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RESEARCH ETHICS

Biosafety and Biosecurity in Context

2.1 Introduction

Discovery and innovation in the life sciences are booming based on significant, recent technological advance and the benefits it holds for health-care provision, food production, sustainable energy generation, environmental protection, etc. Although R&D within the life sciences promise a better future for all people, it is easy to also contemplate scenarios where negative impacts could result from such work. In particular, the intentional misuse of biological material and biotechnologies to develop harmful agents should be proactively considered in an effort to establish well-balanced frameworks that will effectively prevent misuse without hampering legitimate R&D. It is therefore inevitable that any reflections on biosafety and biosecurity will require a strong ethical dimension.

The purpose of this chapter is to reflect on the morality and ethics of R&D and how this relates to the responsibilities of scientists in the life sciences. Dual-use research and the challenges it pose are discussed in particular and mechanisms of how ethics review should be institutionalised and managed with respect to biosafety and biosecurity are proposed.

2.2 Defining morality and ethics

Although the terms 'morality' and 'ethics' are often used interchangeably, it is generally useful and conceptually desirable to distinguish between them. Morality refers to the widely perceptible societal phenomenon that people in all known societies submit their behaviour to normative evaluation. This submission of their behaviour to the judgment of obligation or normativity is the key distinguishing difference between humans and animals. Humans do not simply act in certain ways without the ability to choose to act differently – in contrast to the instinctual actions of animals. People accept that they *ought* to act in a certain way as informed by societal norms.[4]

Ethics, in contrast, refers to an intellectual activity in which we consciously reflect on the nature of our moral behaviour, as well as the norms that guide that behaviour, the sources of our moral judgements and the theories in terms of which we think and argue when we engage in moral deliberation. The kind of normative ethics that relates to the content of this report is referred to as applied ethics, where ethics theories and approaches to moral reasoning are applied to immediate, serious moral issues that require urgent attention because of their potential impact on society. Ethics comes into play particularly in a context where it is evident that callous, deliberate malicious or careless research behaviour could potentially harm or endanger human life and/or

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[4] Norms are strong and widely acknowledged action guides, sometimes also strongly linked to a certain society, though often valid in most societies.

the environment. Concerns regarding life science research and development work, as embodied in biosafety and biosecurity management systems, therefore arise from a widespread realisation that these activities require morally responsible behaviour to guard against their danger and misuse.

The abuse of biological material for harmful actions against humans is indicative of a phenomenon long recognised in philosophical and ethics literature, i.e. that science is not value-free (Feyerabend, 1975; Kuhn, 1962). It is increasingly agreed that value orientations cannot be divorced from the legitimate and responsible practice of science (Rossouw, 1980; Van Niekerk, 1992). Values are in play in particular when the aims of science are to be decided and evaluated. Objectivity and truth are regulative ideals that ought to guide the progresses of science and innovation and at times these ideals do act as important bulwarks against the threat of ideological derailments of science. However, under the direction of malicious intentions and aims, science and its products can also be used as very destructive forces, as illustrated by the infamous use of Zyklon B during the Holocaust to murder millions of people and the development of nuclear weapons during the Second World War.

2.3 Dual-use research – the main moral dilemma related to biosafety and biosecurity

Dual-use research (DUR) is defined as life sciences research that can be reasonably anticipated to provide knowledge, information, products or technologies that could be directly misapplied to pose a significant threat, with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel or national security.[5] The dual-use problematic has evolved in response to ever-growing fears that certain areas of the life sciences are vulnerable to misuse and that research conducted within these areas may be used to develop biological weapons. More specifically, the dual-use literature is driven by concern elicited by the publishing of the results in scientific academic journals of several experiments involving deadly viruses (Cello *et al*., 2002; Jackson *et al*., 2001; Tumpey *et al*., 2005), which could be replicated by nefarious individuals or groups, with catastrophic results. Due to this potential for misuse, there is a distinct polarisation within the scientific community regarding whether or not the results should have been published, which has implications for future research of a similar nature.

