Institutional Framework for Preventing and Managing Research Misconduct

Research Misconduct Workshop
KCB Leadership Center, Karen, Nairobi.
28 February – 1 March 2019

NATIONAL RESEARCH FUND

National Commission for Science, Technology and Innovation

Acknowledgements

This framework was developed through a participatory workshop process by participants from different institutions of research and higher learning led by Moi University (MU) in collaboration with Moi Teaching and Referral Hospital (MTRH) and National Commission for Science Technology and Innovation (NACOSTI).

We sincerely appreciate the workshop participants, the workshop steering committee members, the technical advisory committee members, the speakers and the session moderators for their efforts during this process.

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Executive Summary

Moi University in collaboration with the National Commission for Science Technology and Innovation (NACOSTI) held a national workshop between February 28 and March 1, 2019 at the KCB Leadership Center. The workshop was necessitated by a realization that there was a growing number of research and academic institutions in Kenya and an increasing number of reports about research practices amounting to research misconduct including but not restricted to fabrication, falsification and plagiarism as well as a host of other practices considered to be questionable research practices (QRPs). Some of the QRPs identified include implementation of alterations in the approved protocol without prior ethics committee approval, authorship malpractices among others. It was further noted that these practices were happening in institutions with weak, varied and poorly disseminated institutional policies where they existed and mostly, institutions did not have any guidance on research integrity. The main goal of the workshop was to develop a consensus Institutional Framework for Preventing and Managing cases of research misconduct.

The workshop consisted of brief presentations on the perceptions of stakeholders on the occurrence and factors related to research misconduct among Kenyan HIV researchers; expert talks about global best practices highlighting practices in the USA and South Africa. These brief presentations were followed by discussion and consensus building on the elements of a functioning institutional framework to prevent and manage RM.

Consensus Outcomes

Definition of Research Misconduct in the Kenyan Setting

The final definition of RM adopted was "*Behavior that falls short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld. This includes the fabrication, falsification, plagiarism and /or deception in proposing, carrying out or reporting results of research studies or deliberate, dangerous or negligent deviations from accepted practices in carrying out research."*

The task force indicated that they had adopted this definition from: *The concordat to support research integrity UK and the Wellcome Trust definition.* There is further agreement that the policy makers may find this definition operationally imprecise and may want further to distill it in collaboration with their legal team.

Responsibility of Managing Research Misconduct*.*

Research Misconduct should be handled by a separate entity from a research ethics committee (REC). A Research Integrity Office should be created in NACOSTI at the national level. That office shall delegate its Research Integrity mandate to Institutional Research Integrity Offices (IRIOs) created within the highest office in an Academic or Research Institution – at the level of Institutional Research Directorate or equivalent. The IRIO will report to the national RIO (NRIO). Each IRIO will be free to develop their own structures to address RM in their own facilities.

Institutional Framework for Preventing and Managing RM

Three important considerations were noted in the process, namely (a) adhering to the highest standards of transparency, accountability and fairness in handling and concluding allegations, (b) creating robust mechanisms for preservation of the reputation of both the whistleblower and the accused during the investigation and determination processes and (c) concluding the process in a timely manner.

While recognizing institutional autonomy, there shall be developed within the IRIOs mechanisms that:

A. Promote Research Integrity (prevention)

Research integrity shall be promoted through training in responsible conduct of research (RCR). Depending on the level of the researcher, evidence of such training on RCR should be mandatory and should also be awarded continuing professional development points. The NRIO should collaborate with national and international stakeholders to develop an online curriculum and training materials for relevant short courses. NACOSTI shall consider making evidence of periodic certification in RCR as requirement for issuance of research permits.

B. Receive Allegations of RM

Whistleblowing and being accused of alleged misconduct were a big threat to the reputations of those involved. Robust capacity for safeguarding confidentiality for both the whistle blower and the alleged perpetrator is necessary. Only good faith allegations should be entertained, and frivolous or bad faith allegations should not only be vigorously discouraged but also severely sanctioned / punished.

The potential sources of allegations include a whistleblower, RECs, among others. All possible portals / avenues (hot line, suggestion box, complaints book, online, social media & hard copy reports) for reporting should be explored in developing such systems in the Institutional and national RIOs. RIO offices should mount periodic awareness creation forums for researchers and research managers about reporting RM.

