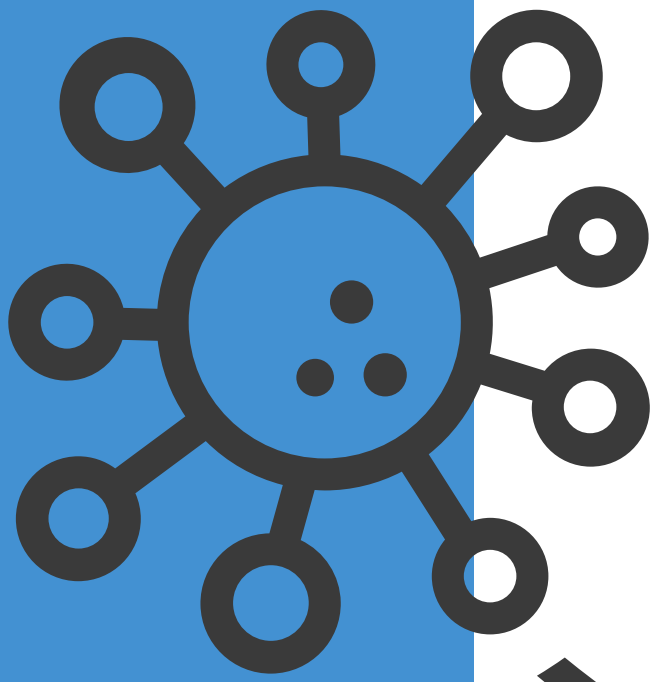
Dual-use research of concern guidelines



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European Virus Archive Global

Acknowledgments

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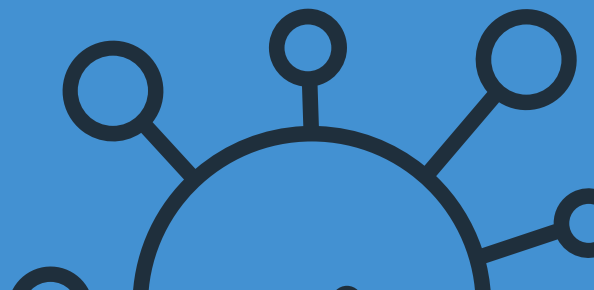
Disclaimer

This document was created to provide support and guidance to EVA GLOBALresearchers and their institutions in identifying and assessing dual-use risks in their research projects. It is not intended to be prescriptive. Researchers and their institutions are still responsible for their own actions and to ensure that the implementation of their research complies with international frameworks and national regulations.

September 2024



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HOW TO USE THIS DOCUMENT

SECTION 1 - INTRODUCTION

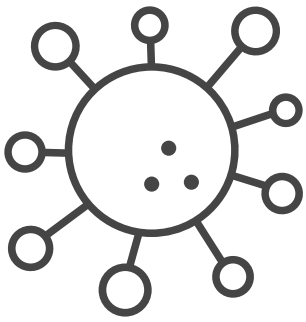
- Read **before or once** you have written your project proposal
- Read **before** you start any practical/laboratory work
- Read **before** you use the researcher's and institutional checklists

SECTION 2 - RESEARCHER´S CHECKLIST

- Read **after** the introduction section
- **Strike through** irrelevant points
- **Tick** boxes that are relevant to you and/or have been addressed

SECTION 3 - INSTITUTIONAL CHECKLIST

- Read **after** the introduction section
- Use to **complement** the responses of the Researcher´s checklist
- **Strike through** irrelevant points
- **Tick** boxes that are relevant and/or have been addressed



Use this document to assess your research project **before** you start with any practical/ laboratory work.

Keep in mind that DURC risks can arise at any time during the research cycle and thus you should continously monitor your research outcomes and potential modifications to your project.

INTRODUCTION

The European Virus Archive GLOBAL (EVA GLOBAL) consortium is aware that, irrespective of researchers' good intentions, some of the viruses and virus-derived materials that are distributed through our network can be misused. This also includes the potential misuse of new knowledge generated and results arising from the use of such materials. This poses a dual-use research of concern or DURC threat (i.e. can be used for good or for bad purposes). The misuse of dual-use material and research findings can be either accidental or intentional and can occur both at a national and/or international level.

