions and Recommendations

The analysis of information provided by both institutions showed that both institutions had sound review mechanisms to ensure ethical standards would be adhered to before the start of any research. While each was housed in different countries by different institutions of higher education and represented different types of reviews, localized and centralized, there were many similarities central to ethical review. However, comparisons revealed several areas of strength and weakness that can inform future attempts to improve the review process.

One significant benefit to researchers at Shepherd was the positive support mechanisms that had developed directly as a result of being localized. Because the board was comprised of fellow faculty members and each college had a representative serving on the board, a great deal of informal guidance was available. Researchers preparing a study for submission were encouraged to seek help from their college's representative and responses were immediate, complete, and came with the invitation to seek further assistance as needed. Communication with board members was promoted by a feeling of teamwork in an institution that encouraged research to increase its reputation in the educational community. It is recognized that supportive individual help is difficult when a review committee is overwhelmed with large numbers of proposals. However, any institution seeking to improve its review process needs to consider how established procedures can prevent a perception of researchers contending with reviewers rather than seeing them as a supportive resource. Systems should promote respect for the value a researcher provides and the expertise a reviewer contributes to strengthening approved research.

In addition to improving their knowledge of research ethics through interactions with the committee, researchers at Shepherd were required to participate in training to further their research ethics knowledge and understanding. NACOSTI also provides an ethics training module, but it is only available for review board members. While Shepherd provided institutional support for this training from an outside organization which may be cost prohibitive for many, institutions should consider creating their own asynchronous online training for researchers. Most institutions already have learning management systems and the expertise for developing online short courses. To be effective, a training module does not require extensive videos like those included in the CITI training. A straight-forward training would be inexpensive

to create, and could help eliminate many common mistakes that could prevent a proposal from being approved. Providing training for researchers, would also benefit the review board by increasing the quality of proposals and reducing the need for extensive feedback and resubmission. The purpose of research is to extend knowledge, it therefore follows that extending the understanding of researchers is important.
Making training available, however, should not add to the cost of review. As noted in the analysis, employment expectations at Shepherd included service to the institution. Consequently, review members contributed their expertise on the board as part of their job description which does not attract any fee for Shepherd researchers. Consequently, researchers are encouraged rather than discouraged or even prevented from engaging in research. It is understood that any process has an associated cost thus there are two considerations that need to be taken under advisement. First, institutions and government agencies need to assess the value they place on research. If the value is deemed worthwhile, then finding the means to support costs for ethical review, at least in part, need to be considered. Expecting individual researchers to bear the expense personally is detrimental to promoting research that can benefit the welfare of all. Second, review processes need to be examined to simplify and streamline wherever possible to reduce the cost of doing business.

Creating efficiencies may also address an additional area of concern found to some extent at both institutions. Researchers need to be able to find current, accurate, and complete information posted online at the link they visit for the research review. Additionally, review processes need to be explicit, delays imposed by lengthy timelines and multiple levels of required approval need to be eliminated. Finally, explicit criteria in the form of rubrics should be set forth to ensure equitable and consistent evaluation of proposals. With the online tools available today the means are readily available. However, institutional motivation to review and, where necessary, change policy and practices within the confines of respective government guidelines is needed to make these changes.

When researchers are knowledgeable about research ethics, when information about the content of submission is accurate and complete, when researchers can turn to clearly specified evaluation criteria, and when they feel supported in the process, there will be more high-quality submissions. When all necessary information is available in a single place and linked to a well-designed submission portal, researcher frustration will be significantly reduced. When policies are examined to improve timelines for approval and reduce or eliminate personal cost to researchers, research that improves our world will increase. There is much to be learned by analyzing different systems and learning from each in order to improve the process of ethical review for quality research.

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