

# PROMOTING RESEARCH INTEGRITY IN AFRICA: AN AFRICAN VOICE OF CONCERN ON RESEARCH MISCONDUCT AND THE WAY FORWARD

FRANCIS KOMBE, EUCHARIA NKECHINYERE ANUNOBI,  
 NYANYUKWENI PANDENI TSHIFUGULA, DOUGLAS WASSENAAR,  
 DIMPHO NJADINGWE, SALIM MWALUKORE, JONATHAN CHINYAMA,  
 BODO RANDRIANASOLO, PERPETUA AKINDEH, PRISCILLA S. DLAMINI,  
 FELASOA NOROSEHENO RAMIANDRISOA AND NAINA RANAIVO

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**ABSTRACT**

African researchers and their collaborators have been making significant contributions to useful research findings and discoveries in Africa. Despite evidence of scientific misconduct even in heavily regulated research environments, there is little documented information that supports prevalence of research misconduct in Africa. Available literature on research misconduct has focused on the developed world, where credible research integrity systems are already in place.

Public attention to research misconduct has lately increased, calling for attention to weaknesses in current research policies and regulatory frameworks. Africa needs policies, structural and governance systems that promote responsible conduct of research.

To begin to offset this relative lack of documented evidence of research misconduct, contributors working in various research institutions from nine African countries agreed to share their experiences to highlight problems and explore the need to identify strategies to promote research integrity in the African continent. The experiences shared include anecdotal but reliable accounts of previously undocumented research misconduct, including some 'normal misbehavior' of frontline staff in those countries.

Two broad approaches to foster greater research integrity are proposed including promotion of institutional and individual capacity building to instil a culture of responsible research conduct in existing and upcoming research scientist and developing deterrent and corrective policies to minimize research misconduct and other questionable research practices. By sharing these experiences and through the strategies proposed, the authors hope to limit the level of research misconduct and promote research integrity in Africa.

## INTRODUCTION

Public attention to scientific research misconduct and the need for greater research integrity have recently grown dramatically.<sup>1</sup> Definitions of scientific misconduct include

<sup>1</sup> Promoting research integrity: a new global effort. *Lancet* 2012; 380: 1445. Empirical Realities of Scientific Misconduct in Publicly Funded

Research: *What can we learn from ORI investigations of U.S. cases in the biomedical and behavioral sciences?* Andrea Pozzi & Paul A. David. Available at: [http://www.siepr.stanford.edu/papers/pdf/Pozzi-David\\_Presentation\\_MisconductRealities\\_v7bis\\_4up\\_15pages.pdf](http://www.siepr.stanford.edu/papers/pdf/Pozzi-David_Presentation_MisconductRealities_v7bis_4up_15pages.pdf) [Accessed 28 Jan 2013]; The Concordat to Support Research Integrity, Universities UK, London 2012. ISBN 978-1-84036-273-2N, London: Available at: <http://www.universitiesuk.ac.uk/Publications/Documents/TheConcordatToSupportResearchIntegrity.pdf> [Accessed 28 Jan 2013].

Address for correspondence: Francis Kombe, Kemri-Wellcome Trust – HSSR P.O.Box 230 Kilifi Kilifi 80108, Kenya, Email: [fkombe@kemri-wellcome.org](mailto:fkombe@kemri-wellcome.org).

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fabrication, falsification, plagiarism,<sup>2</sup> or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.<sup>3</sup> Recently, the role of 'normal misbehavior' as a form of scientific misconduct has also been highlighted.<sup>4</sup> Overall, the need for greater research integrity calls for attention to weaknesses in current scientific research policies, training, and regulatory frameworks. However, there is relatively little systematic information about the rate of scientific research misconduct.<sup>5</sup> It is estimated that as many as 1,000 instances of research misconduct go unreported annually in the United States alone.<sup>6</sup> Moreover, available literature on scientific research misconduct has focused on the developed world, where credible scientific research integrity systems are already in place.<sup>7</sup>

With regard to research oversight as one component to improve research integrity, there has been a recent drive to expand and strengthen the capacity of institutions at local and national levels to review and monitor studies, for example through Institutional Review Boards (IRBs), Research Ethics Committees (RECs) and Community Advisory Boards (CABs).<sup>8</sup> This is based on the recognition that participation of competent independent specialist bodies in research-related decision-making, especially

in low-income settings, is a priority for equitable transnational research collaborations and general ethical conduct of research.<sup>9</sup> However, RECs alone cannot positively promote good conduct of research by researchers; the work of RECs must be complemented by active efforts to promote responsible conduct of research by all scientists and related professionals, as promoted by the Singapore Statement (2010).<sup>10</sup> The scientific community should be alert and vigilant in preventing, detecting and reprimanding scientific misconduct.<sup>11</sup> The scientific community must appeal to the conscience of individual scientists and the scientific community as a whole to invoke the highest possible standards of research behavior.<sup>12</sup>

Professional and public debates concerning the application of guidelines for ethical conduct in studies carried out in developing countries are likely to continue as new information becomes available. Thus, increased awareness of ethical concerns associated with study designs and informed consent processes, use of biomedical samples, collaboration and publication among researchers working in resource-poor settings is needed. But strengthening professional knowledge and institutionalizing research oversight systems is not enough. Investigators also require practical local mechanisms or models for articulating ethical guidelines within specific contexts. Technological and financial resources are also necessary to build capacity for local collaborators, front line research staff, and communities to ensure research meets ethical standards.<sup>13</sup> Much has already been done to improve research ethics oversight in Africa, largely funded by the Fogarty International Center of the US National Institutes of Health, the European and Developing Countries Clinical Trials Partnership (EDCTP), and World Health Organization/United Nations Programme on HIV and AIDS (WHO/UNAIDS) to build capacity of ethics review systems in Africa.<sup>14</sup> Much less appears to have been systematically done to build research integrity in researchers, including front line staff and fieldworkers and it is time that such initiatives were launched.<sup>15</sup>

<sup>2</sup> Federal Policy on Research Misconduct, 2002. Available at: <http://www.aps.org/policy/statements/upload/federalpolicy.pdf>. [Accessed 28 Jan 2013].