As a decentralized globally distributed biobanking infrastructure, EVA strives to promote best practices and foster compliance with international regulations is to enhance awareness and education among our partners. We recognise, however, that there is a broad range of awareness, institutional policies and support provided to researchers in different countries to address these issues.

This DURC document is intended to help and guide researchers and their institutions on how to identify, assess and find mitigation strategies for dual-use risks in research projects. The document is composed of three sections: an overarching introduction, and a researcher and institutional checklist. The introduction package is intended to familiarize the user with definitions and background information, while the checklists are intended to provide a road map with resources and tools for researchers and their institutions to assess their research projects for any dual-use risks. We hope our efforts and training materials will support our EVA GLOBAL partners, both researchers and institutions, in assessing and addressing potential dual-use risks in research projects.

WHERE TO BEGIN?
THE DURC STRATEGY CYCLE

Dual-use risks need to be considered and evaluated throughout the research life cycle[2], from grant application, to practical work, to publication. In practice, however, dual-use considerations often only arise at the moment of publication. Furthermore, while the theory is relatively straightforward, the reality is more complex as research questions can change through time, leading to unexpected results and outcomes that could pose dual-use risks (**Figure 1**).

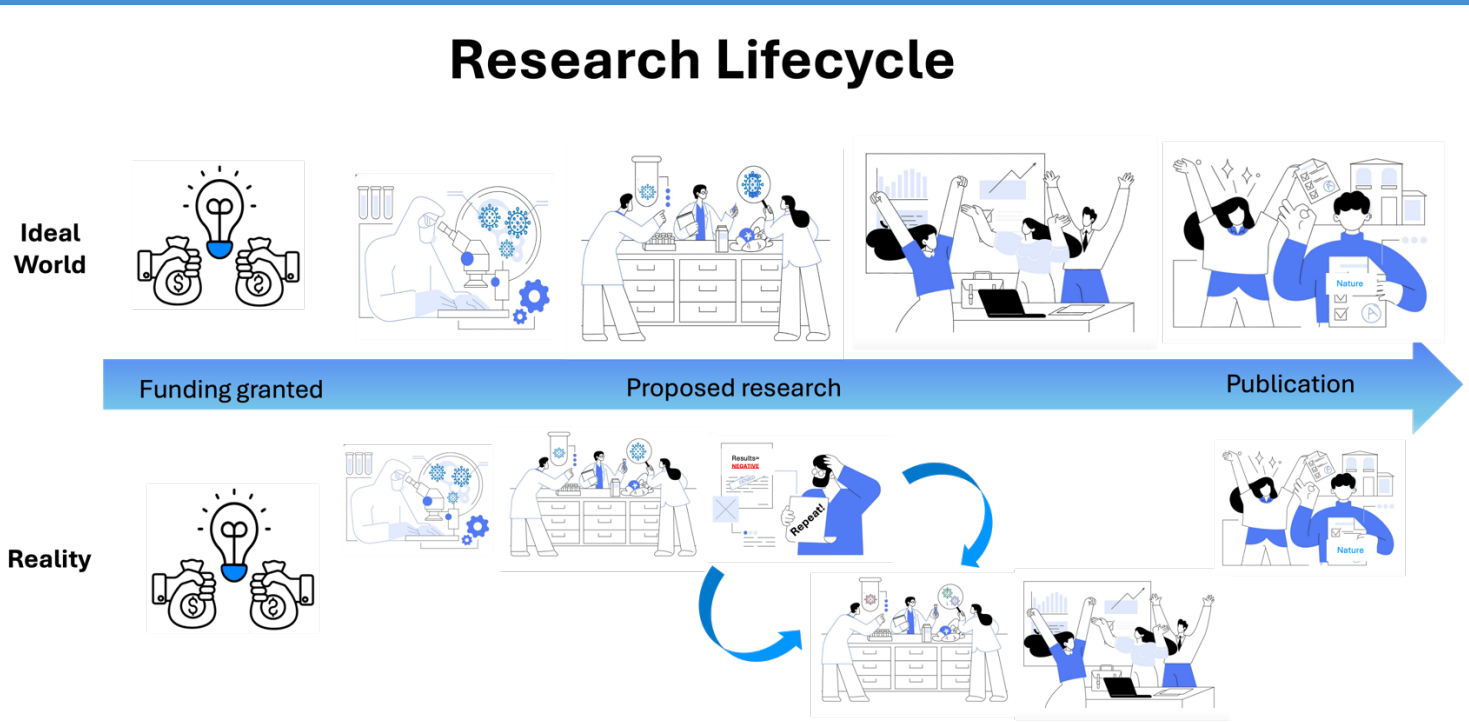
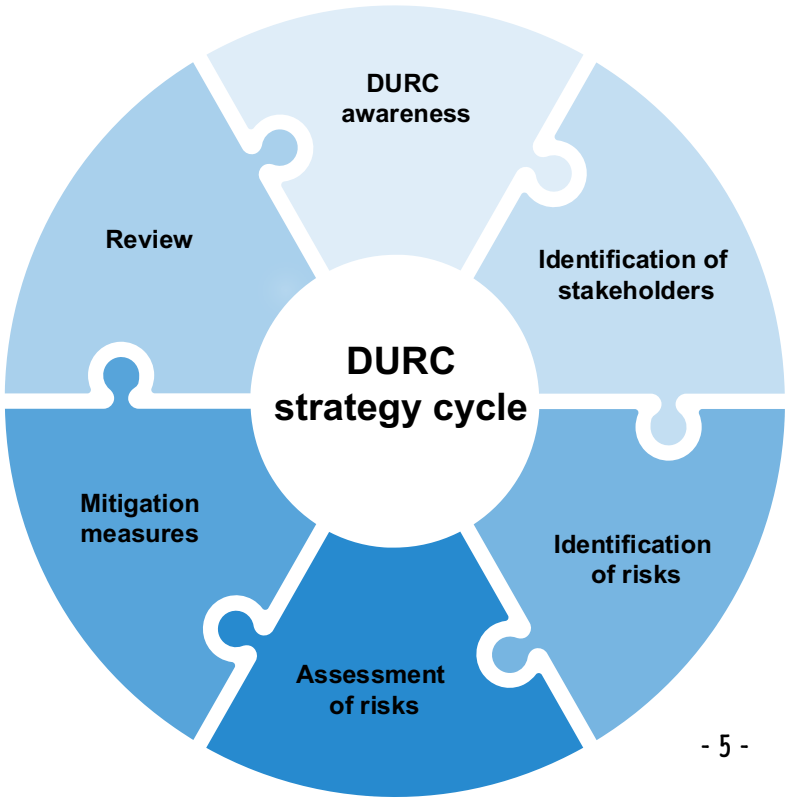


Figure 1. *Illustration of the Research Lifecycle in theory and reality.*



We have identified six key steps that could help researchers and their institutions address dual-use risks (**Figure 2**). In the next sections we will have a look at each step in more detail.

Figure 2*. DURC strategy cycle. Showing key steps to identify, address and review dual-use risks.*

DURC AWARENESS

Dual-use research of concern (DURC) in the life sciences is broadly defined as research that could provide knowledge, information, products, or technologies that could be directly misapplied, cause harm and pose a substantial threat with broad potential consequences to human, animal and plant health, the environment, or national security. Although DURC might be defined slightly different in various international fora, to fit their respective goals and objectives, there is a point of consensus that dual-use research implies there is a potential for **purposeful misuse** of material, knowledge, technologies and information to harm humans, animals, plants or the environment (**Box 1**).

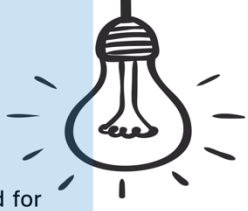
Box 1. Definitions of dual-use according to four organizations.