C. Handling allegations of RM-Inquiry

Once allegations of research misconduct are received at the NRIO or IRIO, there shall be put in place a standard operating procedure for reviewing the allegation and determining if *prima facie* evidence exists. Additionally, there should be a determination as to if the allegation is genuine and of good faith or frivolous. For this purpose, institutions should develop processes that are compatible with other existing human resource processes. The alleged perpetrator should not be informed of the allegation at this stage. This preliminary process shall have a timeframe of no more than 2 weeks.

D. Handing allegations of RM- Investigation

IRIO sets up task force to investigate allegation with prima facie evidence of RM. Task force composed of senior academics and researchers, one of whom must be from the same subject area as the research on which alleged misconduct took place. Mechanisms should be developed to ensure timely access to potential evidence of the misconduct (before there can be any tampering by the alleged perpetrator). After securing the evidence the

alleged perpetrator should be given a right of reply to respond to the allegations. The taskforce shall review the available evidence and decide on whether there was misconduct or not. The taskforce shall then develop a detailed report of the investigation, the determination and suggested sanctions. This stage shall be concluded within 6 months. If additional time is required, the task force through the RIOs shall make an interim report to the relevant authorities explaining the need for more time

E. Distribution of the Task-force Report for action

The report shall be handed over to the IRIO, copied to IREC and NRIO. The IRIO shall escalate the report to the institutional human resource department to act per institutional mechanisms. NRIO shall also decide on next steps within the national legal framework. IREC may act by informing publishers about the case depending on the magnitude of the misconduct and the stage of the research.

Conclusions

The outcome of the first national stakeholder workshop to develop a model institutional framework to prevent and manage research misconduct is presented. Key elements of the structure and functions of the framework are described.

Rationale

The first Kenyan Workshop on research Misconduct was hosted by Moi University in collaboration with the National Commission for Science Technology and Innovation (NACOSTI) between February 28 and March 1, 2019. The workshop was necessitated by a realization that there was a growing number of research and academic institutions in Kenya and an increasing number of reports about research practices amounting to research misconduct including but not restricted to fabrication, falsification and plagiarism as well as a host of other practices considered to be questionable research practices (QRPs). Some of the QRPs identified include implementation of alterations in the approved protocol without prior ethics committee approval, authorship malpractices among others. It was further noted that these practices were happening in institutions with weak, varied and poorly disseminated institutional policies where they existed and mostly, institutions did not have any guidance on research integrity. The goal of the workshop was to simultaneously increased awareness about the threat that research misconduct poses to the scientific enterprise in Kenya and develop a consensus Institutional Framework for Preventing and Managing cases of research misconduct.

Background

The Research Misconduct Workshop was a specific activity in a capacity building project by Moi University through the Moi Institutional Research and Ethics Committee (MUIREC) which is the Research ethics committee for Moi University and Moi Teaching and Referral Hospital. Per the Kenyan laws, the responsibility and authority to advise government on all matters research technology and innovation is invested the national regulator called NACOSTI under the Science Technology and Innovation Act of 2013. NACOSTI delegates its mandate to institutional RECs of which at least 28 have now been created across the country. MUIREC is one of the RECs. As a NACOSTI accredited IREC, MUIREC is required to make annual reports to NACOSTI as part of larger mechanism to maintain its delegated mandate from NACOSTI as an accredited IREC. Additionally, MUIREC through its institutional collaborations is also accredited to the US Office of Human Research Protection (OHRP) through a federal wide assurance agreement that obligates MUIREC to report cases of research misconduct annually and describe how these cases were managed.

In the course of fulfilling these accreditation obligations, MUIREC noted the increasing incidence of cases of research misconduct. Concomitantly, the dearth of guidance, both institutional and national, on how to prevent and manage cases of research misconduct became apparent. This challenge led to the application for a capacity building grant support by the National Institutes of Health to:

(a) Document the occurrence of research misconduct (defined as fabrication, falsification and plagiarism in proposing, reviewing, implementing and reporting research. QRPs were also included) in the context of HIV research;

(b) Identify global best practices related to prevention and management of research misconduct and hold a national workshop to identify and achieve consensus on the elements of an Institutional Framework to Prevent and Manage Research Misconduct in Kenya; and

(c) To pilot test aspects of the Framework in Moi University College of Health Sciences and document lessons learned.

