Research Ethics:

A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research

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A. EXECUTIVE SUMMARY

The following Report titled "**A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research**" is based on discussions among 51 Ethics Experts with previous experience in EU Ethics Screening, Review and Audit and was chaired by Johannes Rath. The discussions took place from December 2009 to March 2010 via the SINAPSE system and concluded that:

Research misconduct and potential misuse constitute an ethical issue in the context of EU funded research and should be systematically addressed in EU Ethic's oversight (Screening, Review and Audit).

In defining the scope of this ethical issue the following definitions were used as guidelines:

A. **"Potential misuse of research"** in the context of this document is defined as: **Research involving or generating materials, methods or knowledge that could be misused for unethical purposes.**

   The **main areas of concern regarding potential misuse** are:

   - Research involving agents or equipment that could be directly misused for criminal, terrorist or unethical military purposes;
   - Research which creates knowledge that could be used for criminal, terrorist and unethical military purposes;
   - Research which can result in stigmatization and discrimination;
   - Application and development of surveillance technologies;
   - Data mining and profiling technologies.

B. **"Research misconduct"** in the context of this document is defined as: **fabrication, falsification and plagiarism.**

   Falsification is defined as the misrepresentation of results.
   Fabrication is defined as the reporting on experiments never performed.
   Plagiarism is defined as taking the writings or ideas of another and representing them as one's own.

Aim of this report: The aim of this document is to provide a comprehensive strategy on how to safeguard EU funded research against misconduct and misuse. In a comprehensive approach the potential role and proposed actions of relevant stakeholders are addressed:

1. The EU Commission and its subsidiary institutions;
2. EU Ethics Screeners, Reviewers and Auditors;
3. Research project applicants, host institutions and national contact points.

B. INTRODUCTION

The **potential misuse of research** has received substantial attention in recent years due to the dramatic impacts such misuse has had in the general public. The Amerithrax case in the United States in year 2001 has not only cost the lives of 5 persons but also created an economic damage estimated to be in the area of 1 billion Dollars (1). The need to safeguard against such misuse has led to numerous legislative initiatives in various countries (2, 3). It has also stimulated the discussion among scientists, scientific institutions and publishers to establish and implement codes of conduct to minimize the risks of misuse of research (4, 5). Several funding institutions have developed and established such oversight mechanisms to ensure that the risks for such misuse are minimized (6). Such as, in the European Union the EU presidency has presented Ethics as the key oversight mechanism to ensure that EU funded research is not misused in the context of bio-warfare or bioterrorism (7).

In addition to the context of terrorist and unethical military use of research other areas of potential misuse have created concerns in recent times. Stigmatization and discrimination of individuals or groups of individuals is one example. National legislators in several countries, for example, have introduced new legislation safeguarding against such misuse in the context of genetic data (8,9).

Another example is the potential misuse of modern Information and Communication Technologies (ICT) for unethical purposes which has been the driving force for legislators to continuously update and develop new legislation mainly in the context of personal data protection to safeguard against such misuse. However, as research progresses sophisticated new tools are developed, that may allow the re-personalization of previously anonymous data (e.g. deep mining, image reconstruction technologies). To balance the needs between security and the risks to privacy for such technologies will remain a continuous challenge for ethics reviewers as well as legislators.

As an ever growing number of people today are working in research so has the number of individuals having access to research materials, technologies or knowledge suitable for misuse. Furthermore, science today is progressing in areas where misuse could have substantial and widespread impacts (e.g. security related research, synthetic biology, nanotechnology) to humans, animals, plants or economies (10).

Potential misuse of research could be addressed at all levels of EU Ethics oversight**. Screening** should ensure that proposals having misuse capabilities are forwarded to the **Ethics Review** in order to define and ensure adequate safeguards. An **Audit** process could verify that safeguards are adequately implemented by the project investigator and any risks that would arise during the course of the project are addressed.

Cases of research **misconduct** are frequently discussed in leading scientific journals and have gained substantial public interest as even highly regarded scientists have been involved in such misconducts recently (11). Such misconduct is not only diminishing scientific integrity but also public acceptance of science. Various institutions have set up mechanisms to counter research misconduct (12, 13, 14). Three areas of scientific misconduct are usually identified in these mechanisms which are falsification, fabrication, and plagiarism.

Within the EU ethics oversight regime auditing could be used to address research misconduct. Such an assessment could have substantial implications to the scientist therefore clear procedures would need to be established. Such procedures do not exist yet and would need to be developed.

EU ethics oversight can substantially contribute to safeguard EU funded research against misconduct and potential misuse by complementing partially existing institutional, national and international mechanisms.