The debate is comprised, on the one hand, by the position that scientific freedom of enquiry, scientific transparency, the right to publish and the need to replicate and verify research are good or valuable things in themselves and should thus be protected;

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[5] NIH, Office of Science Policy (www.osp.nih.gov).

and on the other hand, by security concerns related to the potential for harm that could result from the misuse of such research. Most of life science research which possesses the potential for harmful misuse also results in tangible benefits related to the understanding and treatment of illnesses and diseases and thus for human health in general. The two opposing sets of values, the awareness of an intention to do good in the presence of a possible intention to cause harm, the problems of control and regulation of scientific research to which they give rise to and who must bear responsibility for this, are all aspects of what is generally understood as the dual-use dilemma.

Choice of research focus compels the scientist and associated scientific institution to decide *on behalf of society* between different, but equally compelling, goods. On the one hand there is the good associated not only with the benefits that could arise from successful research, such as the promotion of human health and flourishing, but also the good associated with the freedom or right of the scientist to pursue and generate knowledge itself and on the other hand, there is the good that arise from avoiding potential casualties associated with the possible misuse of research, materials or technologies. The main issue thus lies in how these competing values or goods should be balanced or adjudicated, who is responsible for this endeavour and how it should be regulated.

The burden of this responsibility must be placed not solely upon the individual scientist, but upon the scientific community as a whole. There is an implicit obligation that exists between the institution of science and the public which enables the former to secure particular privileges such as autonomy, public funding and public trust, in exchange for the fulfilment of certain responsibilities and duties. When there is a threat to public safety, safety concerns must override those related to the right to freedom of scientific enquiry. However, such a conclusion presupposes that it is possible to ascertain clear evidence of a threat.

It may be helpful to discern between the *risk* that particular dual-use research may represent and the presence of a clear *threat* that it will in fact be developed for illicit use by nefarious individuals or groups. The presence of such a foreseeable threat would require the enactment of more stringent regulatory measures (Forge, 2010). The real question therefore becomes whether or not it is possible to establish the credibility of a threat regarding the possible misuse of dual-use research. Of course, complexity is added if the manner in which a threat is portrayed serves a particular political agenda.

The way in which a threat is perceived will have direct relevance for how it is addressed – not only at the level of government, but also in terms of the reactions

of scientists who are the key proponents in the dual-use dilemma. In order to ensure that scientists abide by any regulatory measures that are required, they must concur with the established threat credibility. This implies that scientists must not only be informed of relevant information but must also be involved in the process of threat identification. Perceptions of and the degree of threat posed by dual-use research is highly variable and as such, regulations must be flexible and innovative in order to encompass changes in science, as well as possible changes in threat.

Miller and Selgelid (2007) argue against control resting solely in the hands of either scientific institutions or government. They favour a system where dual control is shared between the two, with the formation of an independent body constituted by both scientific and security experts with ultimate power. Development of a mandatory code of ethical conduct for the life sciences as a profession in order to prevent the misuse of research, akin to the Hippocratic Oath to do no harm which is taken by doctors, has received much attention in the literature (Revill and Dando, 2006).

The intention to commit harm will always be present and in this regard, very little control exists. Where control and regulation are possible, it is vital to ensure that absolute vigilance and due care be taken. Such control and regulation is impossible to achieve without the participation of the scientific community. Rather than requesting that the scientific community blindly adheres to a set of rules or accepts concerns that are viewed as foreign to the ethos of science as an institution, it would be more effective to impart knowledge regarding the dual-use dilemma. Acceptance of scientific responsibility will ensure the necessary participation and cooperation of the scientific community in devising strategies to address the possibility of misuse. There is a far greater likelihood of preventing the misuse of research if those working in vulnerable areas are attuned to the nature of the threat and are committed to taking the necessary precautionary steps required of them.

2.4 Ensuring ethical research and development

Experimentation in and the application of biological weapons have been described long before the start of the First World War in 1914. Although international limitations and prohibitions on the abuse of microbes and pathogens for harmful and lethal intent, including the 1925 Geneva Convention and the Biological and Toxins Weapons Convention, were set in place during the 20th century, serious concerns remain. These include concerns regarding the availability and accessibility of microorganisms as well as the technologies based on their use and applications.

