# 19. WHO Project on Responsible Life-Sciences Research for Global Health Security: Why Ethics and How to Strengthen It?

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## Introduction

There has been much discussion over the past years about global health security and how to strengthen it. One area that has raised much activity revolves around the risks posed by accidents and the potential deliberate misuse of life-sciences research.[2] Different actors have proposed a variety of measures to manage such potential risks.[3] Yet little information is available about the needs and capacities of countries, laboratories and research institutions in this area.

The World Health Organisation (WHO) has developed a self-assessment questionnaire for laboratory managers and researchers to assess their needs and

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1 The author is a staff member of the World Health Organisation. The author alone is responsible for the views expressed in this chapter and he does not necessarily represent the decisions or policies of the World Health Organisation.

2 Research accidents are understood as research activities that may unexpectedly pose some risks via 'accidental' discoveries. World Health Organisation (WHO) 2010, *Responsible Life Sciences Research for Global Health Security. A Guidance Document*, WHO/HSE/GAR/BDP/2010.2, World Health Organisation, Geneva.

3 See, for instance: National Research Council 2004, *Biotechnology Research in An Age of Terrorism*, Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, The National Academies Press, Washington, DC; National Science Advisory Board for Biosecurity (NSABB) 2007,*Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*, National Science Advisory Board for Biosecurity, Bethesda, Md; Miller, S. and Selgelid, M. 2008, *Ethical and Philosophical Consideration of the Dual-Use Dilemma in the Biological Sciences*, Springer, Dordrecht; Report prepared by the Centre for Applied Philosophy and Public Ethics at The Australian National University for the Australian Department of Prime Minister and Cabinet, National Security Science and Technology Unit, November 2006; Steinbruner, J. et al. 2007, *Controlling Dangerous Pathogens. A Prototype Protective Oversight System*, March, Center for International and Security Studies at Maryland (CISSM), University of Maryland, College Park; InterAcademy Panel on International Issues (IAP) 2005, *IAP Statement on Biosecurity*, November; 'Statement on the scientific publication and security', *Science*, vol. 299 (2003), p. 1149; United Nations Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction; *Managing Risks of Misuse Associated with Grant Funding Activities. A Joint Biotechnology and Biological Sciences Research Council (BBSRC), Medical Research Council (MRC) and Wellcome Trust Policy Statement*, September 2005; Wellcome Trust 2005, *Guidelines on Good Research Practice*, November; Dando, M. and Rappert, B. 2005, 'Codes of conduct for the life sciences: some insights from UK academia', *Briefing Paper No. 16 (Second series)*, May, University of Bradford, UK.

capacities in regards to responsible life-sciences research. This self-assessment questionnaire is part of a larger project on 'Responsible life-sciences research for global health security', which published several documents on this issue.[4] The responsible life-sciences research framework and its associated self-assessment questionnaire are based on three pillars supporting public health: research excellence, ethics, and biosafety and laboratory biosecurity. The bio-risk framework for responsible life-science research is an integrated approach, where each pillar is equally important and should complement and reinforce the others. This chapter will focus on the ethics pillar because it is often regarded as an area that is complex, underfunded and an obstacle to undertaking research. This chapter starts by giving an overview of the bio-risk management framework for responsible life-sciences research. It then underlines the role of ethics in this area and it ends by discussing how the self-assessment questionnaire can provide useful feedback to countries and institutions to identify needs and capacities in ethics, and ways to strengthen them.

## The bio-risk management framework for responsible life-sciences research

The WHO project on responsible life-sciences research for global health security aims at promoting excellent, safe, secure and responsible life-sciences research through an integrated approach that recommends investing capacities in three pillars supporting public health: research excellence; ethics; biosafety and laboratory biosecurity.[5]

- Pillar 1: Research excellence. This concerns fostering quality in life-science activities, which is the basis for developing new treatments and therapeutics, strengthening health research systems, and promoting public health surveillance and response activities. These elements are essential to protecting and improving the health and wellbeing of all people.