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C. ROLE OF THE EU COMMISSION AND ITS SUBSIDIARY INSTITUTIONS

The EU Commission, together with its subsidiary institutions, play a central role in safeguarding EU funded research against misconduct and potential misuse by defining the framework and organizing Ethics Screening, Review and Audit. Actions that could be taken by the Commission to minimize the risks of research misconduct and misuse are summarized in detail in Table1.

It is anticipated that the implementation of the actions would benefit:

- Awareness of this ethical issue among applicants and ethics experts;
- Consistency of the assessment in ethics screening, review and audit;
- Scientific integrity.

Table 1: Suggested actions for the EU Commission and its subsidiary institutions

ACTION 1: Increase the awareness among applicants:

- Replace the current " Dual-Use" box/ or add as a new box on the **Ethical issues table** the following ethical issue:

  "Can materials, technologies or knowledge used or generated during the project be misused for unethical purposes?
  Examples:
  a. *Materials and technologies that could be used in weapons production, operation or dissemination (e.g. pathogens, toxic chemicals, nuclear material, explosives specific software systems, special robot systems);*
  b. *Information that could be misused for criminal, terrorist or unethical military activities (e.g. vulnerability studies, how to increase harmful consequences of weapons for example antibiotic resistance studies);*
  c. *Information that could result in stigmatization or discrimination of individuals or groups of individuals;*
  d. *Application or development of surveillance technologies that could be misused for unethical purpose ;*
  e. *Data mining and profiling technologies that could be misused for unethical purposes ."*

- Develop a specific guidance document for applicants, which should include potential misuse case studies on and a list of potential consequences in case of research misconduct.

ACTION 2: Increase expertise, awareness and common understanding of this ethical issue among Screeners, Reviewers and Auditors by:

- Providing this document to all Screeners, Reviewers and Auditors;
- Ensuring representation of relevant experts in Screening, Review and Audit panels;
- Providing training to all Ethics Experts participating in Screening, Review and Audit on this ethical issue;
- Establishing an open SINAPSE discussion platform for an informal exchange of experiences and views.

ACTION 3: Ensuring scientific integrity by investigating alleged research misconduct:

- Establish an Ombudsman system where concerns about misconduct in EU funded research could be filed confidentially;
- Establish a standard operating procedure and carry out trial runs on how to investigate and assess research misconduct in the context of EU financed research (e.g. within Ethics Audit);
- Establish a team trained in dealing with alleged research misconduct.

ACTION 4: Review and update current guidance document regularly to enhance practicability and ensure adequate representation of emerging issues

D. ROLE OF THE EU ETHICS SCREENERS, REVIEWERS AND AUDITORS

By carrying out Ethics screening, review and audit, EU Ethics experts play a key role in ensuring that EU funded research is in-line with the current EU standards in ethics. Table 2 of this document provides an overview on what types of research are of key concern with regards to potential misuses; it also provides concepts on how to safeguard such research during Ethics Review. Thereby it shall enhance a common understanding of this ethical issue and improve consistency of evaluation outcomes in the future.

Safeguards should be proportionate to risks resulting from potential misuse. In case the proposed research can not be safeguarded adequately and the risks of misuse outweigh the expected benefits the experts may consider recommending to the EU Commission not to fund the particular work programme or project as a whole.

The list provided is non-exhaustive and should not limit the inclusion of other areas of research that could be misused for unethical purposes.

Ethics Screening should ensure that all relevant proposals enter Ethics Review. Ethics Audit could be used to verify that all safeguards expressed as Requirements are implemented adequately.

Table 2: Key areas of concern, examples and potential requirements

Research activities of concern	Examples	Potential Requirements
a. Research involving human, animal and plant pathogens, toxic chemicals, and radioactive material that when misused could cause severe harm to humans, animals, plants or the environment.	**Agents: Pathogen species, toxic substances**, for examples see COUNCIL REGULATION (EC) No 428/2009 Annex 1	• Any weaponization of such agents needs to be checked for its legitimacy in relation to relevant international conventions and on a national level. • Provide national approvals (e.g. handling of pathogens at biosafety level 3 and above, radioactive substances, toxic chemicals, export licences). • Keep inventories. • Restrict access to locked rooms, locked cabinets. • Require training in bio-security. • Require special training on safety and security for persons handling such substances should receive. • All agents must be inactivated after the project or the applicant must ensure that no unauthorized access to such agents occurs after the end of the project.
	Special manipulations Examples: Disrupting immunity or the effectiveness of an immunization, conferring to a biological agent or toxin, resistance to prophylactic or therapeutic interventions against that agent or toxin facilitate their ability to evade detection methodologies; increasing the stability, transmissibility, or the ability to disseminate a biological agent or toxin.	
b. Research involving other types of materials that when misused could cause severe harm to humans, animals, plants or the environment.	Explosives, conventional weapons, small arms	• Provide national approval for the handling of such materials. • Provide export licences if international movement of agents listed in Annex 1 of Council Regulation 428/2009 is carried out.