In this report we document the approach to and the main outcomes of the Research Misconduct workshop held in KCB Leadership Center, Nairobi from February 28, 2019 to March 1, 2019.

Workshop Objectives

The workshop had the following objectives:

(a) Contextualize research misconduct by presenting preliminary results of an online research misconduct survey with Kenyan HIV researchers who had had a REC approved research protocol in the preceding 5 years;

(b) Review the lessons learned from benchmarking visits to one African country and one US based institution with structures for preventing and managing research misconduct. Additionally, to receive and discuss presentations by research integrity experts from those and other institutions on the best practices related to fostering research integrity.

(c) Develop consensus on a Kenyan institutional framework for preventing and managing research misconduct.

We describe the methodological approach to the organization of the first Research Misconduct workshop in Kenya.

Methods

The Workshop Preparations

Under the capacity building grant, we set up a Workshop Steering Committee consisting of the co-Principal Investigators of the grant, two members of the grant technical advisory committee and two eminent scientists who are also members of the NACOSTI National Bioethics Committee. Commencing about eight (8) months to the workshop date, the Workshop Committee began its sittings. Members of the committee who were not in campus were urged to call into the meeting from their remote locations. In all, eight (8) meetings were held. The Steering Committee identified the venue (KCB Leadership Center in Karen, Nairobi, developed

an interactive 2-day program for the workshop, identified and secured the attendance and participation of five (5) international experts in research integrity. These included experts from South Africa, USA, Netherlands and a regional representative of Africa Research Integrity Network (ARIN). The steering committee also provided guidance on the variety of invited delegates which included representatives of the Ministry of Higher Education, specifically, the Commission of University Education, the NACOSTI, high level administrations of all the major universities and health research institutions in Kenya, selected individual HIV and chronic disease researchers from Kenya and chairs and secretary of all the 28 accredited RECs in Kenya. Invitations were delivered by email.

For all foreign and invited Kenyan participants, the workshop organizers undertook to provide accommodation and meals during the event while they paid for their own transport to and from the workshop. In country logistics for foreign experts were covered by the workshop resources.

The Workshop Structure

Day One

Taking cognizance that Research Misconduct is a rather unfamiliar topic in Kenya, the workshop structure and content was developed to first create awareness of the global definition, occurrence and approaches to managing research misconduct among participants. To achieve this, the workshop was organized to have a keynote address from the Director General of NACOSTI, a presentation of the status of and perceptions about research misconduct among researchers in Kenya by the principal investigator of the capacity building grant. Subsequently, experts from the USA and RSA took turns to apprise the participants of the organization and functions of their institutional research integrity programs. This was followed by a question and answer session on the presentations. Thereafter, the participants went into 90-minute breakout sessions to discuss specific elements of a framework to prevent and manage research misconduct. The key aspects tackled in each breakout group included: prevention, identification, reporting of research misconduct, investigating and then managing a case of research misconduct. Each of these elements was discussed by two groups of 6 – 10

participants with the experts facilitating. All groups discussed the definition of research misconduct to be adopted by Kenya.

The breakout sessions culminated in the day's plenary session during which the rapporteur of each group presented the group consensus on the definition and the specific element of the framework the group had been allocated. Following the two group presentations on each element, plenary moderators, themselves seasoned Kenyan scientist with interest in research integrity, then steered plenary discussion on the group consensus to generate plenary consensus. This approach was then repeated for all the breakout groups. All the issues that had unresolved consensus issues we packed for day two breakout sessions.

To enable free communication, the final session of day one was a one-hour unstructured question and answer panel of discussion with the international experts on research integrity. This session was preceded by of a videotaped presentation by an international expert on research integrity from Netherlands who was unable to make it to the workshop.

Day Two

The day began with a recap by the workshop rapporteurs on all the elements of the framework on which consensus had been achieve on day one. The rapporteurs also presented the areas where consensus had not been achieved for additional discussion. The single area where consensus had not been achieved was the definition of research misconduct to be adopted by Kenya. To unlock, the impasse an ad hoc taskforce was set up to work on a consensus definition and report to plenary. Since there were no other substantive areas with lack of consensus, the second breakout session was brief and plenary consensus dominated. Subsequently, the participants had a presentation from ARIN and another presentation from New York via videoconference on the role of Retraction Watch in managing Research Misconduct. The workshop closed by the Chief Executive Officer of the Kenyan Commission on University Education (CUE).