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4 World Health Organisation (WHO) 2005, *Life Sciences Research: Opportunities and Risks for Public Health. Mapping the Issues*, WHO/CDS/CSR/LYO/2005/20, World Health Organisation, Geneva, <http://www.who.int/csr/resources/publications/deliberate/WHO_CDS_CSR_LYO_2005_20/en/index.html> (viewed 7 February 2012); World Health Organisation 2007, *Scientific Working Group on Life Science Research and Global Health Security. Report of the First Meeting*, WHO/CDS/EPR/2007.4, World Health Organisation, Geneva, <http://www.who.int/csr/resources/publications/deliberate/WHO_CDS_EPR_2007_4/en/index.html> (viewed 7 February 2012); World Health Organisation (WHO) 2008, *Research Policy and Management of Risks in Life Sciences Research for Global Health Security. Report of the Meeting. Bangkok, Thailand, 10–12 December 2007* WHO/HSE/EPR/2008.4, World Health Organisation, Geneva, <http://www.who.int/csr/resources/publications/deliberate/WHO_HSE_EPR_2008_4/en/index.html> (viewed 7 February 2012); World Health Organisation (WHO) 2012, Informal Consultation on Dual-Use Research of Concern (DURC), World Health Organisation, Geneva, 26–28 February 2013, <http://www.who.int/mediacentre/events/meetings/2013/durc/en/> (viewed 2 September 2013).

5 This section draws upon the following WHO guidance document: WHO, 2010, op. cit.

- Pillar 2: Ethics. This involves the promotion of responsible and good research practices, the provision of tools and practices to scientists and institutions that allow them to discuss, analyse and resolve in an open atmosphere the potential dilemmas they may face in their research, including those related to the possibility of accidents or misuse of the life sciences.
- Pillar 3: Biosafety and laboratory biosecurity. This concerns the implementation and strengthening of measures and procedures to: minimise the risk of worker exposure to pathogens and infections; protect the environment and the community; and protect, control and account for valuable biological materials (VBM) within laboratories, in order to prevent their unauthorised access, loss, theft, misuse, diversion or intentional release. Such measures reinforce good research practices and are aimed at ensuring a safe and secure laboratory environment, thereby reducing any potential risks of accidents or deliberate misuse.

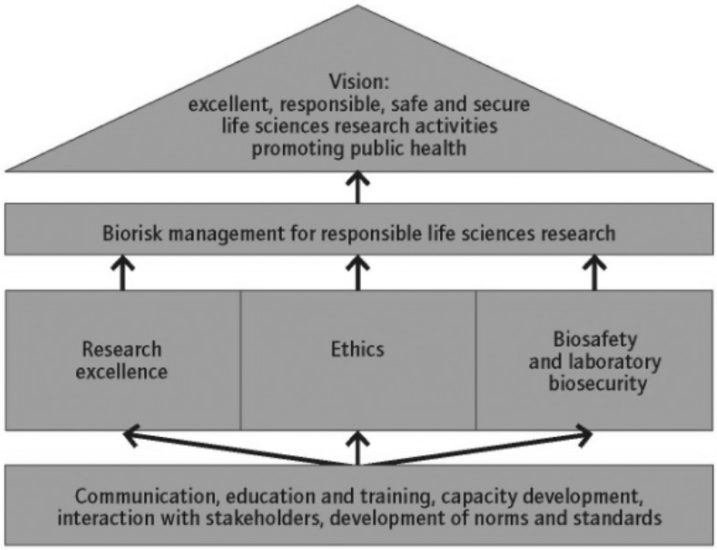


**Figure 19.1 Bio-Risk Management Framework for Responsible Life-Sciences Research**

Source: World Health Organisation (WHO) 2010, *Responsible Life Sciences Research for Global Health Security. A Guidance Document*, WHO/HSE/GAR/BDP/2010.2, World Health Organisation, Geneva.

This approach recognises that there is no single solution or system that will suit all countries, institutions or laboratories. Each country or institution that assesses the extent to which it has systems and practices in place to deal with the risks posed by accidents or the potential deliberate misuse of life-sciences research will decide which measures are most appropriate and relevant according to their own national circumstances and contexts.

Likewise, this approach also acknowledges the fact that there is a multiplicity of stakeholders developing different measures. The public health sector is one stakeholder among others (for example, national academies of science, ethicists and security communities), and coordination at national and international levels is therefore crucial for addressing those types of risks.