The increasing recognition of the role and application of moral values in science practice encouraged the development of various broad ethics guidelines for scientists, which can also be used to assess the ethical standing of R&D projects – especially in

the life sciences. For example, the Singapore Statement on Research Integrity[6] states that *"the value and benefits of research are vitally dependent on the integrity of the research"* and then lists honesty, accountability, professional courtesy and fairness and good stewardship as the fundamental principles on which research integrity is based. It continues to list 14 different responsibilities of researchers to ensure the integrity of their research, of which adherence to regulations, reporting and responding to irresponsible research practices and societal considerations have particular bearing on biosafety and biosecurity matters as discussed in this study.

Similarly, a "universal ethical code for scientists" developed by the United Kingdom's (UK's) Department for Innovation, Universities and Skills endeavours to "renew the trust relationship between scientists and society".[7] In this case the code of conduct is based on the societal values of rigour, respect and responsibility (See text box).

A UNIVERSAL ETHICAL CODE FOR SCIENTISTS

Rigour

Rigour, honesty and integrity

Act with skill and care in all scientific work. Maintain up-to-date skills and assist their development in others. Take steps to prevent corrupt practices and professional misconduct. Declare conflicts of interest. Be alert to the ways in which research derives from and affects the work of other people, and respect the rights and reputations of others.

Respect

Respect for life, the law and the public good

Ensure that your work is lawful and justified. Minimise and justify any adverse effect your work may have on people, animals and the natural environment.

Responsibility

Responsible communication: listening and informing

Seek to discuss the issues that science raises for society. Listen to the aspirations and concerns of others. Do not knowingly mislead, or allow others to be misled, about scientific matters. Present and review scientific evidence, theory or interpretation honestly and accurately.

From "A universal ethical code for scientists", UK Department for Innovation, Universities and Skills.

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6 www.singaporestatement.org.

7 www.dius.gov.uk.

2.5 The institutionalisation and management of research ethics in South Africa

Ethics awareness and the ethical review of scientific research in South Africa have increased exponentially over the past 30 years following trends abroad – particularly in the United States of America (USA). In terms of the South African National Health Act (*Act 61 of 2003*), all scientific research with human participants and animal subjects has to undergo ethical review by a legitimate research ethics committee (REC). All RECs have to be accredited by the National Health Research Ethics Council of South Africa (NHREC).[8] The NHREC is appointed by the Minister of Health for a period of three years and is the highest policymaking body for research ethics in the country. The NHREC formulates and publishes extensive guidelines for ethical research with human participants and animal subjects, drawing on established international guidelines including the Nuremberg Code, the Belmont Report and the (often revised) Declaration of Helsinki.

Ethical review of research protocols involving research with human participants and animal subjects is standard practice globally. Assessing the impact of research and potential harms on human and animal health, as well as on the environment, is a necessary part of the research process. In the light of earlier comments that science is not always value-neutral and acknowledging its potential adverse effects, it is imperative to set procedures and practices in place that aim to protect the legitimate interests of humans, animals and the environment. This needs to be done in such a way that the progress of science is not hampered or unnecessarily delayed.

It is notable that in South Africa the formulation of guidelines for research on other organisms, and in particular microorganisms, that may negatively impact human health, well-being and/or the environment, has been lagging behind relative to the formulation of guidelines for research with human participants and animal subjects. This is increasingly recognised, and efforts are underway within some government departments, e.g. DAFF and some national research agencies to rectify the situation. For the purposes of this report, the panel acknowledges that much work must still be done to improve the applicability of the current system of ethics review to research on microorganisms.

The panel noted that specific RECs to assess the nature of microorganism research must be appointed at, or be made available to, all research facilities. Guidelines to determine which kinds of research require ethical assessment and what the ideal composition of an REC would be for such purposes need to be developed. The term office for REC

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[8] http://www.ethicsapp.co.za.

members and accompanying terms of reference (TOR) and standard operating procedures (SOPs) require formulation.

The panel is of the opinion that members of such an REC should include, first and foremost, experts in the field, as well as people with expertise in ethics, representatives of the community and people with experience in ethical review. It is essential that members of an REC be properly trained for their work. There are a number of relevant certificates, diplomas and Masters programmes available at several South African tertiary institutions. It is important that there not be any direct conflicts of interest in the appointment and practice of members of such an REC.

South Africa should establish clear, encompassing and balanced ethical guidelines for all life science research and development work to ensure our safety and the integrity of the environment we live in.