In the next section on workshop outcomes we summarize the main issues where consensus was reached.

Consensus Workshop Outcomes

We organize this section under two main sub-sections: (a) Definition of research misconduct (b) Institutional Framework Modules

Definition of Research Misconduct in the Kenyan Setting

Through the invited experts, different definitions were identified. In the USA, the OHRP defines research misconduct as "Research misconduct is defined as fabrication, falsification, or plagiarism (FFP) in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up results and recording or reporting them. Falsification is manipulating research, materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit, including those obtained through confidential review of others' research proposals and manuscripts. Research misconduct does not include honest error or honest differences of opinions."

The National Science Foundation, USA recognizes other Detrimental Research Practices (DRPs) also known as Questionable Research Practices (QRPs) but focuses on FFP

During plenary discussion it emerged that there could be two definitions adopted for the Kenyan setting. There was what was described as the broad definition which encompasses FFP and QRP and the narrow definition which focuses on FFPs. It was also recognized and, broadly, agreed that FFPs are not as frequent as QRPs and that focus should be on fostering research integrity rather than searching for the so-called cardinal sins of FFPs and punishing perpetrators. After an initial failure to reach consensus on the definition an ad hoc taskforce was set up to develop a consensus definition to be presented to the plenary. The final taskforce definition adopted by the plenary was: ***"Behavior that falls short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld.***

This includes the fabrication, falsification, plagiarism and /or deception in proposing, carrying out or reporting results of research studies or deliberate, dangerous or negligent deviations from accepted practices in carrying out research.

The task force indicated that they had adopted this definition from: *The concordat to support research integrity UK and the Wellcome Trust definition.* There was further agreement that the policy makers may find this definition still imprecise operationally and may want further to distill it in collaboration with their legal team.

The plenary consensus on this definition specified that the notion of establishing ill-intent was necessary in operationalizing the definition. However, ill intent or not, the consequence of the misconduct to the scientific enterprise should be considered and take precedence in deciding whether an alleged research misconduct was actionable or not.

Responsibility of Managing Research Misconduct.

It was argued that RECs are charged primarily with the responsibility of working with investigators to enhance the quality of their proposed research and promote the safety and welfare of research participants. Consequently, RECs should have cordial relationship with researchers. Research misconduct management, on the other hand, is a murky quasi-legal process that is adversarial and likely to foster antagonism between the REC and the investigators accused of misconduct. Consequently, research misconduct should be handled by a separate entity from a REC. Based on this argument, there should be created a Research Integrity Office in NACOSTI at the national level. That office shall delegate its Research Integrity Oversight mandate to Institutional Research Integrity Offices (IRIOs) created within the highest office in an Academic or Research Institution – at the level of Institutional Research Directorate or equivalent. The IRIO shall report to the national RIO (NRIO). Each IRIO will be free to develop their own structures to address RM in their own facilities.

Institutional Framework for Preventing and Managing RM

Within the Institutional RIOs, there shall be developed and, broadly disseminated, mechanisms for receiving allegations of research misconduct, holding an inquiry to determine if there is *prima facie* evidence of a good faith allegation, proceeding to a full investigation of the alleged

misconduct if there is compelling prima facie evidence and a mechanism for assessing the evidence accruing from investigation and concluding the case. Three important considerations were noted as essential to the process, namely:

(a) adhering to the highest standards of transparency, accountability and fairness in handling and concluding allegations,

(b) creating robust mechanisms for preservation of the reputation of both the whistleblower and the alleged perpetrator during the investigation and determination processes and

(c) concluding the process in a timely manner.

While being cognizant of the institutional autonomy, under the IRIOs, there shall be created mechanisms to:

A. Promote Research Integrity (prevention)

Much of the effort should be directed at promoting research integrity through training in responsible conduct of research (RCR). Depending on the level of the researcher, evidence of such training on RCR should be mandatory and should also be awarded continuing professional development points. The NRIO should collaborate with national and international stakeholders to develop an online curriculum and training materials for relevant short courses. In the meantime, online existing resources such as from the Collaborative Institutional Training Initiative (CITI) could be domesticated and used. The NACOSTI should demand evidence of periodic certification in RCR as part of requirements for ethics approval of research and issuance of research permits.

