4

IMPLEMENTATION

Biosafety and Biosecurity Practice in South African Life Science Facilities

4.1 Introduction

In order to reduce the exposure of laboratory personnel, the public, agriculture, and the environment to potentially infectious agents and other biological hazards, specific biosafety practices and procedures, specific construction features of laboratory facilities, safety equipment, and appropriate occupational health programmes should be implemented in life science research facilities (Bakandize *et al*., 2010). These facilities should also have systems in place to ensure research integrity and ethics and biosecurity measures to mitigate the potential for science to be misused.

The aim of this part of the study was to determine the extent to which the research and diagnostic facilities in South Africa have systems in place to facilitate research excellence, their adherence to ethical guidelines and laboratory biosafety and biosecurity. A questionnaire that was developed and published by the WHO in 2010 as part of the guidance document *Responsible Life Science Research for Global Health Security* (WHO, 2010), formed the basis of this investigation. The questionnaire was designed to assist health policymakers, health professionals, laboratory managers and scientists to assess the extent to which the above-mentioned systems are in place in the national public health system and in private laboratories.

The principle that informed the development of the WHO questionnaire is that the best protection against misuse of science is the development and maintenance of a culture of scientific integrity and excellence characterised by openness, honesty, accountability, responsibility and relevance. This is also the best guarantee of progress and development. Good science and sound scientific research are inextricably linked with the health, development and good policies of a country. Moreover, the confidence of the people and their trust in government and policies depends to a large extent on trustworthy science (WHO, 2010). An early version of the questionnaire was piloted in 2009 in South Africa at the NICD. It was further successfully used in a WHO-supported study in Kenya in 2011 to assess research and diagnostic laboratories in Nairobi (Kenya *et al*., 2012).

At the commencement of the study there was no comprehensive database of public and commercial life science facilities in South Africa. Public life science facilities are facilities located within academic institutions, as well as state-run institutions that are funded by a combination of government and non-South African government donors and that undertake teaching and publish their results in peer-reviewed journals. Commercial facilities are those that perform for-profit services. As the first of a suite of empirical studies, a mapping survey was therefore undertaken to gather information about life science facilities according to their geographic location, focus of activities and main sources of funding.

4.2 Mapping of the life sciences facilities in South Africa

4.2.1 Aim

The aim of this survey was to understand the landscape of South African life sciences facilities and to map and capture the details of the facilities, institutions and companies that make up the life science community in South Africa, including animal, plant and human health facilities.

4.2.2 Specific objectives

The specific objectives of this study were:

1. To enable a point-in-time assessment of research and diagnostic capacity in South Africa.
2. To enable the determination of a representative sample for a perception survey about practice in relation to the implementation of biosafety and biosecurity measures and the application of ethics in South Africa (Section 4.3).
3. To allow the identification of key participants who would be interviewed about measures to prevent, detect and respond to infectious disease outbreaks (Chapter 5).

4.2.3 Methods

Mapping was initially achieved by internet searches to identify facilities, which were in turn contacted telephonically in order to obtain the necessary information. The majority of the sites contacted were unwilling to release the information telephonically and thus project information sheets were mailed to the relevant people identified by such initial contact (See Appendix 7). A questionnaire was also made available online[11] and a request for responses and a link to the questionnaire was circulated widely.[12]

This process was limited by the reluctance of the National Health and Laboratory Services (NHLS) laboratories to participate in the data-gathering without formal ethical approval from the NHLS REC. The NICD did however participate in the study. Furthermore, the private diagnostic facilities were similarly reluctant to release information without express endorsement of the survey by their head office. Delays in obtaining these permissions meant that neither the NHLS nor private diagnostic laboratories were approached directly for participation. The information on these laboratories that was freely available on the company websites was included in the mapping exercise. This is a significant limitation of the study that could be overcome if

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[11] See www.surveymonkey.com/s/CB6JP65.

[12] Circulation means were *inter alia* the ASSAf website, journal articles published in South African Journal of Science and the South African Medical Journal, appeals to scientific societies and through the circulation of a call for responses amongst contacts identified through internet searches.

the database were to be updated and maintained by a central authority in accordance with the recommendation of this study.

In addition, although it was anticipated that scientific research and diagnostic facilities in South Africa would be familiar with ASSAf, and would therefore accept the credentials of the researcher and the credibility of the research, this proved not to be true and several institutions were reluctant to make information available. This meant that most of the information in the database was gathered through internet searches. The information available on institutional websites often did not include the detail we sought such as: sources of funding, number of staff members, range of research or diagnostic tests undertaken.[13] Thus the final dataset described should be augmented with additional data as they become available, and should be regarded as a work in progress.

4.2.4 Results

A database of facilities, institutions and companies that make up the life science community in South Africa was generated and is located at ASSAf, Pretoria, South Africa. In accordance with the commitments made on the project information sheet, these data will not be available for commercial reuse and will only be available to projects sanctioned by the Academy and the DST. The main findings from the survey with respect to geographic location, focus of activities and funding sources are summarised below.

The national database comprises 979 different facilities, of which 214 (22%) conducted research and 700 (72%) performed diagnostic services. Sixty-five facilities performed both research and diagnostic services. Each of these categories were further divided into business sector, i.e. public (as defined above) or commercial (for-profit) facilities (Figure 4.1).

Most of the laboratories fall into the Human life science sector (64%), followed by those in the Animal (22%) and Plant (13%) sectors (Figure 4.2). A further breakdown by province (Figure 4.3) shows that over two-thirds of the laboratories in Gauteng focus on research and diagnostics in the human sector. A similar dominance of human sector laboratories is also notable for all the other provinces; although less pronounced in some cases.

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[13] When analysing the responses it was noticed that many laboratories ticked more than one category for range of research (public/private research/diagnostics). It must be recognised that these multiple categories would often not be identifiable from facility websites, where one main category is normally highlighted (such as academic research). It is therefore possible that as the database is augmented additional categories may be added to a number of the facilities that were identified through web searches.