World Health Organization

Research that is intended to provide a clear benefit, but which could easily be misapplied (purposefully) to cause harm.

World Organisation for Animal Health
Founded as OIE

Knowledge, research, technologies, and materials that can be used for good, can also be misused to harm animals, humans or the environment.



EU

items, including software and technology, which can be used for both civil and military purposes, and includes items which can be used for the design, development, production or use of nuclear, chemical or biological weapons or their means of delivery...

NATIONAL SECURITY AGENCY
UNITED STATES OF AMERICA

Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety

DURC studies raise important ethical and safety considerations for the EVA GLOBAL consortium. Some examples of DURC include Gain of Function (GoF) and Loss of Function (LoF) experiments, both valuable methodologies enabling researchers to have a deeper understanding of how pathogens function by adding or removing a desired function. The latter inherently less risky than the former. A recent study[1] showed that pathogens used in GoF and LoF experiments spanned the four biosafety levels (BSLs) and that they frequently co-occurred in the same studies, with LoF studies appearing in more publications than GoF studies.

Dual-use risks can also appear in other types of experiments and some research fields might be more prone to dual-use risks than others. In 2021, the World Health Organization (WHO) conducted a study[2] which aimed at proactively identifying dual-use research of concern research areas. The study proposed a list of fifteen priority areas that could become high risk for dual-use over different timeframes. For example, within the next 5 years, technological risks such as cloud laboratories and synthetic genomic

platforms pose a risk by allowing access to data and information, without the physical access to the laboratory itself or to tangible material. Another example, laboratory research that focuses on diseases of concern and large societal impact, like SARS-CoV-2, might provide knowledge on immune evasion strategies or infectivity that could pose serious dual-use risk applications. Areas predicted to pose a higher risk in 10 years are related to technological advances such as computational approaches and deep learning algorithms that might not require laboratory work. The identified list is not exhaustive but it gives an overview of research areas where results can be potentially misused.

Therefore, for scientists working with (highly) pathogenic microorganisms, biosecurity, biosafety and bioethics concerns need to be anticipated and considered before undertaking any practical work (**Figure 3**). Biosafety covers principles of containment, technologies or measures that can be implemented at institutions to prevent intentional and unintentional release or access to material. Biosecurity covers principles, technologies or measures that can be implemented at institutions for the protection, control and accountability of biological material, data, equipment, technology and information related to the handling of those resources. Biosecurity measures aim at preventing the unauthorized access or release of those resources. Bioethics covers aspects regarding ethical considerations and international standards and legislation around dual-use research. An overarching principle of bioethics is "do no harm – accidentally or on purpose"; there is a moral obligation to limit any possibility of causing harm, either through lack of foresight or intentionally.