<sup>3</sup> B. Schneider & U. Schuklenk. Module six: special issues. *Dev World Bioeth* 2005; 5: 92–108.

<sup>4</sup> G. True, L.B. Alexander & K.A. Richman. Misbehaviors of front-line research personnel and the integrity of community-based research. *J Empir Res Hum Res Ethics* 2011; 6: 3–12, R. de Vries, M.S. Anderson & B.C. Martinson. Normal Misbehavior: Scientists Talk about the Ethics of Research. *J Empir Res Hum Res Ethics* 2006; 1: 43–50.

<sup>5</sup> E.J. Hackett. A new perspective on scientific misconduct. *Acad Med* 1993; 68: S72–S76.

<sup>6</sup> D.S. Kornfeld. Perspective: research misconduct: the search for a remedy. *Ibid.* 2012; 87: 877–882.

<sup>7</sup> S.M. Vasconcelos, N.H. Steneck, M. Anderson, H. Masuda, M. Palacios, J.C. Pinto & M.M. Sorenson. The new geography of scientific collaborations. Changing patterns in the geography of science pose ethical challenges for collaborations between established and emerging scientific powers. *EMBO Rep* 2012; 13: 404–407.

<sup>8</sup> International ethical guidelines for biomedical research involving human subjects. *Bull Med Ethics* 2002; 17–23, K.G. Alberti. Multicentre research ethics committees: has the cure been worse than the disease? No, but idiosyncrasies and obstructions to good research must be removed. *BMJ* 2000; 320: 1157–1158, E.J. Emanuel, D. Wendler, J. Killen & C. Grady. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *J Infect Dis* 2004; 189: 930–937, C. IJsselmuiden, D. Marais, D. Wassenaar & B. Mokgatla-Moipolai. Mapping african ethical review committee activity onto capacity needs: the marc initiative and hrweb's interactive database of recs in Africa. *Dev World Bioeth* 2012; 12: 74–86, J. Legemaate. The CIOMS guidelines for biomedical research involving human subjects. *Eur J Health Law* 1994; 1: 161–165, C. Weijer. Protecting communities in research: philosophical and pragmatic challenges. *Camb Q Health Ethics* 1999; 8: 501–513, C. Weijer & E.J. Emanuel. Ethics. Protecting communities in biomedical research. *Science* 2000; 289: 1142–1144.

<sup>9</sup> S. Molyneux & P.W. Geissler. Ethics and the ethnography of medical research in Africa. *Soc Sci Med* 2008; 67: 685–695.

<sup>10</sup> D.B. Resnik & A.E. Shamoo. The singapore statement on research integrity. *Account Res* 2011; 18: 71–75, A. Marusic. The Singapore statement on research integrity. *Croat Med J* 2010; 51: 381–382.

<sup>11</sup> P. Okonta & T. Rossouw. Prevalence of Scientific Misconduct Among a Group of Researchers in Nigeria. *Dev World Bioeth* 2012.; IAC and IAP; *Responsible Conduct in the Global Research Enterprise*, A Policy Report: Available at: <http://www.interacademies.net/File.aspx?id=19789>. [Accessed 28 Jan 2013].

<sup>12</sup> D.S. Kornfeld. Perspective: research misconduct: the search for a remedy. *Acad Med* 2012; 87: 877–882.

<sup>13</sup> Molyneux & Geissler.

<sup>14</sup> IJsselmuiden, Marais, Wassenaar & Mokgatla-Moipolai.

<sup>15</sup> IAC and IAP; *Responsible Conduct in the Global Research Enterprise*, A Policy Report: Available at: <http://www.interacademies.net/File.aspx?id=19789> [Accessed 28 Jan 2013].

This paper brings together experiences from various parts of Africa to reflect on concerns related to scientific research misconduct. Through this combined effort, the authors hope to share some African accounts of experiences related to research misconduct, including ‘normal misbehavior’, and suggest possible mechanisms to proactively promote responsible conduct of research, to monitor the conduct of research in Africa and address existing forms of scientific research misconduct in Africa and beyond.

### *Why does scientific research misconduct happen?*

As described earlier, scientific research misconduct covers a range of challenges to research integrity including fabrication, falsification, plagiarism<sup>16</sup> and other practices that seriously deviate from those commonly accepted within the scientific community for proposing, conducting, or reporting research.<sup>17</sup> The reasons for research misconduct are numerous and diverse.<sup>18</sup> In the 2012 Okonta and Rossouw study, over fifty percent of the researchers interviewed thought pressure for external funding, need for recognition, need for publications and insufficient censure of misconduct had a ‘strong influence’ on scientific misconduct.<sup>19</sup> More recently, misconduct related to more mundane problems in the work environment has been described as ‘normal misbehavior’ with particular issues arising from data handling, negotiating rules seen as over-prescriptive, interpersonal relationships and the pressures of production in scientific careers.<sup>20</sup> For front line research staff, particularly where they are also members of a community involved in a study, conflicts of interest and perceived pressure to recruit have been described as causes of scientifically and ethically important forms of normal misbehavior.<sup>21</sup> Of particular note for front line staff is that underlying motivations for ‘misbehavior’ may at the same time reflect a sincere wish to assist participants and communities, generating moral dilemmas for this group of staff.<sup>22</sup>

<sup>16</sup> Federal Policy on Research Misconduct. 2002. Available at: <http://www.aps.org/policy/statements/upload/federalpolicy.pdf>. [Accessed 28 Jan 2013].