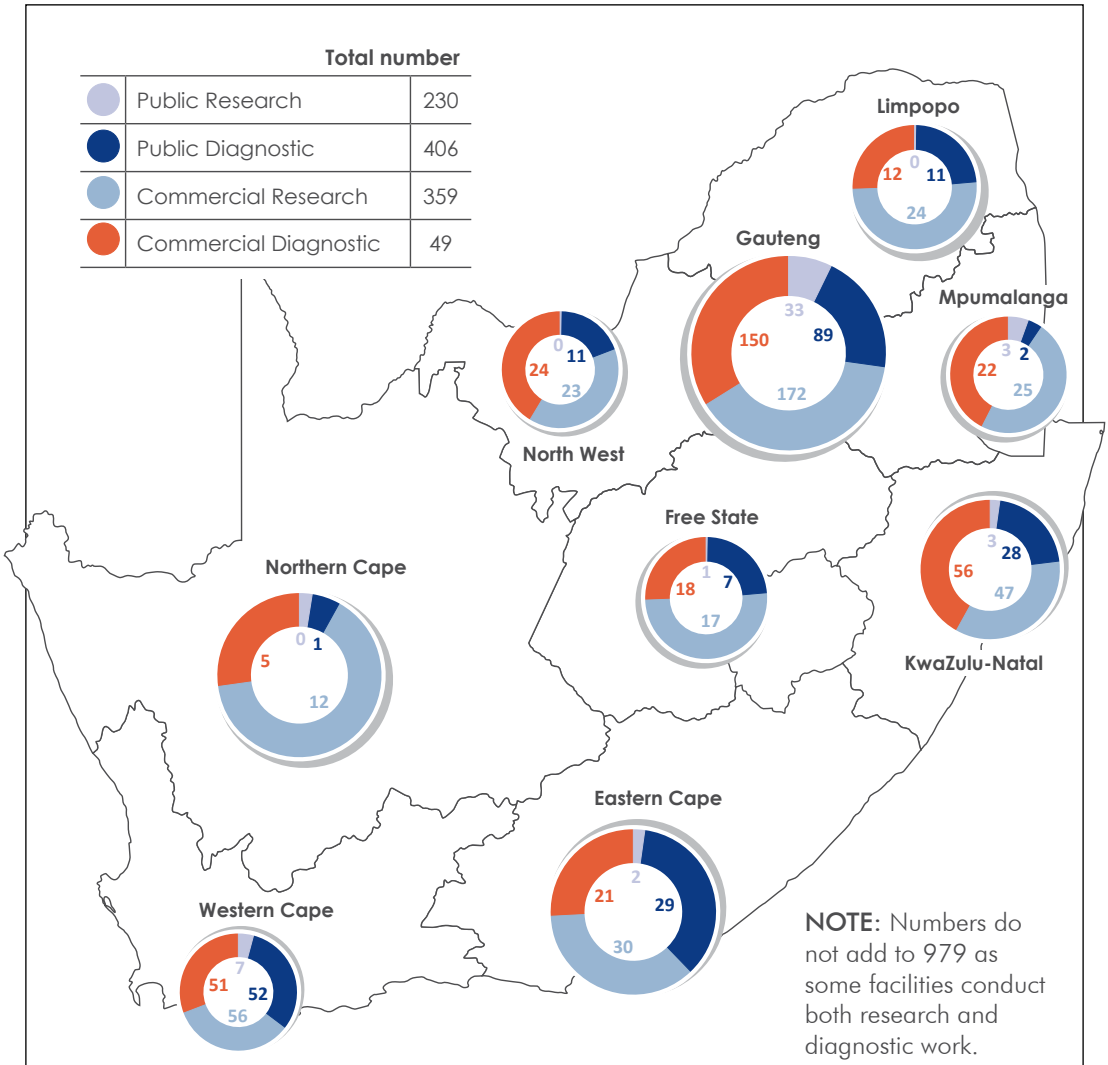

Figure 4.1: *Map of life science facilities: number of laboratories by business sector, activity and province.*

Figure 4.2: *Number of laboratories by sector.*

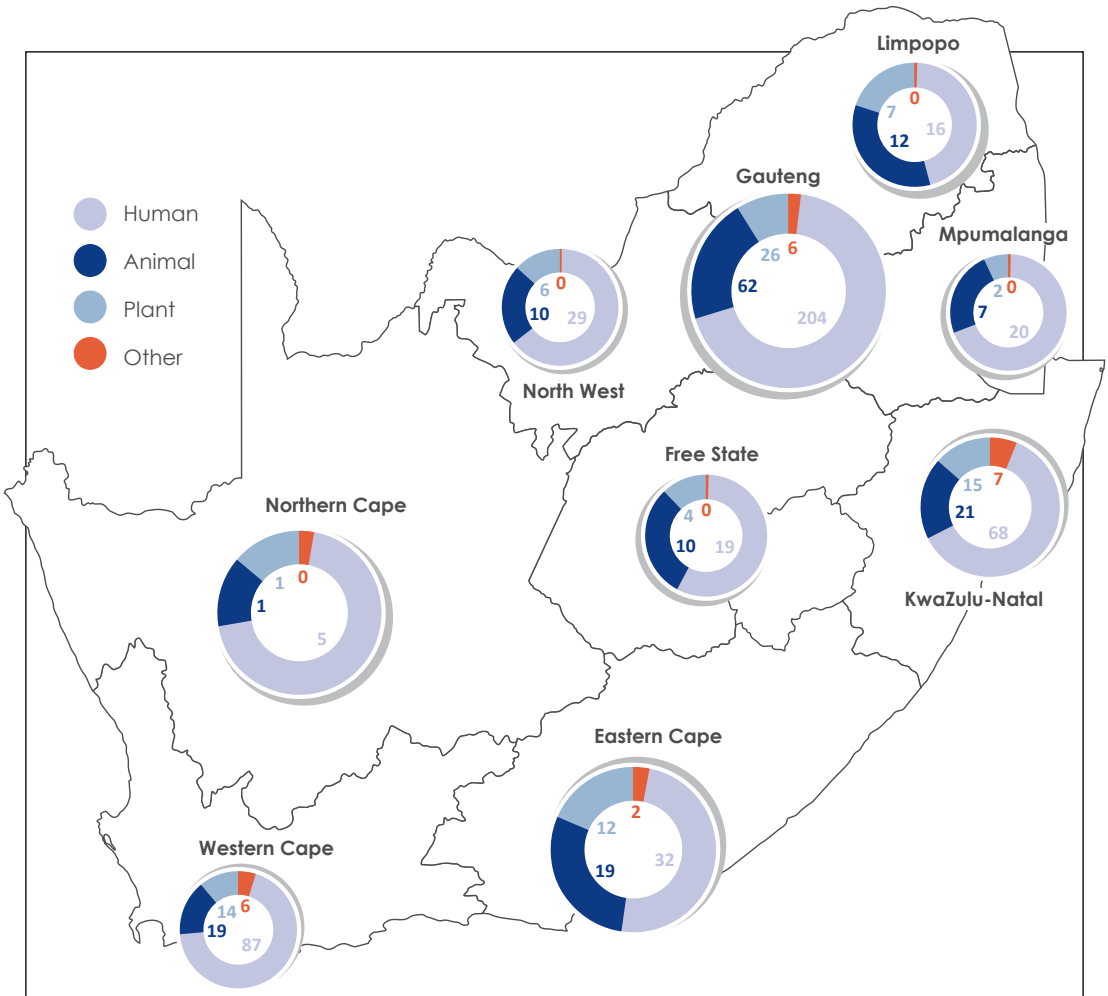

Figure 4.3: *Map of life science facilities: number of laboratories by life science sector and province.*

The breakdown of funding sources is presented in Figure 4.4. Sixty percent of funding is from local private sources, while government provides 18% direct funding plus an additional 12% through the research councils.