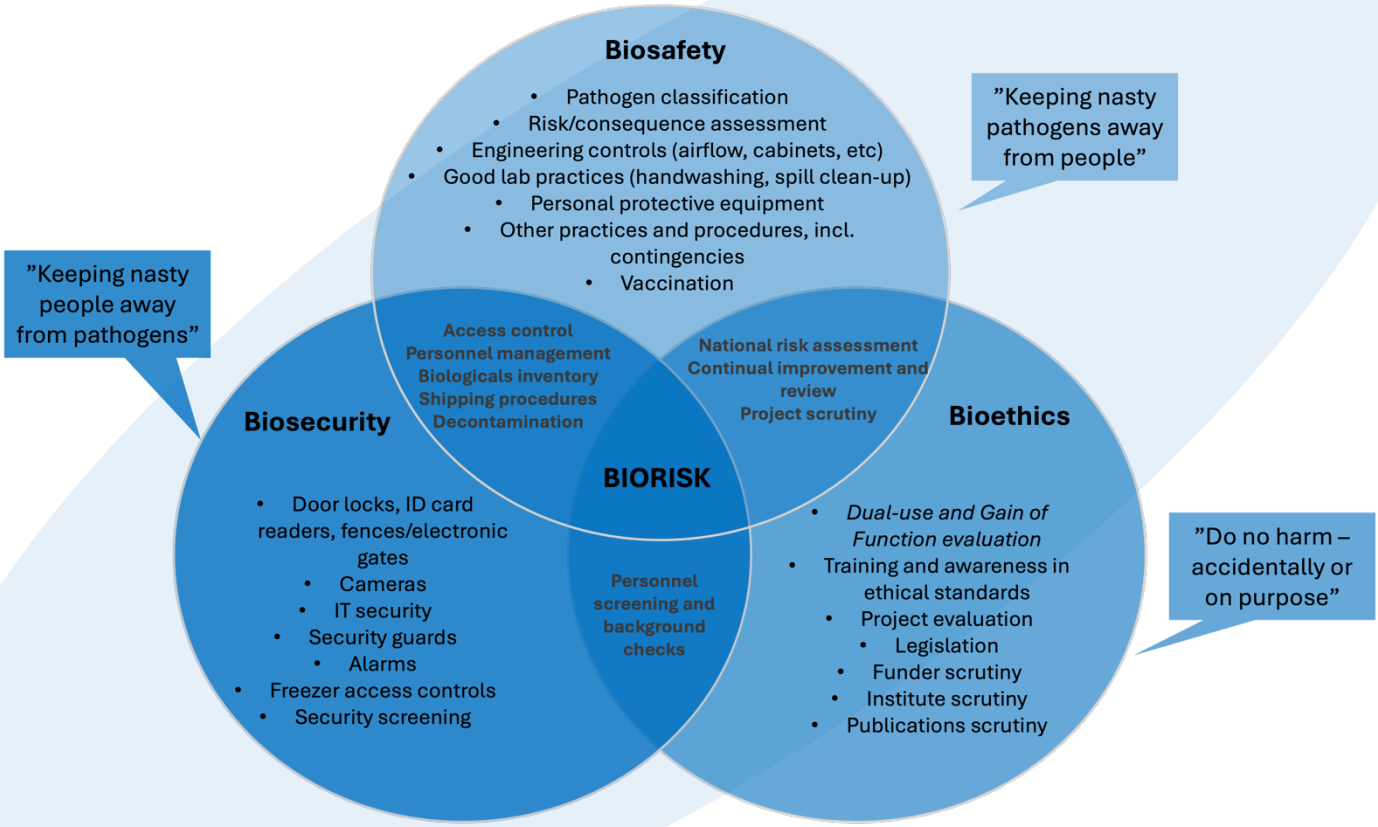


***Figure 3**. Biorisk map of biosafety, biosecurity and bioethics aspects with points of commonality and singularity.*

Most of the research by the EVA consortium uses tangible material (e.g. pathogens and their derivatives) to address human, animal and health research questions. It is relatively clear how such material could be misused (e.g. through deliberate release). However, dual-use risks can also arise from non-tangible material, the new knowledge and technologies that are generated, as exemplified in Case Study 1[3].

CASE STUDY 1

Dual-use risks from non-tangible material results.
Researchers from a pharmaceutical company developed an artificial intelligence system for virtual drug discovery. The developed machine learning model (MLM) looked for compounds with increased target activity, searched for new molecules with low toxicity, generated de novo libraries of compounds and predicted whether the identified compounds could be synthesised easily. Although the MLM was originally intended to search for harmless molecules, when tested to search for biotoxins the machine was able to find over 40,000 putative highly toxic molecules in less than 6 hours. The creators of the programme did not foresee these consequences and risks.

At the moment, there is little to no consensus internationally regarding appropriate policies to best address dual-use risks and the dissemination of life sciences research that might qualify as dual-use research. Nevertheless, we provide a list of useful (and most recent) reading recommendations, as detailed below.