One important advantage of this integrated framework is that it recommends investing capacities in public health areas that either are already in place in many countries or are being developed for strengthening research capacities and for addressing laboratory bio-risks. This approach therefore promotes a sustainable and effective way to address such bio-risks. Indeed it emphasises that one of the most effective ways to prepare for deliberately caused disease is to strengthen public health measures for naturally occurring and accidentally occurring diseases.[6] In a similar manner, the promotion of a culture of scientific integrity and excellence is considered as one of the best protections against the possibility of accidents and deliberate misuse of life-sciences research and offers the best prospect for scientific progress and development. A culture of scientific integrity and excellence can be strengthened through the development and reinforcement of capacities in the three aforementioned public health pillars. In adopting the bio-risk management framework for responsible life-sciences research, countries and institutions are encouraged to consider

- reinforcing public health capacities in terms of research for health, biosafety and laboratory biosecurity management and ethics
- investing in training personnel (laboratory staff and researchers) and students in ethics, the responsible conduct of research, and biosafety and laboratory biosecurity
- ensuring compliance with biosafety and laboratory biosecurity
- identifying multi-stakeholder issues, with different layers of responsibilities and encouraging coordination among stakeholders
- using existing mechanisms, procedures and systems and reinforcing local institutional bodies (if they exist).

While recognising the above, countries and institutions may consider drawing on a bio-risk management framework for responsible life-sciences research, which has been developed to help countries and institutions identify where public health resources can be used for addressing the above risks. To facilitate such analysis, a self-assessment questionnaire on responsible life-science research has been developed to support health researchers, laboratory managers and research institutions to identify strengths and to address weaknesses in

6 World Health Assembly Resolution WHA55.16 of 18 May 2002, *Global Public Health Response to Natural Occurrence, Accidental Release or Deliberate Use of Biological and Chemical Agents or Radionuclear Material that Affect Health*, World Health Organisation, Geneva.

each of the three pillars. Among these three pillars, ethics is an important public health area where countries and institutions can invest capacities to address such bio-risks.

# An ethics framework

## Context and related initiatives

The potential duality of research and science, and related moral concerns, is not a new issue. Following the invention of atomic weapons, many scientists, including Einstein, Oppenheimer and Russell, voiced concern about the potential dangers to humanity arising from scientific discoveries.[7]

Ethical issues arising in research and the corresponding obligations of scientists have for a long time been one of the key areas of work on ethics of the UN Educational, Scientific and Cultural Organisation (UNESCO). Already in 1974, UNESCO's eighteenth general conference adopted the *Recommendation on the Status of Scientific Researchers*,[8] which enumerated ethical responsibilities and rights of scientists.

In 1999, UNESCO organised the World Conference on Science, in Budapest, which gave special attention to ethical principles and responsibilities in the practice of science.

Since 2005, UNESCO has led a new project, with regional consultations, to survey the field of science ethics and to evaluate the need for an update of the 1974 document.[9]

Until recently, however, the bioethics community concerned with research has focused on the protection of human subjects in clinical trials, and other kinds of ethical issues raised by genetics and related disciplines. It is only in the past few years that ethicists have become more engaged with the scientific community and security experts regarding the ethical questions raised by the potential misuse of science.

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7 See, for example: 'Russell-Einstein Manifesto and the Pugwash Conferences on Science and World Affairs', <http://www.pugwash.org/about/manifesto.htm> (viewed 7 February 2012).

8 United Nations Educational, Scientific and Cultural Organisation (UNESCO) 1974, *Recommendation Adopted on the Report of the Commission for Science at the Thirty-Eighth Plenary Meeting on 20 November 1974*, Paris.

9 Scholze, S. 2006, 'Setting standards for scientists: for almost ten years, COMEST has advised UNESCO on the formulation of ethical guidelines', *EMBO Reports*, vol. 7 (SI) (July), pp. S65–7.

Ethics is now recognised in the field as providing a useful framework for the identification of dilemmas, and the discussion and evaluation of responsibilities of different stakeholders. Ethics can help promote understanding of the nature of decisions that researchers and other actors have to make.[10] The discussion of ethical issues can contribute to consensus-building among the stakeholders, who sometimes have competing interests.

## Ethics framework in the WHO project

WHO has, since its establishment in 1948, given great importance to ethical considerations in its programs. In 1967, the World Health Assembly (WHA) resolved that 'scientific achievements, and particularly in the field of biology and medicine—that most humane science—should be used only for mankind's benefit, but never to do it any harm'.[11] A WHO report in 2005 discussed in more detail the ethical questions raised.[12]

Some of the basic dilemmas addressed in the current WHO project, 'Responsible life science research for global health security', are

- how to weigh the potential benefits of research against the risk of misuse
- how to weigh the individual interests of researchers against the common good of public health
- how to best manage the risks associated with research, without hindering its beneficial application to public health
- what are the responsibilities of individual researchers, and of the scientific community as a whole to society?