<sup>17</sup> Schneider & Schuklenk.

<sup>18</sup> D. Fanelli. How many scientists fabricate and falsify research? A systematic review and meta-analysis of survey data. *PLoS One* 2009; 4: e5738, D. Fanelli. Do pressures to publish increase scientists’ bias? An empirical support from US States Data. *PLoS One* 2010; 5: e10271, D. Fanelli. ‘Positive’ results increase down the Hierarchy of the Sciences. *PLoS One* 2010; 5: e10068.

<sup>19</sup> Okonta & Rossouw.

<sup>20</sup> de Vries, Anderson & Martinson.

<sup>21</sup> G. True, L.B. Alexander & K.A. Richman. Misbehaviors of front-line research personnel and the integrity of community-based research. *Ibid.* 2011; 6: 3–12.

<sup>22</sup> D. Kamuya, S. Theobald, P. Munyoki, D. Koech, W. Geissler and S. Molyneux ‘Evolving friendships and shifting ethical dilemmas: field-

In these situations, regardless of discipline and institution, the investigator’s primary responsibility is to ensure the quality of research and research practices. Investigators should be honest about their own work, adhering to proper scientific practices such as ensuring veracity of data and acknowledging the contributions of colleagues or collaborators. Investigators are also expected to be honest in relation to the work of their colleagues and peers. In addition, investigators have a moral obligation to comply with all the legislation relevant to their profession, including national and international regulatory bodies.<sup>23</sup>

Researchers should report to the appropriate authorities any suspected research misconduct and irresponsible research practices that undermine the trustworthiness of research. On the other hand, research institutions, journals, and agencies that have commitments to research, should put in place procedures for responding to allegations of misconduct and other irresponsible research practices.<sup>24</sup>

This paper aims to add an African voice of concern and highlight areas that might need attention. Contributors from nine African countries working in various institutions agreed to share their experiences in an attempt to highlight problems and explore the need to identify strategies to promote research integrity in Africa. The experiences include anecdotal but reliable accounts of previously undocumented scientific research misconduct in those countries. Although the authors represent only nine African countries, their experiences reflect a sample of concerns from the entire African continent. The proposed measures should therefore be applicable in most settings in Africa.

### *Is there evidence of scientific research misconduct in Africa?*

African researchers and their collaborators have been making significant contributions to useful research findings and discoveries in Africa. Despite evidence of systematic scientific misconduct even in heavily regulated research environments, there is little documented information that supports prevalence of research misconduct in Africa, with only a few research misconduct cases attributable to African scientists.<sup>25</sup> Conversely, there is no evidence to suggest that all research conducted in developing

workers’ experiences in a short term community based study in Kenya’, *Developing World Bioethics*, in press.

<sup>23</sup> A. Newman & R. Jones. Authorship of research papers: ethical and professional issues for short-term researchers. *J Med Ethics* 2006; 32: 420–423.

<sup>24</sup> Kornfeld.

<sup>25</sup> IAC and IAP; *Responsible Conduct in the Global Research Enterprise*, A Policy Report: Available at: <http://www.interacademies.net/File.aspx?id=19789>. [Accessed 28 Jan 2013].

countries meets ethical standards and that scientific misconduct does not exist. It is therefore more likely that the prevalence of scientific misconduct amongst researchers in Africa has not been systematically investigated.<sup>26</sup>

A recent study by Okonta and Rossouw in Nigeria reported that 68% (n = 91) of researchers surveyed admitted to having committed at least one form of scientific misconduct.<sup>27</sup> Research misconduct taints the image of science and the scientists (if discovered) and can undermine the confidence that the public and research participants have in the reliability of researchers and research findings. Undiscovered misconduct may lead to publication of misleading data and results; sometimes in high impact journals. Misconduct can cause a waste of financial and human resources and might pose a risk to human health.<sup>28</sup> Despite scientists being obliged to respect existing scientific and ethical norms, available literature suggests that the known frauds are just a 'tip of the iceberg', and that many cases are never discovered.<sup>29</sup> Indeed, if most research misconduct still eludes strategies in place in developed countries and the situation in many under-regulated and under-resourced countries is largely unknown, this hiatus itself is a cause of grave concern.

## EXPERIENCES OF SCIENTIFIC RESEARCH MISCONDUCT IN AFRICA

A literature search revealed limited documented cases in Africa. Cases found include that of a renowned oncologist and professor at the University of the Witwatersrand in Johannesburg, South Africa.<sup>30</sup> According to Weiss et al., and Cleaton-Jones, the professor reported positive results for a clinical trial which treated breast cancer using a combination of high-dose chemotherapy (HDC) and bone-marrow transplants. Before beginning a large-scale international follow-up study, an independent review was conducted which revealed that the original study protocol was actually written just before the review began.<sup>31</sup> The reviewers were only able to access records

<sup>26</sup> Okonta & Rossouw.