B. Receive Allegations of RM

Both whistleblowing and being accused of alleged misconduct were a big threat to the reputations of those involved. Consequently, mechanisms for receiving allegation of research misconduct must have robust capacity for safeguarding confidentiality for both the whistle blower and the alleged perpetrator. Additionally, only good faith allegations should be entertained. Temptations for frivolous or bad faith allegations should not only be vigorously discouraged but also severely sanctioned / punished.

The potential sources of allegations could be a whistleblower, RECs, among others. All possible portals / avenues (hot line, suggestion box, complaints book, online, social media, hard copy reports etc) for reporting should be explored in developing such reporting systems in the Institutional and national RIOs. However, mechanisms should include receiving allegations in a specified format that fosters further evaluation to determine prima facie substance.

To improve the visibility of the RIOS with respect to reporting of misconduct, the RIO offices should mount periodic awareness creation forums for researchers and research managers.

C. Handling allegations of RM-Inquiry

Once allegations of research misconduct are received at the NRIO or IRIO, there shall be put in place a standard operating procedure for reviewing the allegation and determining if *prima facie* evidence exists. Additionally, there should be a determination as to if the allegation is genuine and of good faith or frivolous. For this purpose, institutions should develop processes that are compatible with their existing human resource guidelines. At this stage of the inquiry, the alleged perpetrator should not be informed of the allegation. This preliminary process shall have a timeframe of no more than 2 weeks.

D. Handing allegations of RM- Investigation

If the evidence provided in the allegation meets the minimum threshold for *prima facie* evidence supportive of the allegation of misconduct, then the RIO shall proceed to full investigation of the allegation. To enable a productive investigation, the RIO office should convene a task force which should include senior academics and researchers one of whom must be from the same subject area as the research on which alleged misconduct took place. Mechanisms shall be developed to ensure timely access to potential evidence of the misconduct (before there can be any tampering by the alleged perpetrator). After securing the evidence the alleged perpetrator should be given a right of reply to respond to the allegations.

E. Handling the allegations of RM - Determination

The taskforce shall then review the available evidence and decide on whether there was misconduct or not. The taskforce shall then develop a detailed report of the investigation, the determination and suggested sanctions.

Finally, the report shall be handed over to the IRIO, copied to IREC and NRIO. The IRIO shall then have the mandate to escalate the report to the institutional human resource department to act per institutional mechanisms. NRIO shall also decide on next steps within the national legal framework. IREC may act by informing publishers about the case depending on the magnitude of the misconduct and the stage of the research. This stage shall be concluded within 6 months. If additional time is required, the task force shall make an interim report to the IRIO explaining the need for more time.

Proposed Organizational Structure of Research Integrity Oversight in Kenya.