Figure 4.4: *Funding sources of life sciences laboratories.*

4.2.5 Discussion

This database represents the first comprehensive database of research and diagnostic laboratories in South Africa. Despite its limitations, it represents an important source of information in the event of a disease outbreak. It is important for relevant government departments and agencies to be aware of the research and diagnostic capacity that exists, and to be able to assess gaps in the provision of services in particular areas. It is recommended that the DST becomes the custodian of this database and that it be updated and audited on a regular basis – perhaps as part of the broader bio-portal initiative currently under development. The DST is correctly placed to take on this responsibility because laboratories work in the fields of human, animal and plant health and thus fall neither neatly into the scope of the DoH nor the DAFF.

Given the limitations of this survey it was not possible to develop a geographic information system (GIS) map of research and diagnostic facilities due to the inconsistent availability of the precise addresses of the laboratories on their websites. However, it is recommended that the creation of a GIS map be a future objective for a variety of reasons. For example, a GIS map with additional information overlays would be able to visually represent the ratio of diagnostic laboratories to human population and even to burden of disease. Such information may be valuable when determining the location for new laboratory services. In addition, information about the location and capacity of laboratories is necessary if any monitoring or inspection is to take place to ensure compliance with legislation.

It is recommended that:

- The DST becomes the custodian of this database of South African life science facilities and that it is updated and audited on a regular basis.
- This information is integrated into a comprehensive GIS map to improve the usefulness and accessibility of the information.

4.3 Assessment of measures to ensure ethical, biosafety and biosecurity practices in life science facilities in South Africa

4.3.1 Aim

The aim of this study was to assess the extent to which South African life science laboratories have implemented relevant ethical, biosafety and biosecurity measures to answer questions such as:

1. Are South African life scientists adequately prepared to conduct quality life science research, while simultaneously being able to recognise and address research misuse?

2. What systems are in place in the national public health system and in private laboratories to strengthen ethics, biosecurity and biosafety?
3. What are the knowledge, attitudes and practices of South African life scientists working in public and commercial laboratory facilities?

4.3.2 Specific objectives

The two specific objectives of this study were:

1. To assess the extent to which research and diagnostic laboratories have measures or systems in place to ensure and facilitate research excellence, adherence to ethical practices and laboratory biosafety and biosecurity requirements.
2. To raise awareness amongst laboratory scientists, laboratory managers and public health officials about the requirements for ensuring high-quality research, adherence to ethics and laboratory biosafety and biosecurity.

4.3.3 Methods

4.3.3.1 Ethics approval

Ethical approval for the study was obtained from the University of Cape Town (UCT) Human Research Ethics Committee (HREC), and the Nelson Mandela Metropolitan University (NMMU) REC (Human).[14] Approval to conduct the study was also granted by the National Manager: Academic Affairs and Research of the NHLS.

4.3.3.2 Questionnaires

The questionnaire used for data collection was a revised form of the aforementioned WHO 'self-assessment' questionnaire (WHO, 2010). A pilot study consisting of five sites in the Western Cape province was conducted in July 2013 to test the local applicability of the WHO questionnaire for relevant sectors: commercial, academic and state-funded facilities in the animal, plant and human health sectors, and encompassing facilities undertaking both diagnostic and research. The pilot included facilities working in animal, human and plant health in the public and private sector.

Based on feedback from responses obtained in the pilot study, the aforementioned WHO 'self-assessment' questionnaire (WHO, 2010) was revised to be more in keeping with a South African audience particularly with respect to the appropriateness of the language used in the questionnaire, and to make it equally relevant to research and diagnostic laboratories.

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[14] Although the vast majority of facilities were satisfied by UCT ethics approval, a small number of institutions required in-house ethics oversight. All efforts were made to accommodate institutional preferences, including applying for formal ethics approval from Nelson Mandela Metropolitan University. The questionnaire and information sheets were also checked by the University of the Witwatersrand Research Ethics Committee (Human) prior to distribution.

The final questionnaire consisted of three sections: 1) research excellence; 2) ethics, and 3) biosafety and/or biosecurity. The questionnaire consisted of a set of statements with responses graded on a Likert scale (including options for the responses 'not applicable' or 'don't know'). The details within each section are outlined in Appendix 11.

4.3.3.3 Sampling

1. Database sampling

A purposive sample of 50 facilities[15] was drawn from the database developed as part of the first aim of this study of facilities to ensure geographic and sector[16] representation. This did not include NHLS laboratories as approval to undertake the survey at NHLS facilities was not granted until very late in the research process.[17]

Of the 50 facilities that formed part of the sample, 12 were substituted due to an inability to establish communication with those facilities. The substitutions of the unreachable facilities were made purposively such that the facilities included matched those that were unreachable in terms of geographic location and sector. Saturation was reached when it was no longer possible to substitute laboratories as the number of applicable laboratories in a province had been exhausted. Five additional sites were then selected due to concerns about low response rates in some provinces[18] and to ensure that at least one laboratory from each province participated. These sites were selected at random from the provincial lists in the database of national laboratories (described earlier in Chapter 4).

2. Public sampling

In addition to the purposive sample, a public call for participation by diagnostic and research scientists was issued through the ASSAf mailing list, through journal articles, scientific society mailing lists, directed emails, and by placing advertisements in journals, and on society and commercial supplier websites. The advertisement invited practising life scientists to complete the online survey.

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[15] The statistical analysis was conducted by the Consultant Statistical Services at UCT.

[16] Public, commercial, research and diagnostic.

[17] Permission was delayed by an inability to identify who was responsible for granting permission for the study, and by difficulties in obtaining responses from the responsible individuals by telephone or email. While private diagnostic laboratories were included in the sample, problems associated with getting permission meant that many of them subsequently refused to participate. They were left in the sample but noted as "declined to participate". These problems are indicative of a larger problem related to social science research engaging natural scientists in that ethics committees are not designed to deal with sociological and anthropological studies of science cultures.

[18] Sites that did not respond initially received at least two phone calls and five emails.

4.3.3.4 Survey administration

Each laboratory identified in the database sample was initially contacted telephonically to inform them of the survey and request their participation. An email was subsequently sent containing a copy of the survey and information sheet (See Appendices 7 and 11 and the UCT ethics approval certificate). The email also contained details of the feedback report that would be produced for each laboratory on the basis of the results gathered from their students and staff. The contact person (usually the head of the facility) was invited to discuss their preferences with regard to participation and feedback.

The original intention was for the survey to be administered at each site by the study's contracted researcher, and to provide each facility with a report of the findings from their facility shortly after completion of the survey process at that facility. Many of the heads of departments expressed willingness to participate in the survey, but had reservations about a site visit from the researcher, citing either concerns about the disruption to work routines or low staff numbers (a number of laboratories had between one and five staff members).