For the development of an ethics framework, it is helpful to analyse the responsibilities and dilemmas of different stakeholders involved in life sciences, and to develop corresponding tools to support them in making ethical choices.

## Researchers, science societies and codes of conduct/ethics

Individual scientists have been at the centre of the debate on ethical responsibilities in dual-use research. On the one hand, they will aim to carry out and publish beneficial research, while on the other hand they want to refrain from research that could lead to the potential malevolent use of the results. They

10 WHO, 2007, op. cit.
11 WHA20.54.
12 World Health Organisation (WHO) 2005, *Life Sciences Research*, WHO/CDS/CSR/LYO/2005/20, World Health Organisation, Geneva, <http://www.who.int/csr/resources/publications/deliberate/WHO_CDS_CSR_LYO_2005_20/en/index.html> (viewed 7 February 2012).

have a widely acknowledged obligation to carry out their research in accordance with good research practices and laws and regulations, including codes (see below). In addition, the debate on dual-use research has made clear that there are also some expectations on the individual scientists to make judgments about the outcomes and potential security implications of their research projects; however, often researchers will not be security experts and may face difficulties in making such assessments. Therefore, while education can help to raise awareness among scientists, in case of doubt, they should be able to turn to mechanisms for reporting and consultation, including for whistleblowing, provided by their institutions.

Codes for researchers have for a long time been proposed as potentially useful tools to address the potential misuse of life-science research at the level of the individual scientists. In fact, codes for professional behaviour date back at least two millennia (the Hippocratic Oath, Maimonides, and so on). Two types of codes are usually distinguished

1. codes of conduct: these provide specific guidelines with respect to what is considered appropriate behaviour
2. codes of ethics: these are more aspirational, setting forth the ideas to which practitioners should aspire, such as standards of objectivity or honesty.

Some prominent examples of codes for scientists include those proposed by scientific and academic societies (such as the American Society for Microbiology, the Chinese Academy of Sciences, The Royal Society in the United Kingdom and the US National Science Advisory Board for Biosecurity), and medical associations (such as the World Medical Association and the American Medical Association).[13] Recently, the International Centre for Genetic Engineering and Biotechnology has been undertaking a project to review codes of conduct.

There has been considerable debate on the effectiveness of codes of conduct/ethics for researchers.[14] Critics have insisted that there is little evidence about their effectiveness in practice. For example, the Hippocratic Oath has not hindered medical doctors from doing horrendous things to their patients. Scientists may simply not comply with such non-binding instruments as codes, and terrorists will not be deterred from using biotechnology with bad intentions. Even with the best intentions, and fully aware of their duties, scientists are not security experts and may thus not foresee the consequences of their experiments, which might have dual-use potential.

13 For more examples, see WHO, 2010, op. cit., pp. 58–9.

14 Rappert, B. 2007, 'Codes of conduct and biological weapons: an in-process assessment', *Biosecurity and Bioterrorism: Biodefense Strategy, Practice and Science*, vol. 5, pp. 145–54.

On the other side, the proponents of such codes—for example, Margaret Somerville and Ronald Atlas[15]—have argued that they serve their purpose in raising awareness, fostering norms among the scientific community and establishing public accountability mechanisms. They can help sensitise scientists who might be used by malevolent individuals or organisations and the public health community to the risks of dual-use research. Codes can also foster an environment in research institutions in which whistleblowing could be encouraged. There is an ongoing discussion between the proponents of a universal code, arguing that national codes of conduct will have little effect on the global behaviour of life scientists, and those who prefer developing some basic principles that would then be applicable to and implemented at local settings, institutions or countries.

Education and training in biosecurity and ethics are other tools for raising awareness among scientists. A report published in 2008 by the American Association for the Advancement of Science (AAAS) examined such education programs and emphasised their importance.[16]

## Research institutions

As most research takes place in institutions, these also have important responsibilities in the prevention of accidents and the deliberate misuse of research. Research institutions have an obligation to ensure that research within their premises is conducted according to national laws and relevant codes of conduct. They should sensitise their researchers to dual-use issues—for example, through education and specific training, promoting discussion and reflection on research practices, and creating a climate that encourages scientists to come forward in case of difficulties. Procedures and standards for whistleblowing should be in place for cases of scientific misconduct.