<sup>27</sup> Ibid.

<sup>28</sup> Fanelli. How many scientists fabricate and falsify research? A systematic review and meta-analysis of survey data.

<sup>29</sup> Kornfeld, Fanelli. How many scientists fabricate and falsify research? A systematic review and meta-analysis of survey data.

<sup>30</sup> P. Cleaton-Jones. Scientific misconduct in a breast-cancer chemotherapy trial: response of University of the Witwatersrand. *Lancet* 2000; 355: 1011–1012.

<sup>31</sup> R.B. Weiss, R.M. Rifkin, F.M. Stewart, R.L. Theriault, L.A. Williams, A.A. Herman & R.A. Beveridge. High-dose chemotherapy for high-risk primary breast cancer: an on-site review of the Bezwoda study. *Ibid.*: 999–1003, R.B. Weiss, G.G. Gill & C.A. Hudis. An on-site audit of the South African trial of high-dose chemotherapy for metastatic breast cancer and associated publications. *J Clin Oncol* 2001; 19: 2771–2777.

for 58 of the 75 patients from the HDC group. Of these, none contained a signed consent form. No records of the control group were available for review. Most of the 58 individuals with available records were ineligible for enrolment in the study and in some cases their treatment differed from that outlined in the original protocol. Further, the protocol had not been reviewed by the university's REC.<sup>32</sup>

Other reported cases in South Africa include a series of alleged plagiarism and cheating cases in KwaZulu-Natal, University of South Africa, Stellenbosch, Cape Town, Free State and Pretoria universities, which on June 10th 2007 were reported as 'institutes of higher cheating' by the *Sunday Times* newspaper following a series of plagiarism, falsification and false authorship committed in 2006.<sup>33</sup>

One well-known published example of misconduct in Africa is the controversial Trovan trial conducted by a US based renowned drug manufacturing company in Northern Nigeria in 2001. In this study, more than two hundred children were enrolled in an open label drug trial that resulted in the deaths of eleven of the children while a further two hundred became blind, deaf or lame.<sup>34</sup> It was later discovered that this drug was tested without proper ethics approval and no informed consent was obtained from the parents of the children.<sup>35</sup> The issue came to light through a public outcry.<sup>36</sup> Reportedly, no ancillary care was made available to patients; laboratory investigations were done in Geneva and the published articles never included or acknowledged the Nigerian principal investigator.<sup>37</sup>

In another case of misconduct in Nigeria, a medical doctor reportedly claimed to have developed new HIV prophylactic and therapeutic vaccines from the blood of HIV positive people.<sup>38</sup> The doctor claimed to have treated over four thousand HIV positive Nigerian patients in six years. According to Olusegun Oke, Vice-President of the Nigerian Academy of Science and former Vice-Chancellor of the University of Technology in Ogbomoso, the doctor did not even have the laboratory facilities to produce

<sup>32</sup> Schneider & Schuklenk.

<sup>33</sup> Institutions of Higher Cheating. *South Africa Sunday Times*: 10 June 2007.

<sup>34</sup> C. Willyard. Pfizer lawsuit spotlights ethics of developing world clinical trials. *Nat Med* 2007; 13: 763, J. Lenzer. Secret report surfaces showing that Pfizer was at fault in Nigerian drug tests. *BMJ* 2006; 332: 1233, K. Ahmad. Nigerian government investigates Pfizer drug trial allegations. *Lancet* 2001; 357: 129.

<sup>35</sup> Ahmad. Nigerian government investigates Pfizer drug trial allegations, Ahmad. Public protests as Nigeria bans use of untested HIV vaccine.

<sup>36</sup> R. Macklin. Bioethics, vulnerability, and protection. *Bioethics* 2003; 17: 472–486.

<sup>37</sup> A.S. Jegede. Understanding informed consent for participation in international health research. *Dev World Bioeth* 2009; 9: 81–87.

<sup>38</sup> Lenzer. Nigerian Doctor Finds HIV 'Cure'. Available at: <http://news.bbc.co.uk/2/hi/africa/740523.stm> [Accessed 28 Jan 2013].

a vaccine. He described the laboratory as virtually bare. The then acting co-ordinator of the joint World Health Organization/UNAIDS cautioned Nigerians against using the doctor's vaccine saying it had not been evaluated under the strict protocols required, and the work had not been independently reviewed by experts.<sup>39</sup> The government also suspended the use of all similar locally developed agents for HIV/AIDS therapies.<sup>40</sup>

Despite limited documented data on research misconduct, there is anecdotal evidence that many forms of misconduct may be common in Africa, as suggested by Okonta and Rossouw's study.<sup>41</sup> Particular issues known to the authors, and shared in the preparation of this paper, were about failure to adhere to recognized ethical standards in research; relationships between researchers involved in international collaborations; and dilemmas generated by the ground realities of recruiting participants and collecting data. Examples of these experiences are described in the following paragraphs:

- Research conducted by international researchers in a vulnerable community in a developing country without ethical clearance or government approval in the country where the study was conducted; including the export of human samples without following data or materials transfer procedures. Results from this study were published in a high impact journal without due consideration and involvement of the relevant stakeholders in the host country.
- Inadequate recognition of the contribution of developing country partners in international research collaborations where an African co-investigator undertook most of the work, including data collection, patient treatment, and writing up the study. The principal investigator (PI), from a developed country, left the study site with the data at the end of the research. When the findings of this study were published, local researchers, the local hospital and the host community were not acknowledged, and investigators unknown to the host country researchers were listed as authors.
- Perceived pressure to meet study recruitment was reported to the authors by front line research staff in training seminars. Front line staff described forms of misconduct such as not disclosing all the information in informed consent forms, or 'cutting corners' by not clearly explaining procedures perceived to be particularly uncomfortable or sensitive. Similarly, some front line staff described putting particular emphasis on study benefits to encourage participation. Other examples of more or less serious deviation from informed consent protocols were not describing the

need for a witness for participants who were illiterate; and falsifying the types of benefits offered to participants in studies, including access to free healthcare where this was not in fact the case. In some cases, particularly where misconduct was seen as minor, practices were reportedly undertaken with apparent acceptance by supervisors and principal investigators. Misconduct was also seen as more likely where unrealistic enrollment targets had been set. A lack of training in research ethics amongst study supervisors, usually junior researchers, was believed to contribute to a tendency for this group to focus more on recruitment outcomes than ethical aspects of the processes used. A more extreme lapse of research integrity was described in a group of medical students asked to collect routine health and demographic data in a rural area who intentionally fabricated data in order to save time and the money allocated for transport costs. In this case, inadequate training and negligent monitoring of the data collectors seem likely to be the main issues.

## JUSTIFICATION FOR PROMOTING RESEARCH INTEGRITY

Given the limited documented cases of research misconduct in Africa and the experiences shared, the need to develop coherent and effective policies and governance structures to enhance the integrity of research is clear. Indeed, the World Health Organization (WHO) stipulates the need to develop national and local regulatory authorities to regulate the conduct of research.<sup>42</sup> However, based on the absence of published literature, little appears to have been done in developing countries to heed this call.

The recent past has seen an increased drive by governments and international sponsors such as the US NIH Fogarty International Center and EDCTP to expand and strengthen the research oversight capacity of institutions at local and national levels to review and monitor studies, for example through IRBs, RECs and CABs.<sup>43</sup> This literature underscores the need for increased participation of competent independent specialist bodies in research-related decision-making, especially in low-income settings and gives priority for equitable transnational

<sup>39</sup> Ibid.

<sup>40</sup> Ahmad. Public protests as Nigeria bans use of untested HIV vaccine.

<sup>41</sup> Okonta & Rossouw.

<sup>42</sup> World Health Organization (WHO). 2005. *Handbook for Good Clinical Research Practice (GCP). Guidance for Implementation*. Available at: <http://apps.who.int/medicinedocs/index/assoc/s14084e/s14084e.pdf> [Accessed 28 Jan 2013].

<sup>43</sup> Weijer & Emanuel. Ethics. Protecting communities in biomedical research, C. Weijer, G. Goldsand & E.J. Emanuel. Protecting communities in research: current guidelines and limits of extrapolation. *Nat Genet* 1999; 23: 275–280.

research collaborations and general ethical conduct of research.<sup>44</sup>

Increased awareness of ethical concerns associated with study designs and informed consent processes, use of biomedical samples, collaboration and authorship issues among researchers working in resource-poor settings is likely to have a significant positive influence on the conduct of research in Africa. This can be achieved through systematic investment in technological and financial resources to build capacity for local scientists and communities to ensure that research meets acceptable ethical standards.<sup>45</sup>

### *What can be learnt from settings with existing research integrity systems?*

The US Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of participants involved in research conducted or supported by the Department of Health and Human Services (HHS).<sup>46</sup> OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research. OHRP also supports the Secretary's Advisory Committee on Human Research Protections (SACHRP) which advises the HHS Secretary on issues of human subject protections.<sup>47</sup>

The Federal Policy for the Protection of Human Subjects or the 'Common Rule',<sup>48</sup> is the baseline procedural standard with which all US government funded research conducted within and without the US must comply. A weakness in the US system is that the Common Rule is only mandatory for federally funded research, and not for research funded by other sources, e.g. private pharmaceutical manufacturers, although many IRBs apparently seek OHRP assurances and apply the Common Rule to all their reviews, irrespective of funding source.

With regard to research integrity, the US Department of Health and Human Services has also established an Office of Research Integrity (ORI)<sup>49</sup> with a specific mandate to oversee and direct Public Health Service (PHS) research integrity activities. Through these structures, the US government ensures that all federally funded research con-

forms to the highest standards of research integrity by facilitating responsible conduct of research through educational, preventive, and service activities.

Some aspects of US research oversight have recently been criticized in the US Presidential Committee on Bioethics Report (2012) and are likely to be reviewed in future.<sup>50</sup>

With regard to research oversight in the United Kingdom (UK), the Medical Research Council (MRC) is the national regulatory body that governs the conduct of health research. The Ethics, Regulation and Public Involvement Committee (ERPIC) provides the MRC with expert ethical advice on a wide range of issues relating to medical research. The ERPIC also advises the MRC on legislation, policy and guidance concerning the conduct of research involving human participants as well as advising the council on the MRC's support for the Nuffield Council on Bioethics.<sup>51</sup>

With specific regard to research integrity, the UK Research Integrity Office (UKRIO) is an independent advisory body that provides guidance and support on good research and addressing fraud and misconduct in research. UKRIO provides assistance to researchers, research organizations and members of the public, including universities, the NHS, private sector bodies and charities in the UK. UKRIO is not a regulatory body and has no formal legal powers and therefore the advice UKRIO offers is not mandatory.<sup>52</sup>

Most recently, a consortium of science and research stakeholders in the UK have published a Concordat to Support Research Integrity<sup>53</sup> signed by representatives from the MRC, the National Health Service, other major science funders, UK universities and the Government Department for Employment and Learning. This document promotes the importance of those involved in science acknowledging and discharging their specific responsibilities, working together to maintain the highest standards and developing clear policies, practices and procedures that support responsible conduct of research.<sup>54</sup>

Steps have also been taken to strengthen the conduct of research in Canada. Here, research governance is overseen by the Canadian Institute of Health Research (CIHR). Together, the Natural Sciences and Engineering Council of

<sup>44</sup> Molyneux & Geissler.