These sites were provided with an opportunity to participate in the survey by completing the questionnaire electronically or through using a weblink to the survey.[19] Sites choosing the online survey were issued with a project information sheet containing a site-specific number to circulate to their staff.[20] This ensured that their responses could be collated into a site-specific report. Each site was provided with the findings from their facility.

The site-specific numbers ensured that completed questionnaires received in response to the open call could be kept distinct from responses from the purposive sample. The data collected from the open call were compared to data collected during the site-specific visits. As there was little difference in the distribution of the data, these two sample sets were combined.

4.3.3.5 Data analysis

The dataset of responses was analysed by the UCT Statistical Consulting Services, and descriptive statistics were provided to the researchers.

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[19] Available at www.surveymonkey.com/s/ASSAf_survey.

[20] The combination of modalities offered for participation – site visits, completion of an emailed survey or online – assisted in recruiting sites, as sites were able to tailor their participation to the specific situation in their laboratory.

4.3.4 Results

4.3.4.1 Response rate

In total, 161 individuals responded directly to the survey request. The public call yielded a further 222 responses. Together, the 383 individual responses were combined to form one final dataset for analysis. Of the 383 responses, 33 questionnaires had to be excluded as the questionnaires were not completed (only demographic data obtained).

Of the 55 sites selected from the database, 31 sites participated in the survey and five refused, as shown in Table 4.1. Eight provinces were represented, with no facility from the Northern Cape participating.

Table 4.1: *Detail of survey sample and distribution*

Province	Number of sites (total)	Positive responses	Negative responses	No response
Eastern Cape	7	3	0	4
Free State	7	5	1	1
Gauteng	9	8	1	0
KwaZulu-Natal	8	7	0	1
Limpopo	4	1	1	2
Mpumalanga	5	1	2	2
Northern Cape	3	0	0	3
North West	5	2	1	2
Western Cape	7	4	0	3
Total	55	31	6	18

4.3.4.2 Mode of response

It was apparent that in order to ensure the participation of sites, it was important that they were allowed to dictate a manner in which the surveys could be distributed that would cause minimal interruption of work while fitting closely with the way in which the institution was run. There was thus a variation in the manner in which sites participated in the survey, organised their staff and dealt with feedback. For example, some sites organised a laboratory meeting at which the questionnaires were distributed, while others gave the researcher a tour of the laboratories while distributing questionnaires *en route*.

A number of the laboratories preferred to participate remotely and either sent back completed questionnaires or made use of the survey weblink. Of the sites that participated in the survey, nine sent back completed questionnaires directly, ten participated online, and 11 were visited in person.

4.3.4.3 Demographic details of respondents

Most respondents worked in the public research sector. Additional details for sector by recruitment source are shown in Figure 4.5.

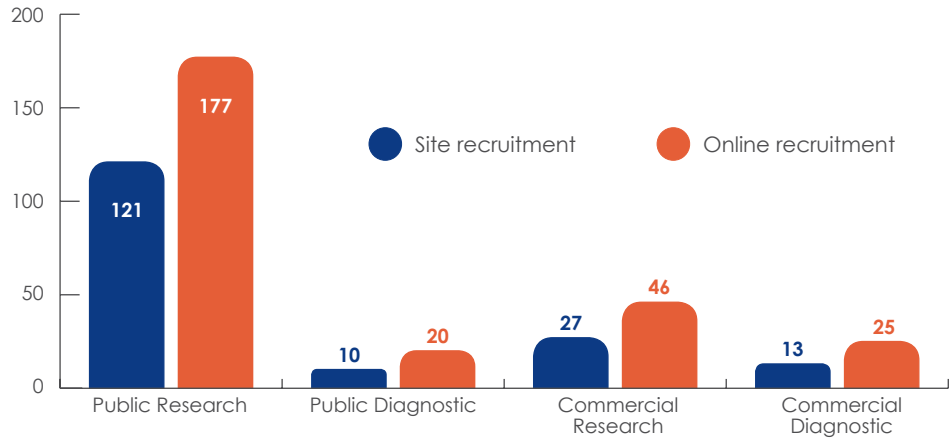

Figure 4.5: *Sample demographics according to recruitment source and sector.*

NOTE: Fifty-two respondents selected more than one sector for their work, e.g. ticked the boxes for commercial and public research; or public research and public diagnostic. Thus the numbers represented in the graph are higher than the total number of responses. Public diagnostic facilities refer mainly to those engaged in plant and animal life science activities.

The geographic spread and business sectors of the samples are outlined in Figure 4.6. Responses from Gauteng, KwaZulu-Natal and the Western Cape considerably outnumbered those from other provinces.