Another potentially useful approach to address the dual-use dilemma, which has been proposed at the institutional level, is the ethical review of sensitive research by an ethics committee. In practice, however, it is not clear which committees could take on this role. Traditional research ethics committees review research with human subjects, and not bench science, and their members are not usually trained in biosecurity issues. With specific training, the members of research ethics committees could probably be enabled to play this role. Another

15 Somerville, M. and Atlas, R. 2005, 'Ethics: a weapon to counter bioterrorism', *Science*, vol. 307, pp. 1881–2.

16 American Association for the Advancement of Science (AAAS) 2008, *Professional and Graduate-Level Programs on Dual Use Research and Biosecurity for Scientists Working in the Biological Sciences: Workshop Report*, American Association for the Advancement of Science, Washington, DC.

option would be to supplement institutional biosafety committees (IBCs) with ethicists. A further difficulty to resolve is the proper identification of the research proposals that should be subjected to such a review.

## Publishers and journal editors

Freedom of intellectual inquiry, sharing of knowledge and publication are at the very heart of science. So one of the most contentious debates about the governance of dual-use research involves the extent to which the publication of potentially dangerous information should be restricted, or censored.[17]

Publications enable progress in beneficial research and can inform about new kinds of threats. In particular, sufficiently detailed 'materials and methods' parts of publications are essential for other scientists to reproduce and verify results. Yet, these sections are precisely the ones that could potentially be misused by ill-minded individuals. Publishers and journal editors have a responsibility to prevent the publication of research results that may be misused. In February 2003, recognising this responsibility, a joint *Statement on Scientific Publication and Security* of the Journal Editors and Authors Group was simultaneously published by *Science*, *Nature*, the *Proceedings of the National Academy of Sciences* and the American Society for Microbiology Journals.[18] While reminding readers of publishers' 'unique responsibility' for the integrity and the advancement of research, the statement accepts that at times censorship of science may be warranted: 'We recognize that on occasion an editor may conclude that the potential harm of publication outweighs the potential societal benefits. Under such circumstances, the paper should be modified, or not be published.'[19]

## Governments, international organisations and funding bodies

Finally, governments, international organisations and funding bodies all face dilemmas in managing the risks related to deliberate misuse of research. On the one hand, they play a key role in promoting scientific development, and in creating an environment that is conducive to stimulating life-sciences research. On the other hand, they have important responsibilities in promoting global health security and in minimising the potential harm to public health, at a national and a global level.

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17 Miller, S. and Selgelid, M. 2007, 'Ethical and philosophical considerations of the dual-use dilemma in the biological sciences', *Science and Engineering Ethics*, vol. 13, pp. 523–80.

18 Selgelid, M. 2007, 'A tale of two studies: ethics, bioterrorism, and the censorship of science', *Hastings Center Report*, vol. 37, no. 3.

19 Journal Editors and Authors Group 2003, 'Statement on scientific publication and security', *Science*, vol. 299, no. 5610, p. 1149.

There are different risk-management options for governing life-science research with dual-use potential. It is essential to find and maintain the right mix of policies in order to allow the public health benefits of life-science research to be maximised while minimising the risks. Besides the promotion of research excellence, biosafety and laboratory biosecurity, an ethical framework is a key component of a public health approach. While no magic bullet, codes of ethics for scientists, as well as for publishers, can make essential contributions. Further discussion about the usefulness and feasibility of an ethics review of sensitive research is needed. Finally, assessments, awareness-raising and training at local and facility levels are key to the implementation of effective policies. The WHO self-assessment questionnaire can help countries and institutions to identify these needs and capacities and take the necessary actions.

## Ethics and the self-assessment questionnaire

The process of self-assessment starts with an identification of strengths, weaknesses and gaps, and concludes with action to address the gaps and weaknesses and to build on or consolidate the strengths. Going through this process will first provide an assessment of the extent to which systems are in place in the national public health system, in research institutions and in laboratories to facilitate and ensure excellence in science, ethics, safety and security.