<sup>45</sup> IJsselmuiden, Marais, Wassenaar & Mokgatla-Moipolai, Molyneux & Geissler.

<sup>46</sup> U.S Department of Health & Human Services. *The Office of Research Integrity*. Available at: <http://ori.hhs.gov> [Accessed 28 Jan 2013].

<sup>47</sup> U.S Department of Health & Human Services. *Office for Human Research Protections (OHRP)*. Available at: <http://www.hhs.gov/ohrp>. [Accessed 28 Jan 2013].

<sup>48</sup> Ibid.

<sup>49</sup> U.S. Department of Health & Human Services. *Office of Research Integrity*. Available at: <http://ori.hhs.gov> [Accessed 28 Jan 2013].

<sup>50</sup> Presidential Commission for the Study of Bioethical Issues. President Obama Asks Bioethics Commission to Review Protections for Human Research Subjects. Available at: <http://bioethics.gov/cms/node/82>. [Accessed 28 Jan 2013].

<sup>51</sup> *Medical Research Council (MRC)*. Available at: <http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/ERPIC/index.htm> [Accessed 28 Jan 2013].

<sup>52</sup> *UK Research Integrity Office*. Available at: <http://www.ukrio.org> [Accessed 28 Jan 2013].

<sup>53</sup> Ibid.

<sup>54</sup> *The Concordat to Support Research Integrity*, Universities UK, London 2012. ISBN 978-1-84036-273-2N, London: Available at: <http://www.universitiesuk.ac.uk/Publications/Documents/TheConcordatToSupportResearchIntegrity.pdf> [Accessed 28 Jan 2013].

Canada (NSERC), and the Social Sciences and Humanities Council of Canada (SSHRC) require that the research they fund be carried out in accordance with high standards of ethics and integrity, and that grant funds be spent in compliance with certain procedures and requirements.<sup>55</sup>

In Australia, conduct of research is overseen by the Australian Research Council (ARC) which is committed to fostering the highest ethical standards in research. Projects approved for funding by the ARC may not begin without appropriate ethical clearances from the relevant committees and/or authorities. With regard to research integrity, ARC-funded research should also comply with the Australian Code for the Responsible Conduct of Research.<sup>56</sup>

South Africa established statutory structures to promote responsible conduct of research in 2003. The National Health Research Ethics Council (NHREC) was established under the National Health Act No 61 of 2003.<sup>57</sup> The NHREC's functions involve giving direction on ethical issues relating to health and develop guidelines for the conduct of research involving humans. The NHREC observes and advises on international developments in health research ethics issues through liaison with relevant international organizations.<sup>58</sup>

In Nigeria, a National Health Research Ethics Committee (NHREC) was inaugurated in October 2005 under the Federal Minister of Health (FMOH). As the national health research regulatory body, NHREC is the apex body responsible for the provision of and ensuring adherence to guidelines that govern ethical research practice in order to ensure the protection of human research participants.<sup>59</sup> However, the NHREC has no data on scientific misconduct in the country.<sup>60</sup>

As suggested above, with some exceptions, established systems for promoting, coordinating and monitoring responsible conduct of research are currently mostly found in the developed world. As a result, these countries are increasingly able to monitor, investigate and use investigatory findings to propose administrative and disciplinary actions against those who commit misconduct. By establishing and implementing a program of advice and technical assistance to entities that conduct inquiries and investigations, or otherwise respond to research misconduct, developed countries are able to promote responsible conduct of research and thereby minimize research misconduct.

<sup>55</sup> Canadian Institute of Health Research. Available at: <http://www.cihr-irsc.gc.ca/e/193.html> [Accessed 28 Jan 2013].

<sup>56</sup> Australian Government. *Australian Research Council*. Available at: [http://www.arc.gov.au/general/research\\_integrity.htm](http://www.arc.gov.au/general/research_integrity.htm) [Accessed 28 Jan 2013].

<sup>57</sup> The National Health Research Ethics Council. A Statutory Body Established Under the National Health Act No 61 of 2003. Available at: <http://www.nhrec.org.za> [Accessed 28 Jan 2013].

<sup>58</sup> *Ibid.*

<sup>59</sup> *Ibid.*

<sup>60</sup> Okonta & Rossouw.

Against this background, this paper proposes two broad approaches to foster research integrity in Africa. The proposed approaches include promotion of institutional and individual capacity building to instill a culture of responsible research conduct in existing and upcoming research scientists; and identifying deterrent and corrective measures to minimize the likelihood of research misconduct and other questionable research practices.