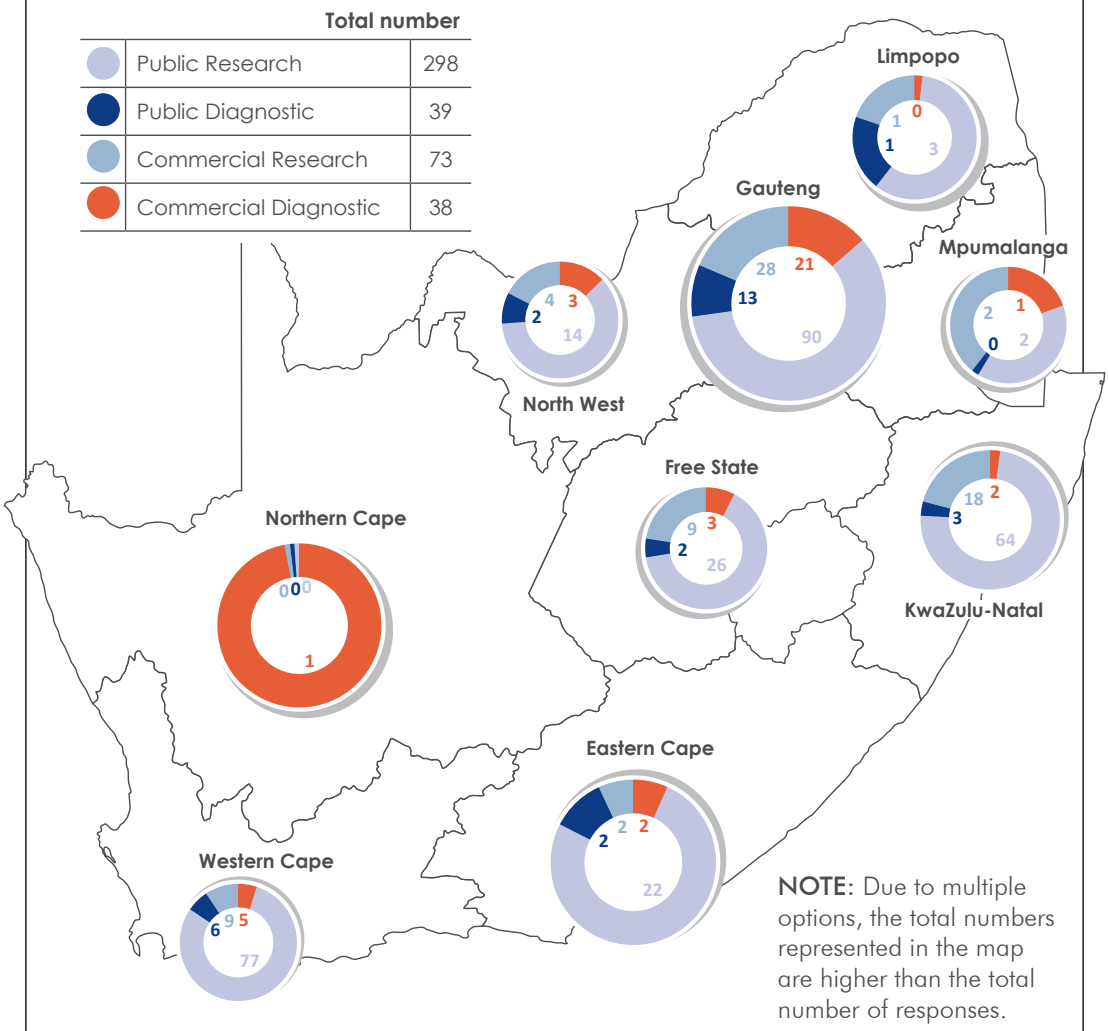

Figure 4.6: *Sample demographics according to province and sector.*

4.3.4.4 Selected findings

The findings are reported below for all responses and, where relevant, reflect responses specifically from the following groups:

- **Senior staff:** Including senior researchers and technologists and technicians, as well as NHLS laboratory managers and NHLS technologists.
- **Junior staff:** Junior researchers, junior technicians, NHLS technicians, postgraduate students, support staff.
- **Technical staff:** Senior technicians, junior technicians, NHLS laboratory managers, NHLS technologists, NHLS technicians, support staff.
- **Research staff:** Senior researchers, junior researchers, graduate students.

The full response tables including denominators and percentages are included in Appendix 12. Percentages have been rounded off in the following report. The low response rate from NHLS diagnostic laboratories and commercial diagnostic laboratories means that the findings of the survey can only be generalised to commercial and public research facilities.

1. Research collaboration

Three statements were posed relating to respondents' perceptions of the extent to which scientific collaboration is encouraged, within their department, within their institution and between institutions.

- Three-quarters (261/350; 75%) of respondents agreed that intra-departmental collaboration is *always* or *often* encouraged.
- Over 70% (254/348; 73%) of respondents said that scientific collaboration within their institution was encouraged *always* or *often*.
- Scientific collaboration between institutions was less likely to be encouraged with just over half (189/348; 54%) of the respondents saying that inter-institutional collaboration is encouraged and facilitated *always* or *often*.

2. Financial and research accountability and transparency

Openness about funding sources at institutions was perceived to be less common than financial accountability.

- Fifty-eight percent (202/350) of respondents said that their institutions *always* or *often* made an effort to reveal their funding sources.
- Eighty-nine percent (310/348) of participants said that their institution demands financial and research accountability through regular reporting.
- Three-quarters (262/348; 75.2%) of respondents said that their institution *always* or *often* stated its research priorities.
- Eighty-three percent (288/349) of respondents agreed that research findings are routinely published, while 10% (35/349) said this was not the case at their institution.

3. Training and capacity building

A number of statements in the questionnaire sought responses to questions about the extent to which training is offered on key issues such as ethics and dual-use.

- The majority of respondents agreed that on-going skills training does take place at their institution, with 77% (268/347) agreeing that this is *always*, *often* or *sometimes* the case.
- Three-quarters (259/345) of all respondents *agreed* or *strongly agreed* with the

statement: *Staff conducting life science activities have been properly trained*, but there was less agreement about the extent to which training about dual-use issues was offered – 54% of all respondents (184/344) said that dual-use training was either not offered, or that they did not know whether it was offered at their institution.

- Fewer than half of respondents (141/323; 44%) agreed with the statement: *Education and/or training is offered on research ethics including issues such as scientific misconduct (falsification, fabrication and plagiarism)*. Junior staff were more likely than senior staff to indicate that ethics training happens *rarely* or *never*.
- With respect to training in biosafety and biosecurity measures, two-thirds (198/300; 66%) of respondents *agreed* or *strongly agreed* with the statement: *Biosafety training is provided to all those working in laboratories when appropriate*.
- Only approximately a quarter (81/302; 27%) of respondents agreed that biosafety training *always* or *often* includes a test of competence.

4. Staff satisfaction

The statement: *Junior researchers and/or staff are nurtured and supported* sought to determine how respondents felt about the support offered to junior staff members.

- Senior staff were somewhat more likely to believe that junior staff were nurtured and supported with 56% (119/211) saying this was *always* or *often* the case and 26% (54/211) saying this happened *sometimes*, while 45% (60/133) of junior staff felt that they were *always* or *often* nurtured and supported, and 35% (47/133) said this was *sometimes* the case.
- Just under a third (110/347; 32%) of all respondents agreed with the statement: *Skilled staff are valued and retained* with 38% (132/347) stating that they were *sometimes* valued and retained.

5. Policy and legislation

- Slightly more than half (182/347; 52%) of all respondents *disagreed* or *strongly disagreed* with the statement: *Good communication exists between policymakers at a national level and the life science community*.
- Respondents were divided on the statement: *National legislation and policy fosters scientific development and freedom* with 41% (139/336) *agreeing* and 40% (133/336) *disagreeing* or *strongly disagreeing* with the statement.
- Fewer than half (166/350; 47%) of respondents *agreed* or *strongly agreed* with the statement: *Researchers are aware of and informed about national and international conventions, laws and regulations related to their research*. With regard to accessibility of information about the national and international conventions and regulations related to life science, 39% (135/350) of respondents agreed information was accessible, 33% (114/350) disagreed, and 21% (72/350) said they don't know.

- Over two-thirds (196/304; 64%) of respondents agreed with the statement: *National legislation/regulation exists that sets safety and security practices and procedures for laboratories*, but only 35% (122/350) agreed that: *National legislation and policy relevant to the life sciences provides protection against the misuse of science*.

6. Application of ethics

A series of statements sought to determine the extent to which respondents were aware of the existence of ethical guidelines and the application of these in decision-making about life science research. Other statements sought to determine the scope of ethical review.

- Sixty-four percent (206/323) of all respondents agreed with the statement: *Appropriate ethical research guidelines and practices have been published*. Junior staff were more likely to say that such guidelines have been published.[21]
- Two-thirds (215/322; 67%) of all respondents reported that appropriate ethical research guidelines and practices are implemented *always* or *often*.
- Forty-five percent (156/350) of respondents agreed that ethical approval process exists for studies not involving human or animal subjects.
- Only half of all respondents (170/350; 49%) agreed with the statement: *Adequate mechanisms exist for investigating and responding to non-adherence to ethical standards*.