Second, it will identify priority areas where action is necessary to ensure such practices. In coordination with other stakeholders, the knowledge gained through this process will help countries and institutions to align available resources with local needs and circumstances. This is therefore an important step in the identification of appropriate training and a sustainable way to enhance global health security. This self-assessment tool could also be used as a simple and cost-effective way for interested countries and institutions to raise awareness about responsible life-sciences research. Health researchers, laboratory managers and research institutions are the primary audiences for this self-assessment questionnaire. It was not developed to evaluate the adequacy of measures developed by other sectors (for example, security, academia, publishers and editors). Yet, it recognises the importance of collaboration and coordination between different sectors, especially when priority areas have been identified and when action will unfold.

### Methodology

The self-assessment questionnaire on responsible life-sciences research lists several statements associated with each pillar, using the Likert scale. A

statement for which a respondent answered 'don't know' or 'disagree' may mean that further information is needed in certain areas and may indicate some weaknesses. On the other hand, responses of 'agree' and 'strongly agree' suggest that appropriate measures are already in place.

The strengths and weaknesses of an institution can then be reported by pillars, giving some overview of advantages and gaps. It is therefore strongly advised to fill in the questionnaire as a whole and not in parts. The self-assessment tool is a voluntary, anonymous and innovative tool in this field.

The ethics pillar lists some of the following statements to which respondents are being asked to give their opinion[20]

- education and/or training is offered on research ethics
- appropriate ethical research guidelines and practices have been published and implemented
- adequate mechanisms exist for investigating and responding to non-adherence to ethical standards
- researchers know how to assess whether the risk outweighs the benefit of continuing with their research or activities
- researchers are aware of and informed about national and international conventions, laws and regulations related to their research
- an ethics committee assesses research proposals involving human subjects
- a review process exists to assess ethical issues raised by research proposals not involving human or animal subjects
- information about the national and international conventions and regulations related to all fields of science is easily accessible.

The self-assessment questionnaire was piloted in a South African facility in 2009.[21] A seminar on responsible life-sciences research and dual-use issues was presented to the audience as a way to introduce the questionnaire to the laboratory scientists and managers. The audience was also informed about the purpose and content of the questionnaire, noting that this was an anonymous and voluntary process. Of the 20 scientists present, 18 completed the questionnaire. The respondents were coming from different laboratories, all part of the same facility. Feedback on the questionnaire was provided to the respondents at the end of the seminar.

20 WHO, 2010, op. cit.

21 Gould, C. 2011, 'Biosecurity: a public health approach to reducing risk', *Research Report for the Wellcome Trust Project on 'Building a Sustainable Capacity in Dual-Use Bioethics'*, <http://www.brad.ac.uk/bioethics/Monographs> (viewed 22 September 2011).

The pilot study had some limitations. First, the sample size of the pilot study is too small to draw conclusions that would be representative of the whole facility. The collected data are therefore only illustrative of potential needs and capacities. A second limitation of the self-assessment questionnaire is that these questions may be considered subjective. The validity and reliability of the subjective measures have been enhanced through multiple questions measuring the same subjective state. The self-assessment questionnaire has indeed been designed in a way that statements regarding the different pillars can be analysed in combination, thereby reinforcing the data analysis. It should be noted, however, that one important strength of the questionnaire is its ability to identify differences in opinions about existing systems and measures so that the discrepancies can be dealt with—not necessarily through a change in the system itself but just with, sometimes, further discussion with the staff about existing measures.

## Results

The data collected by the pilot study regarding the ethics pillar showed the[22] following.

- Seventeen of the 18 respondents agreed or strongly agreed that education and/or training is offered on research ethics. One respondent was undecided. This is reinforced with the fact that 15 respondents agreed or strongly agreed with the statement that ongoing research training takes place.
- Likewise, a majority of respondents (15) agreed or strongly agreed that research proposals raising ethical issues (whether or not human or animal subjects are involved) are subject to review.
- A majority of respondents, however, disagreed with the statement that education and/or training is offered on dual use. Nine respondents disagree or strongly disagreed, and seven respondents were undecided about the statement. Only two agreed with it.
- Eight respondents also disagreed with the statement that researchers are aware of and informed about national and international laws and regulations related to their research, and three respondents were undecided. This can be read in conjunction with the fact that 14 respondents were undecided or disagreed with the statement that information about the national and international laws and regulations related to all fields of science is easily accessible.
- In addition, 13 respondents were undecided or disagreed with the statement that whistleblowing mechanisms exist and make provision for the protection

22 Ibid.

of whistleblowers. Related to this, 10 respondents were undecided or disagreed with the statement that researchers have somewhere to turn for competent advice if they have ethical, safety or security questions relating to their research. Yet five respondents agreed or strongly agreed with the first statement and eight respondents agreed with the second one.