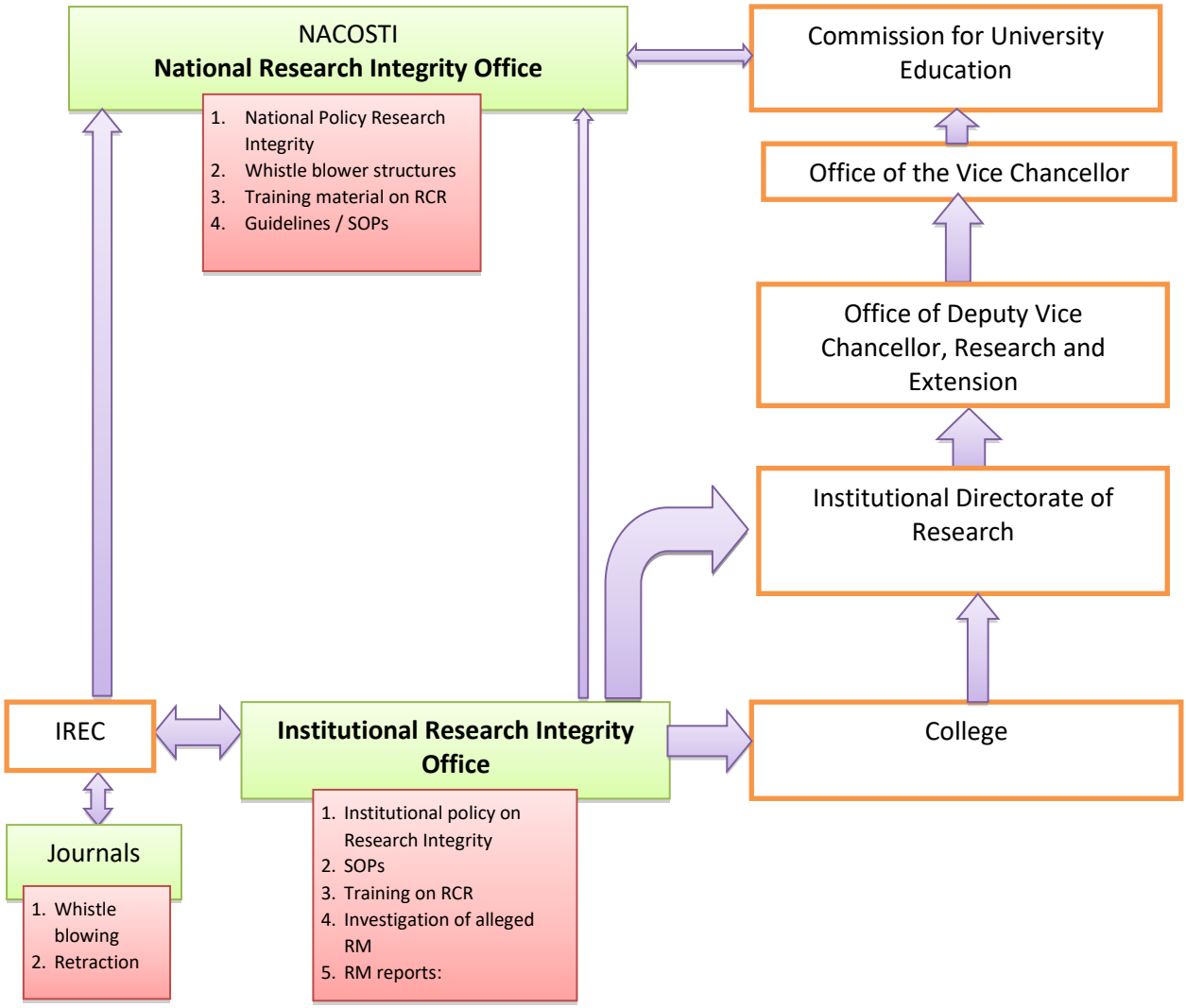

Figure 1: Proposed Organizational Structure of Research Integrity Oversight in Kenya

Conclusions

The outcome of the first national stakeholder workshop to develop a model institutional framework to prevent and manage research misconduct is presented. Key elements of the structure and functions of the framework are described.

Secondary Objectives of the Workshop

Pre and Post Test Survey

The achievement of awareness creation was achieved through a Pre/Post-test assessment