## STRATEGIES FOR PROMOTING RESEARCH INTEGRITY IN AFRICA

We propose two broad thematic strategies to address problems related to research integrity in Africa. Firstly efforts should focus on the promotion of research integrity through institutional and individual capacity building i.e., educational and developmental initiatives to instill the concept and value of research integrity into the research community (both individually and collectively), including an understanding of the implications of good practice by research funders. This involves a positive approach to promoting new norms of research practice (through a universal standard like the Singapore Statement)<sup>61</sup> and behavior incorporating good research practices in all research active institutions. Secondly, there is a need to develop deterrent and corrective policies and mechanisms such as investigating and giving objective reports about those found guilty of research misconduct as well as initiating appropriate disciplinary measures against them. This would help to mitigate research misconduct and other research malpractices in Africa.

### *Capacity building*

Practicing research integrity should be considered as part of the ethos of being a researcher. Individuals need to be aware of their responsibilities in the conduct of ethically approved research. One way to achieve this is to develop a model curriculum for health research ethics for undergraduate and postgraduate students to enable them to learn research ethics and responsible conduct of research from their earliest academic years. An ethics training certificate should be made a prerequisite for any person who applies for approval to conduct research. This is in line with what Okonta and Rossouw recommended.<sup>62</sup> Development of relevant standards and guidelines are important prerequisites to a successful implementation of this framework. In addition, African efforts to institutionalize research integrity programs in Africa should ideally seek harmonized approaches that bind researchers working anywhere on the continent.

<sup>61</sup> Resnik & Shamoo, Marusic.

<sup>62</sup> Okonta & Rossouw.

African stakeholders should also unite and develop customized research integrity courses for researchers working in Africa. It is not known to what extent current US NIH-Fogarty funded research ethics training programs in Africa focus on research integrity. Ongoing up-to-date trainings should also be institutionalized for those working in research institutions so that researchers are up to date with relevant policies and best practices.

Another key component of capacity building involves mentoring. Mentoring of research trainees by senior colleagues is key in imparting knowledge and skills on good research practices. Best practices should be sought and identified, and a formalized mentorship program should be developed to guide senior researchers on how best to mentor undergraduate and postgraduate students, post-doctoral fellows or other research staff more effectively. It is important for a mentor to be cognizant of his/her position as a role model and to lead by example in maintaining a research environment that upholds and values research integrity.

#### *Monitoring and investigation of reported scientific research misconduct*

One major challenge facing RECs in Africa is their inability to monitor and investigate researchers' adherence to ethical standards. There is therefore a need to establish systems to proactively investigate and process reports of misconduct, address the underlying causes and – where needed – ensure that appropriate penalties and sanctions are implemented when misconduct is confirmed. This function should ideally be independent of REC functions.

Specifically, the following could be done to monitor and investigate instances of research misconduct:

- a) Each country should develop ethics guidelines compatible with international guidance, to govern the conduct of health research. A research oversight agency with legal powers should be set up at national level to ensure that country specific regulations are adhered to in the conduct of research.
- b) Monitoring of approved research work by RECs will ensure timely identification of issues that may develop into misconduct if left to continue. RECs should be mandated and supported to monitor ongoing studies. This can be done by making monitoring of research an integral component of a study proposal and budget.
- c) Collaborative research work with non-national researchers should always have a local researcher as the co-investigator with equal responsibility as the external PI. This should be made a prerequisite for approving any collaborative research work. Guidelines should be put in place to ensure that the roles of all the PIs are clarified out to avoid future conflicts.
- d) During publication, journal editors should ensure that all listed authors confirm and describe their level of involvement in the work before publication. It is also important for journals to establish a mechanism for addressing any conflicts that may arise concerning any published work, for example, allowing those who feel they have been unfairly treated in a given published work to lodge their complaints; investigate them and take action such as withdrawing the paper if such complaints are proved to be true. Journal editors should routinely require written proof of ethics approval and this should be mentioned in each article.<sup>63</sup>
- e) African governments should set up harmonized research ethics and integrity commissions/boards that should be mandated by law to investigate, publish cases of misconduct and sanction researchers found guilty of scientific research misconduct. The commission/board should also be charged with the responsibility of reporting cases of misconduct to the public. To avoid implicating researchers unfairly, clear procedures and guidelines should be formulated to guide how cases of misconduct shall be investigated to ensure objectivity and consistency. The US and the UK have useful comprehensive guidance on how misconduct allegations should be processed<sup>64</sup> and these could be adapted to the African research context.
- f) African governments, commissions and integrity boards should establish a common internet-based platform which can be used to maintain a record of research misconduct findings and easy exchange of information to ensure that all cases of misconduct reported by individual countries are timeously uploaded and shared. Country research oversight agencies or boards can be charged with the responsibility of ensuring that country reports on research misconduct are updated on the common websites such as [www.researchethicsweb.org](http://www.researchethicsweb.org)<sup>65</sup>
- g) Clear punitive and remedial actions should be put in place and enforced so that researchers found guilty of misconduct can be appropriately dealt with such that others could learn from such misconduct and hopefully deter scientists from engaging in malpractices.

<sup>63</sup> R.G. Steen. Retractions in the medical literature: how can patients be protected from risk? *J Med Ethics* 2012; 38: 228–232, R.G. Steen. Retractions in the scientific literature: do authors deliberately commit research fraud? *J Med Ethics* 2011; 37: 113–117, R.G. Steen. Retractions in the scientific literature: is the incidence of research fraud increasing? *J Med Ethics* 2011; 37: 249–253, R.G. Steen. Retractions in the medical literature: how many patients are put at risk by flawed research? *J Med Ethics* 2011; 37: 688–692.