		• Access should be restricted (locked rooms, locked cabinets). • Persons handling such materials should receive special training. • After the project such materials should be destroyed or the applicant must ensure that no unauthorized access to such materials will occur.
c. Research that, based on current understanding, can be reasonably anticipated to provide knowledge, which could be misused for criminal, terrorist or unethical military purposes	Knowledge on how to enhance the harmful consequences of weapons, infrastructural vulnerabilities, autonomous robots with self organizing computing and networking capabilities Weapons support systems (e.g. software in the context of the EU dual use directive);	• Include Security Experts in Advisory functions. • Restrict access of such information to key stakeholders. • Ensure adequate data protection during the course of project. • Workpackage on security impacts of the generated knowledge and potential safeguards.
d. Research involving ICT and surveillance with the potential for misuse	Personal data protection (e.g. data mining and profiling technologies); Surveillance technologies with the potential to violate core spheres of privacy (e.g. family communication).	• Ensure EU standards on data protection are met by Non-EU applicants. • Ensure that technical and/or organisational safeguards are introduced so that results can only be employed in an EU ethics standards compliant manner. • Ensure that technical personnel (e.g. IT service provider) is also bound by confidentiality.
e. Research with the potential for stigmatization and discrimination	Genetic or other (e.g. social, medical) studies creating information that could be misused for stigmatization and discrimination (e.g. insurance, employment).	• Require local ethical approval Ensure personal data protection at EU standards. • Verify national legislations exists to prohibit discrimination in the context of genetic information life • Establish a project advisory group on this issue. • Include minority representatives in the project management/advisory group. • Provide copies of national approvals in case the relevant jurisdiction foresees such approvals. • Ensure adequate data protection to avoid illegitimate access by third parties. • Ensure that research subjects are well informed about this potential misuse during informed consent.

E. ROLE OF THE RESEARCHER (PROJECT APPLICANTS), NATIONAL CONTACT POINTS AND HOST INSTITUTIONS

Researchers creating risks to the society have a responsibility to safeguard their research against such risks. No oversight system can fully compensate for this responsibility. Awareness of this issue among researchers has increased however; practical arrangements to address misuse or to incorporate safeguards in their work are often missing (e.g. biosecurity). Applicants should be assisted through expertise provided by their respective national contact points and host institutions in identifying relevant existing national and international safeguards and, if needed, develop project specific safeguards to ensure potential misuse is minimized.
The following checklist (Table 3) provides some ideas on what elements should be addressed.

Table 3: Potential misuse of research: CHECKLIST FOR APPLICANTS, HOST INSTITUTIONS AND NATIONAL CONTACT POINTS

1. Do you foresee any potential misuse for unethical purposes that could result from this research project?

2. Does your project involve any of the following key areas of concern:
    a. Agents and technologies that could be misused in weapons context (e.g. pathogens, toxic chemicals, nuclear material, explosives, software robotic systems)
    b. Information that could be misused for criminal, terrorist or unethical military activities (e.g. vulnerability studies, how to increase harmful consequences of weapons for example antibiotic resistance studies)
    c. Information that could result in stigmatization or discrimination of individuals or groups of individuals
    d. Surveillance technologies that could be misused for unethical purposes
    e. Data mining and profiling technologies that could be misused for unethical purposes

If so:

1. Tick relevant box on “Ethical Issues Table”
2. Provide an assessment of this misuse potential in the “Ethical Issues” section of the application
3. Provide information on safeguards on how to minimize the potential for misuse. Such safeguards could be for example
    a. existing national legislation and approvals (e.g. Dual-Use export import legislation, work in contained environments, etc)
    b. incorporation of adequate advisory boards into the project management
    c. access restrictions
    d. transfer restrictions

F. CONCLUSION

In conclusion, the discussion group **clearly identified misconduct and the potential misuse of research as an ethical issue**. Adequately safeguarding against such risks will not only protect individuals and the society as a whole, but also scientific integrity and the scientists.

This document provides a comprehensive framework for such action by proposing an integrated mechanism involving funding institutions, ethics experts and researchers. It identifies the scope of the ethical issue, provides safeguarding ideas and describes the roles relevant stakeholders could play. The framework which is clearly laid out in three tables is not only comprehensive; it is also practical and can be utilized in the context of EU Ethics oversight as a tool with immediate results.
To ensure and further enhance practicability the concepts outlined in this document should be evaluated on a regular basis for their relevance and efficiency, and amended as necessary.

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