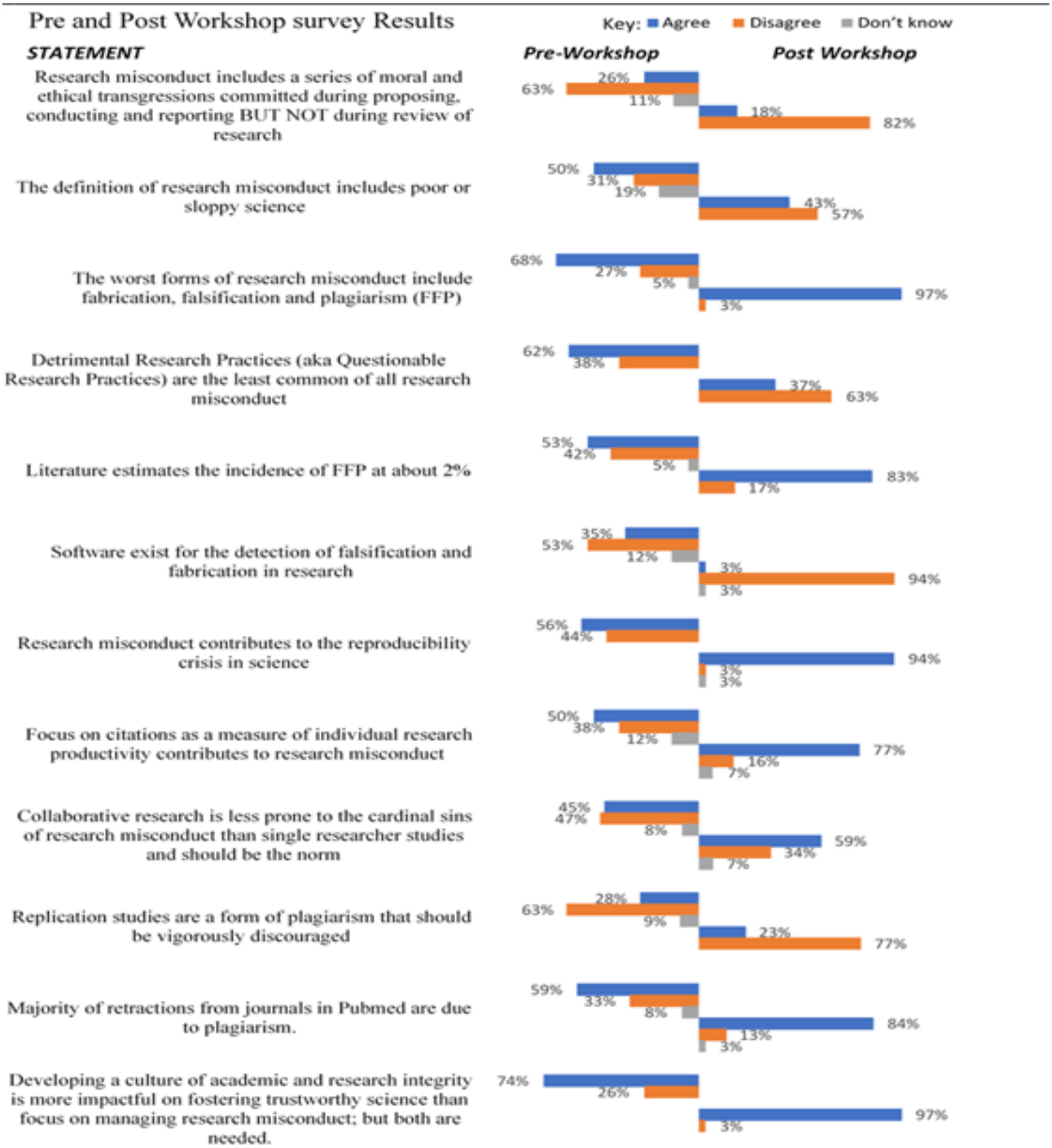

Figure 2: Pre and Post Test Summary Report

Workshop Evaluation

The Workshop was also evaluated using a predesigned evaluation instrument.

The workshop evaluation was generally positive. Overall, participants scored most questions as good to excellent. The diversity of participants the clarity of workshop objective, achievement of objective and quality of discussions were specifically lauded. The hospitality arrangements we also rated by and large better than average. Overall, administration of the workshop program was scored excellent by 48% and good by 48% as well.

Table 1: Workshop Evaluation Results

Statement	*Excellent*	*Good*	*Average*	*Fair*	*Poor*	*No response*
Clarity of workshop objective was	65.5%	34.5%	0	0	0	0
Achievement of workshop objective was	37.9%	56.9%	0	0	0	5.2%
Time for group discussions and questions was	34.5%	55.2%	8.6%	0	1.7%	0
Quality of discussions was	50%	48.3%	0	0	0	1.7%
Speakers/resource persons were	65.5%	27.6%	1.7%	0	0	5.2%
Time management of the sessions/talks was	24.1%	56.9%	10.3%	3.4%	0	5.2%
Networking opportunities were	32.8%	51.7%	10.3%	3.4%	0	1.7%
conference facilities were	56.9%	29.3%	10.3%	1.7%	0	1.7%
Accommodation was	56.9%	27.6%	3.4%	1.7%	0	10.3%
Food was	44.8%	46.6%	8.6%	0	0	0
Overall administration of the workshop was	48.3%	48.3%	0	0	0	3.4%

Next Steps

These workshop resolutions shall be shared with NACOSTI to inform their ongoing amendment of the Science Technology and Innovation Act of 2013. The report shall also be distributed to all participants and management of all invited institutions.

Within Moi University, the workshop report shall be submitted to the Directorate of Research for institutional implementation. Within the Moi College of Health Sciences, preparations for trainings on RCR as part of the capacity building grant are being finalized. Five trainings are planned.

Appendix 1: List of participants and institutions

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* Presentations via videoconference

Appendix 2: List of members of the Definitions Taskforce.

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