<sup>64</sup> Requirements for Institutional Policies and Procedures on Research Misconduct Under the New PHS Policies on Research Misconduct, 42 CFR Part 93. Available at: <http://ori.dhhs.gov/documents/requrimnts.pdf> [Accessed 28 Jan 2013].

<sup>65</sup> Research Ethics Web. Mapping African Research Ethics Review Capacity. Available at: <http://www.researchethicsweb.org> [Accessed 28 Jan 2013].



## CONCLUSION

Generally, the need to establish appropriate mechanisms to address scientific misconduct in Africa cannot be over-emphasized. Professional and public debates on how best to promote research integrity in Africa must be fostered as new information becomes available. Two main approaches are likely to be needed. The first is promoting individual integrity of all individual research staff and institutions through training, mentoring and supportive supervision. The second is ensuring appropriate national and institutional frameworks that take potential instances of research misconduct seriously. Such systems should be transparent, accountable and include an understanding of the local circumstances, challenges and dilemmas encountered by staff in practice. In addition to effective mechanisms to promote research integrity, increased awareness of ethical concerns associated with research is needed.

Although a limitation of this paper is the anecdotal nature of some of the cases described, the experiences of the authors support others' recommendations<sup>66</sup> on the need to establish effective institutional policies. The proposed strategies will not only benefit the nine countries from which the authors come, but possibly the rest of the African continent and beyond.

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### Biographies

**Francis Kombe** (MPH, PGD, CBPPM) works with the KWTRP as a senior community facilitator. He currently coordinates ethics training for interface staff at the programme and has deep interest in building interface staff and community members' capacity in research ethics through participatory and reflective training technics.

**Eucharika Nkchinyere Anunobi** (MB; BS, MWACP, FMCpaed) holds a certificate training in Health Research Ethics and is an International study coordinator from the School of Nursing, University of Alabama (UAB). She works as a Consultant Pediatrician and research clinician at Asokoro District Hospital, Asokoro, Abuja, Nigeria and worked at MRC, UK, The Gambia and University of Ilorin Teaching Hospital, Ilorin, Nigeria.

**Nyanyukweni Pandeni Tshifugula** holds an MPH and PGDPH. He is a Faculty/Lecturer in the School of Nursing and Public Health at the

University of Namibia (UNAM), Oshakati Campus, Namibia. He attended three Master's Modules in Research Ethics at the University of KwaZulu-Natal's School of Psychology and A Post-Graduate Diploma Module on Dual Review of Research at the University of Stellenbosch, Tygerberg Campus, South Africa. His interest lies in the field of research integrity.

**Douglas Wassenaar** is a clinical psychologist and Director of the South African Research Training Initiative (SARETI). He is a professor at the University of KwaZulu-Natal, South Africa, and chairs the UKZN Biomedical Research Ethics Committee and the Research Ethics Committee of the Human Sciences Research Council. He is principal investigator and collaborator on several grants focussed on aspects of research ethics.

**Dimpho Njadingwe** is a Health Systems Research Training Coordinator at the School of Medicine, University of Botswana (UB). She holds a Bachelor's degree in Environmental Science and a Post Graduate Diploma in Education, both from the University of Botswana. She has also completed a number of Research Ethics training programs including an intensive one year training course in Bioethics at the Johns Hopkins University in the United States of America and three Masters' modules in Health Research Ethics offered through the SARETI programme at the University of KwaZulu-Natal in South Africa.

**Salim Mwalukore** works with the KEMRI-Wellcome Trust Research Programme in Kilifi, Kenya as the Community Liaison Manager. He holds a BSc in Biological Science, a certificate in Health Research Ethics, and a Certificate in Health Communication for Quality Healthcare and Research and good clinical practice. His roles include sitting on the institutional review committee, the Scientific Coordinating Committee (SCC) and Consent and Communication Committee (CCC) to review research proposals especially making input on the community engagement and ethical aspects of research.

**Jonathan Chinyama** holds an MSc in Clinical Neuropsychology, a BA in Psychology, a Diploma in Clinical Medical Sciences, and a certificate of attendance in Health Research Ethics.

**Bodo Randrianasolo**, MD, is a consultant for the University of North Carolina project entitled: 'Strengthening Bioethics Capacity and Justice in Health' based in Madagascar, in collaboration with Institut National de Santé Publique et Communautaire of Madagascar. The Project is funded by the Fogarty International Center of the US National Institutes of Health.

**Perpetua Akindeh** is a member of Cameroon Bioethics Initiative, an Ethical committee based in Yaoundé Cameroon. A jurist by profession, Perpetua works with the Ministry of Justice as a prosecuting magistrate.

**Priscilla S. Dlamini** is an associate Professor in nursing and a director of the institute of research on traditional medicines, medicinal and indigenous food and fruit plants. Her main activities include teaching, research and community services. She underwent a course for two months at the University of Kwazulu Natal in 2011.

**Felasoa Noroseheno Ramiandrisoa** is a medical doctors and Medical researcher on medical and public health issues. She is also a Consultant for the University of North Carolina project entitled: "Strengthening Bioethics Capacity and Justice in Health" based in Madagascar, in collaboration with Institut National de Santé Publique et Communautaire of Madagascar. The Project is funded by the Fogarty International Center of the US National Institutes of Health.

**Naina Ranaivo** works with the Tianshi Company in Tamatave, Madagascar. He holds a BSc in Biological Science and a doctorate of medical science and a certificate of attendance in Health Research Ethics.

<sup>66</sup> Okonta & Roussow; Kornfield.