7. Implications of research and work

- Seventy percent (246/350) of respondents agreed that scientists are competent to assess the societal implications of their work. There was no distinction between responses from junior and senior staff or technical and research staff.[22]
- Less than half (142/320; 44%) of respondents agreed with the statement: *Research is subject to a risk assessment that includes considerations of the broader implications of their life science activities for the environment*.
- More than half (192/350; 55%) of all respondents agreed with the statement: *Researchers know how to assess whether the risk outweighs the benefit of continuing with their research activities*, with 19% (67/350) of respondents disagreeing.

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[21] It must be noted that this response may in some way reflect a contrast in what junior and senior staff members consider 'appropriate' guidelines – something that may be influenced by experience and visits to other research institutions.

[22] It is interesting that there is little differentiation across the career trajectory in the responses to this question. What scientists perceive as 'competent' should be investigated in further detail, as should their perceptions on what such an assessment would comprise.

8. Biosafety and biosecurity

- Over 60% (219/350; 63%) of respondents agreed with the statement: *Measures are in place to prevent non-laboratory individuals from obtaining access to samples or biological materials*.
- Half of all respondents (175/350; 50%) agreed with the statement: *Potential for misuse of the research is considered at all stages of research/diagnostic processes and appropriate action taken if necessary*.
- Almost three-quarters of all respondents (222/305; 73%) agreed with the statement: *Facilities and equipment are appropriate to the level of work being done and are adequately maintained*.
- Close to 80% (237/304; 78%) of respondents agreed with the statement: *Training of staff is appropriate to the facilities and equipment and the work being conducted*.
- Forty-four percent (133/305) of respondents stated that assessment of the biosafety and biosecurity risk associated with research activities is conducted *always* or *often*.
- Almost 60% (177/298; 59%) of respondents agreed with the statement: *Risk assessments are able to identify requirements for risk reduction measures including the level of containment required*.
- Three-quarters (225/300; 75%) of respondents agreed that SOPs exist, with two-thirds (200/301; 67%) agreeing that staff were trained to implement these procedures. Thirty percent (91/304) of respondents agreed that staff are regularly tested to ensure competence in SOPs, with 48% (147/304) saying this is not the case.[23]
- Almost two-thirds (186/303; 61%) of respondents agreed or strongly agreed with the statement: *Occupational health surveillance mechanisms exist and are followed (at institutional level)*.
- Less than half (132/299; 44%) of respondents agreed that occupational health reporting mechanisms are *always* or *often* effective at institutional level.
- The great majority (269/302; 89%) of respondents agreed that staff are required to report laboratories incidents and accidents.
- Just over half (207/302; 52%) of respondents agreed with the statement: *A record of hazardous biological materials exists and is maintained at institutional level* and more than two-thirds (208/305; 68%) said that hazardous biological material is *always* or *often* safely and securely stored.
- With regard to whistle-blower protection, 64% (194/302) of respondents *agreed* or *strongly agreed* that there are measures to report irregular or unlawful conduct, but only approximately half of these (111/298; 37%) agreeing that measures exist to protect whistle-blowers.

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[23] While the issue of SOPs is important, it is possible that the disjunction between the existence of and the training for SOPs may reflect traditions of academic research. While many laboratories have standardised protocols from which many laboratory activities are conducted, they are developed and taught in-house informally by staff. Thus, the training and testing questions might not reflect the true nature of this situation.

4.3.5 Discussion

Scientific integrity is most often considered to refer to accuracy and honesty in relation to the collection, management and reporting of research data, and to accurate and full citation of texts in publications (Barr, 2007). But it also encompasses the management and communication of science and protection against misconduct. In short, scientific integrity is required to establish and maintain trust amongst scientists, between scientists and the policymakers, and between scientists and citizens. In recognition of the importance of scientific integrity, the US Department of Interior developed a policy on scientific integrity, the Scientific and Scholarly Integrity Policy (US Department of Interior, 2011). The policy has as its stated goals:

- Decisions based on science and scholarship are respected as credible.
- Science is conducted with integrity and excellence.
- Science has a culture of scientific and scholarly integrity that is enduring.
- Scientists and scholars are widely recognised for excellence.
- Employees are proud to uphold the high standards and lead by example.

The US Departmental Manual developed to give effect to this policy identifies management, communication, collaboration and information-sharing as relevant to scientific integrity. Integrity is further ensured by guidelines for reporting of misconduct, protection of those who report such misconduct, and safeguards to ensure that recruitment is based on a candidate's integrity, knowledge, credentials, and experience relevant to the responsibility of the position (Office of the Deputy Secretary Department of the Interior, 2011).

The questionnaire used for the purposes of this consensus study offers insights into each of these issues, as well as the scope of ethical review and the extent to which communication is perceived to take place between the policy community and the scientific community in South Africa. The survey offers an opportunity for us to establish a baseline assessment of scientific integrity in South Africa.

4.3.5.1 Openness and transparency

Resnik stated that: "*Openness is one of the most important principles of scientific research. It is necessary for achieving the goals of science and for enabling society to benefit from the results of research. It plays a key role in confirmation and collaboration, and it promotes innovation and discovery. Additionally, openness is important for holding scientists publicly accountable and for developing well-informed public policy*" (Resnik, 2006).

While openness and transparency are regarded as important for scientific progress, there are a number of legitimate reasons why researchers may not be able to be

entirely open about their research or findings. Reasons may range from the need to protect intellectual property (IP) to the need to protect the identity of research participants.[24] While these constraints on openness may be legitimate and even necessary, the norm should be towards openness and sharing of information, as openness and knowledge-sharing serve the interests of scientific progress. Given South Africa's past experience where medical professionals, microbiologists and veterinarians were recruited into a secret military programme aimed at developing biological assassination weapons (Truth and Reconciliation Commission, 1998), South Africa has a special responsibility to prevent the recurrence of such activities.

Globally there is a move towards open science with many scientists and scholars choosing to publish their findings in open-access journals[25], or the editorial boards of journals themselves choosing to remain freely available rather than have their content available only to subscribers. ASSAf promotes quality open-access publications through its precise, full-text, open access journal database, SciELO SA. Other forms of openness include open funding (where funding is sought using public platforms, such as through so-called crowd-sourcing) or where applications for funding are opened for review beyond the staff or collaborators of funding institutions. Other initiatives to promote openness in the sciences are outlined in Box 4.1 (Eisfeld-Reschike *et al*., 2014).

We will consider the findings of the survey in relation to the following forms of openness: 1) scientific collaboration; 2) transparency about funding; 3) publication of research results; 4) openness about the research priorities of institutions.