- Eleven respondents were undecided or disagreed with the statement that adequate mechanisms exist for investigating and responding to non-adherence to ethical standards, and half of the respondents were undecided or disagreed with the statement that appropriate ethical guidelines and practices have been published and implemented. Yet seven respondents agreed with the first statement and nine agreed with the second one.

## Discussion

The pilot study at the South African facility illustrates the type of useful and informative feedback the self-assessment questionnaire can provide to laboratory managers and their staff.[23] In this case, the pilot study may seem to indicate that ethics training is an asset of the facility and that research proposals are being regularly reviewed. But it also seems to point out some areas for action.

For instance, disagreements occurred in four areas

- about the education and/or training on dual-use issues
- about their awareness of and information regarding national and international laws and regulations related to their research
- about the existence of mechanisms for staff to report unlawful or irregular conduct (that is, whistleblowing mechanisms) and where to turn for competent advice if they have ethical, safety or security questions relating to their research
- about the publication and implementation of ethical guidelines and practices and mechanisms for investigating non-adherence to ethical standards.

When a majority of respondents disagreed with a statement or was undecided, this may point to a certain weakness that needs to be addressed. In this case, a majority of respondents noted the lack of training and/or education on dual-use issues.

Disagreement among respondents may indicate that there may be measures in place but these are not sufficiently well communicated to all employees. This may mean that ethical standards for research may be in place in the facility,

23 Although the pilot study implemented the whole self-assessment questionnaire, only the ethics data are being reported in this chapter.

as well as mechanisms to deal with non-adherence to ethical standards, but the employees should be better informed about them. Likewise, employees may need to have more accessible information about national and international laws and regulations related to their research as well as additional information as to where to turn for competent advice if they have ethical, safety or security questions associated with their research.

In summary, the analysis of the data associated with the ethics pillar tends to suggest that the facility has important capacities in terms of ethics training and on ethical review of research proposals while some needs may have been identified in terms of dual-use training. As well, additional information may be provided on the availability of competent advice; publication and implementation of ethical guidelines and practices and mechanisms for investigating non-adherence to them; and on national and international laws and regulations.

This process of self-assessment should therefore provide useful and practical information for research institutions and their managers about research excellence and management, ethics, biosafety and laboratory biosecurity practices within their facilities. When comparing the results of the three pillars, the institution can also identify capacities and needs for each pillar. It can then assess which pillar looks stronger compared with the others and then identify priority areas for action. One way to address potential needs might be to organise a seminar for all staff to share the data analysis, to underline the strengths of the institution and to propose measures to address identified gaps.

In this case, the identified needs could be addressed through a seminar that would be aimed at sharing information about national and international laws and regulations related to their research and the setting up of a web link to encourage staff to make themselves aware of any changes in national and international regulations. A seminar could also be held on the mechanisms or processes in place in the institution if staff have ethical, safety or security questions regarding their research and to make clear where the ethical standards can be found and how whistleblowing mechanisms can be accessed. Information regarding ethical standards can be distributed to the staff or could be put on a web site easily accessed by the employees. Staff should also be able to keep themselves regularly informed about any changes in ethical procedures. Another way of addressing needs might be to invite other facilities and research institutions to share information about their best practices, how they train their staff on specific topics, how they have identified ways for making information on certain issues available to staff and how to keep them regularly updated. Finally the self-assessment questionnaire could be proposed again to the facility employees after the implementation of activities that were aimed at addressing needs to evaluate the progress made.

Self-assessment should therefore not be seen as an end in itself but as a process for achieving better research management, enhanced ethics practices, the implementation of biosafety and laboratory biosecurity measures and procedures, and their continuous improvement. This would contribute to fostering responsible life-sciences research activities in countries and institutions and promoting public health. The questionnaire was also used in Kenya, to assess the capacity of research and diagnostic laboratories in Nairobi and surrounds.[24]

Ethics is essential to address the risks posed by life-sciences research. The pilot study on the self-assessment questionnaire on responsible life-sciences research illustrates how ethics needs can be identified and what kind of activities can be put in place to address those needs.

24 Kenya E. et al., *An Assessment of the Capacity of Research and Diagnostic Laboratories in Nairobi and Surrounds*, June 2012.