1. Scientific collaboration

According to the US National Institute of Allergy and Infectious Disease (NIAID), collaborations occur when scientists in different laboratories work together to move their research forward by investigating common research questions and sharing resources and information (United States National Institute for Health, 2014). The South African National Research Foundation (NRF) and the DST also identify scientific collaboration as a necessary requirement for the advancement of South African science and have established systems to encourage such collaboration.[26]

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[24] For example, see the special edition of *The British Journal for the History of Science*, Vol 45, 2012 titled "The states of secrecy", available at http://journals.cambridge.org/action/displayIssue?jid=BJH&volumeId=45&seriesId=0&issueId=02 (Last accessed 25 May 2014).

[25] See the 2012 Budapest Open Access Initiative recommendations http://www.budapestopenaccessinitiative.org/boai-10-recommendations.

[26] See http://www.nrf.ac.za/risa.php?fdid=13 (Last accessed 24 May 2014).

Box 4.1: Initiatives to promote openness in science

1. *Open Review*, which includes both review of funding proposals and articles that are submitted for publication, the latter traditionally conducted as a peer review. Open Review does not so much aim for Openness according to the Open Definition or the Open Source Principles, rather it is meant to make the review processes more transparent, impeding cliquishness between colleagues as submitting scientists and reviewers.
2. *Open Metrics* as a tool for establishing metrics for the scientific relevance of publications and data that are independent from proprietary databases like the *Web of Science* or the *SCOPUS* database which do not only charge fees, but also disallow unrestricted access to their raw data.
3. *Open Access to scientific data* according to the Panton Principles (available at http://pantonprinciples.org/).
4. *Open Access* to scientific publications.
5. *Open Bibliography*, meaning Open Access to bibliographic data.
6. *Open Data*.
7. *Open Notebook Science* (practice of making the entire primary record of a research project publicly available online as it is recorded).

From: http://book.openingscience.org/vision/research_funding.html

The results of the survey indicate that research scientists in South Africa are supported and encouraged to collaborate less often with researchers from other institutions than they are with colleagues from their own institutions. The reasons for this can only be speculated, but are likely to include the effect of competition, particularly between academic institutions. Since most survey respondents were from research institutions receiving public funds, the finding that only slightly more than half of the respondents felt that collaboration with colleagues outside of their institution was routinely facilitated or encouraged suggests that such collaboration is not considered a priority and support for such collaboration could be increased.

2. Transparency about funding

While financial accountability appears to be the norm in research facilities, and would be demanded by funders and academic institutions, openness about the sources of funding is not routine, or recognised by scientists. There are several ways in which such openness could be encouraged at institutional level, including requiring staff who received grants to list these on their staff profiles, through the maintenance of

an online open access list of projects and their donors, or by encouraging funders themselves to require grant recipients to declare the source of their funds when publishing or presenting research results. Similarly, creating awareness about funding information within the science community may offset such perceptions.

3. Publication of research results

It can be expected that there would be routine publication of research results by scientists at research facilities, and indeed this is the case. In the interests of assessing the extent to which South African scientists are supported to embrace the move towards open access, it would be useful to conduct an assessment of the extent to which scientists do, or are encouraged to, publish in open-access journals. Moreover, the extent to which universities in South Africa provide curated and searchable repositories in which staff can upload research as 'find-able' and open content is unclear. This is an important element of open research and something that is becoming increasingly topical in data discussions as a means to satisfy data-sharing requirements of funders and priorities of institutions.

4. Openness about the research priorities of institutions

Openness about the research priorities of an institution is also important, not only to ensure alignment between work undertaken and identified priorities, but also to ensure alignment between national developmental priorities and needs and work undertaken at institutional level. One in five respondents to the survey said that their institution did not make their institutional research priorities clear, or they were not aware of such priorities at institutional level.

4.3.5.2 Staff retention and confidence in staff capacity

As noted earlier, one of the goals of the US Department of Interior policy on scientific integrity was to establish scientific excellence, and pride amongst scientists to be associated with the Department (US Department of Interior, 2011). There was some doubt expressed by respondents about the capacity of some staff to conduct research, with 17% disagreeing with the statement: *Staff conducting life science activities have been properly trained*. Since confidence in the excellence of science is both in the national interest and in the interest of individual research institutions, this aspect needs to be addressed.

Equally important, given the need to develop a strong national capacity to undertake life science research is to ensure that junior research staff are supported and encouraged and that senior staff with experience are retained. The survey finding that fewer than half of all junior research staff feel consistently supported and nurtured suggests that at institutional and national levels, attention needs to be paid to develop the capacity of senior staff to mentor junior staff. Perhaps even more concerning is

the perception that senior staff are not valued, nor are efforts made to retain their skills. More than half of the respondents in this survey felt that senior staff are not consistently valued by their institutions, indicating an imperative to incentivise and encourage staff to remain in the life sciences.

4.3.5.3 Ethics

The integrity of the life sciences in South Africa relies on scientists understanding, being conscious of, and adhering to the basic principles of scientific practice of *inter alia* not falsifying data and ensuring proper citation of others' work. Yet, one of the most concerning findings from the survey was that South African research scientists do not perceive training and education about basic research ethics – including scientific misconduct – as routine. While ethics review of research and experimentation involving human participants or animal subjects are routine, this does not extend to all research, including research on micro-organisms.

There is a clear need for the scope of ethics training and review to be examined both at national and institutional level. In addition, findings from the survey show that gaps exist in knowledge about dual-use issues, biosafety and biosecurity.

1. Ethics training

Much reflection has gone into the question as to how to adequately train scientists in moral matters, and how successful or efficacious such training can be (Van Niekerk, 2003). There seems to be a growing consensus that ethics training ought not to be a small 'add-on', attached to the 'real' scientific training that a scientist undergoes. Scientists, particularly in the life sciences, ought to be made aware at the outset of the possible harm that could arise from their work, and ought to be encouraged to be sensitive not only to the possible misuse of results, but also to discuss these issues amongst colleagues throughout the development of each research project. Science that is not responsible science is bad science (Van Niekerk and Nortjé, 2013). It might yield new insights and it might have numerous applications, but if it is prone to be utilised for harmful purposes, it loses its value and desirability.

Many theorists argue that it is futile to teach ethics (Van Niekerk, 2011; Van Niekerk, 2003); they argue, ethics is "caught, not taught". It is undoubtedly true that mere instruction in ethics does not guarantee more morality. Moral knowledge and the moral dispositions fostered by that knowledge are shaped by many influences, ranging from parents, teachers, friends, television, cultural practices, and books among others. This knowledge and dispositions are carried into the world of work.

As a considerable amount of teaching within laboratories occurs with a highly technical focus at the hands of supervisors and senior colleagues, it is of paramount

importance that there be widespread recognition within the scientific community of the responsibility to foster ethical working environments and to reinforce and perpetuate the ethics of scientific research – including the implementation of codes of conduct.

Ethics education is likely to equip scientists to cope better with a world that is increasingly morally complex. To have the ability to analyse morally-problematic situations, to be able to identify the precepts that are applicable to them and the argumentative strategies that one might follow in order to make more sense of them and, in the end, to come to responsible judgements about them, is to become significantly better empowered for the world of work and for life in general.

2. Ethics review

The system of ethical review by means of RECs is operational in South Africa as in most other countries. It is essential that all research in the life sciences be submitted to such committees, and that these committees are all registered, as required by law[27], with the NHREC. If the size and scope of the work of a research laboratory warrants it, such a committee could be created for that institution. If not, permission can be obtained from committees at other, larger institutions to consider and approve research protocols originating from smaller institutions.

The NHREC identifies the following nine guiding principles for health research[28]:

1. Respect for persons.
2. Relevance and value of research.
3. Scientific integrity.
4. Risk of harm and likelihood of benefit.
5. Informed consent.
6. Distributive justice.
7. Investigator competence.
8. Privacy and confidentiality.
9. Publication of results.

The practice of submitting research protocols in the life sciences to ethical review raises the issue of which ethical guidelines ought to be utilised. In South Africa, no guidelines specifically formulated for life sciences that do not entail research on human participants have been formulated or published. When research does include human participants, such as in this survey, the guidelines can be very complicated in that they are designed to deal specifically with certain types of research (particularly

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[27] Health Act 61, 2003, Chapter 9, Section 73.

[28] See http://www.mrc.ac.za/ethics/DOHEthics.pdf.

medical research) and not social science research. The guidelines in Chapter 2 of the NHREC Research Guidelines, which are currently (2014) being revised (personal communication, Van Niekerk), are of general relevance to life sciences research on non-human subjects, but they need to be supplemented with more specific guidelines for the latter branch of science. The formulation of such guidelines should be a high priority for non-human life science researchers. Leadership for such an effort would likely require formally professionalising the life sciences.

3. Ethical conduct

It is advisable that a code of conduct (COC) be developed for every research institution dealing with research on non-human live entities. The possibility of devising a code of ethical conduct for the life sciences as a profession in order to prevent the misuse of research has received some attention in the literature. The myriad ethical breaches of the twentieth century, coupled with the aftermath of the creation and unleashing of the atomic bomb and the use of chemical agents in the Vietnam war, as well as unease regarding new areas of research, such as cloning and genetic intervention which developed in the second half of the twentieth century, solidified the notion that certain areas of research ought to be either prohibited or at least subject to restrictions (Badash, 2004). The unease created by these events prompted the formation of organisations such as the Committee on Scientific Freedom and Responsibility created by the American Association for the Advancement of Science which aimed to establish the degree to which scientists are accountable for their activities. The possibility of a code of ethical conduct for scientists akin to the Hippocratic Oath taken by doctors to do no harm has also been considered as a means of addressing the dual-use problem (Keuleyan, 2010).

In terms of developing a code of ethical conduct for the life sciences, Interacademy Partnership (IAP) has suggested five principles which may serve as guidelines for institutions wishing to devise their own codes of conduct (Atlas, 2009). These principles include: 1) awareness of possible harm and misuse; 2) safety and security in terms of conduct; 3) education and information referring to the knowledge that scientists should possess regarding the relevant legislation and other important areas; 4) accountability in terms of the fact that scientists must report breaches of the above areas; 5) oversight which refers to the duty of those in supervisory positions who should ensure the above principles are observed.

Kant and Mourya (2010) discuss the possibility of a code of ethical conduct for scientists which would comprise three levels moving from general to specific principles and developed a toolkit to develop institution-specific codes of conduct. The toolkit provides examples of several complete codes that can serve as a useful point of departure for the process. The efficacy of an effective code largely depends on strong

leadership during development as well as buy-in from, and ownership by, all members of the organisation.

The development of a code of conduct, while no guarantee against unethical behaviour, may serve the purpose of both creating awareness about the ethical responsibilities of scientists, and the basis for holding scientists to account, at least at institutional level. However, it is not a substitute for more substantial ethics training and education that should include information about relevant national and international laws and agreements (such as the Biological Weapons Convention and the Non-Proliferation of Weapons of Mass Destruction Act).

4.3.5.4 Science and policy

The survey has brought to light that gaps exist in scientists' awareness of national and international conventions, laws and policies, with less than half of the respondents acknowledging awareness. Few respondents (35%) agreed that these conventions and regulations are easily accessible to scientists. This is supported by the observation that more than half of respondents (53%) indicated that there was poor communication between policymakers and scientists, pointing to an overall lack of knowledge and training in national and international laws relevant to the life sciences.

While a large proportion of respondents (65%) agreed that national and international policies relating to safety and security protocols exist, it is of major concern that one-third had no knowledge of such mandatory practices. A single practice that does appear to be well understood is legislation pertaining to disposal of hazardous waste, although a worryingly 4% of respondents indicated that rules pertaining to its disposal are not followed.

It is worth noting that there is a considerable discrepancy among life scientists with respect to their perception of the extent to which national and international policies facilitate scientific development and freedom. Forty-one percent of respondents agreed that policies foster these principles but a similar proportion (40%) disagreed that this was the case. This, together with findings outlined above, indicates a general lack of awareness and understanding in the life sciences communities about rules and regulations pertaining to scientific research and the opportunities such policies might afford to the advancement of science.

4.3.5.5 Biosafety and biosecurity

The survey revealed a slight disconnect between the perceived knowledge and appreciation of existing regulatory frameworks for biosafety and biosecurity matters and the practical implementation thereof. In general, life scientists seem to be confident in their theoretical knowledge and skills, but less so for some of the practical

implementation requirements – especially in terms of risk assessments and the handling of accidents and/or security breaches. Hands-on professional development courses, as part of an effort to professionalise the life sciences as discussed elsewhere, could eliminate such disparity.

4.3.6 Conclusion

The findings from the survey show that life scientists in South Africa lack adequate knowledge about the safety and security rules and regulations pertaining to their work. There are also significant gaps in the training of scientists pertaining to ethics, biosafety, biosecurity and dual-use issues, as well as in relation to how and where to report concern about possible breaches. There also appear to be gaps in relation to the implementation of existing rules and regulations, including in relation to SOPs, tests of competence (in biosafety and biosecurity) and even in some instances in the maintenance of laboratory equipment.

In Chapter 3, reference was made to the comprehensive legal framework to control biological agents and to act against the malicious use of pathogens. Such a legal and policy framework is important, but its effect is limited if those who should know about it, do not. The findings of this survey suggest that there is an urgent need to ensure that life scientists are informed about national and international laws and policies relevant to their work.

The panel recommends:

1. Comprehensive ethical review of research and development in the life sciences is an appropriate tool which will also help ensure biosafety and biosecurity compliance.
2. Ethical review guidelines for the life sciences in South Africa should be formulated.
3. Education of scientists needs to include comprehensive ethics training which must make reference to the relevant national and international laws, regulations and conventions.