The WHO Global guidance framework for the responsible use of the life sciences[4], published in 2022, is a framework that aims to provide values and principles, tools and mechanisms to support member states and key stakeholders to mitigate and prevent biorisks. It is broad in scope but has interesting chapters for researchers and institutions. Values and principles are classified into nine categories to considered ethical judgements to support the development and implementation of effective mechanisms for biorisk management. Different stakeholders are also identified and defined as well as overarching goals, such as reducing accidents, or reducing opportunities for malicious misuse. It also explains how the framework should be put in action with a 6-step approach for implementing and developing biorisk management activities. It also provides a checklist of the various stakeholders with relevant questions to address. The document can be used in complement with the more practical WHO Laboratory biosafety manual[5] published in 2020 and the WHO Laboratory biosecurity manual[6] published in 2024. Both documents aim to improve management of biorisks and prevention of incidents and were developed in consultation with experts in the relevant fields.

WOAH Guidelines for responsible conduct in veterinary research[7], published in 2019, provides guidelines for identifying, assessing and managing dual-use in veterinary research activities. It provides various case studies with dual-use risks in the veterinary field and a roadmap for a risk assessment process, with a responsible conduct section highlighting how each stakeholder can address dual-use.

The Biorisk Management System – ISO 35001:2019[8] is an ISO norm regarding biorisk management for laboratories. It describes what is required to establish an operational biosecurity management system. This international norm is applicable to any laboratory or organization that works with, stores, transports, and/or disposes of hazardous biological materials. It can be complemented with the newly published Competence Requirements for Biorisk Management Advisors ISO/TS 5441:2024[9] that defines the requirements for competence of individuals who provide guidance and advice associated with hazardous biological materials in laboratory or related organizations. Both documents define a process to identify, assess, control and monitor the risks associated with hazardous biological materials and describe how to achieve this within an organization.

The International experts group of biosafety and biosecurity regulators (IEGBBR)[10] mobile app provides an overview of biosafety, biosecurity and dual-use frameworks and legislations from the 11 national government authorities that comprise the group (i.e. Australia, Canada, Denmark, France, Germany, Japan, The Netherlands, Singapore, Switzerland, United Kingdom and United States), with WHO and WOAH participating as non-member observers. The group was created in 2007 under the leadership of the Public Health Agency of Canada. The app is composed of two modules: 1) a comprehensive collection of international biosafety and biosecurity oversight systems for human and animal pathogens and toxins and 2) a review of oversight of dual-use in life sciences in the 11 countries. This reference tool can be used by countries or relevant stakeholders that want to strengthen their capacities in regards to biosafety, biosecurity and dual-use oversight.

The Biosecurity Central[11] website provides a collection of available tools and training material for biosafety, biosecurity and dual-use resources. This is a useful website to access material to develop institutional policies and to enhance awareness about biosafety and biosecurity issues.

The US Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential[12] are guidelines published in 2024 for US federally funded life sciences research on biological agents and toxins. This policy is relevant for researchers working abroad with federal US financed projects as they are required to abide by these guidelines. An Implementation Guidance[13] document is also available to complement the policy document, with further clarifications and explanations.

IDENTIFICATION OF STAKEHOLDERS

One of the first steps is to identify relevant stakeholders and their responsibilities. We have identified five main stakeholders in the DURC strategy cycle relevant for EVA GLOBAL and its partners.

Some stakeholders might belong to the same sector (e.g. researchers and institutions in the academic sector) while others will be in different sectors (e.g. funding and publishing bodies, policy makers and general public). It is therefore important to keep in mind that stakeholders will have different views, risk perceptions, interests and knowledge when assessing dual-use risks. For example, a research team working during an outbreak of a previously unknown disease can be portrayed in the media as being irresponsible, if data coming out of the research activities can be misused. Such research is, however, likely to be necessary to understand pathogenic transmission, how mutations might enhance or decrease pathogenicity, develop an urgently-needed vaccine, etc. Clear communication and dialogue between relevant stakeholders is crucial to find cohesive solutions and ensure risks have been considered to address the concerns of the different groups while at the same time informing the other stakeholders why those measures or considerations are relevant.

Researchers

- **Need to take personal responsibility for their research!**
- Need to think about the benefits, risks and dual-use implications, at all stages of their research, as they are the main undertaker of the practical work.
- If dual-use concerns are identified, they need to address them with peers, institutional regulatory boards and/or independent qualified professionals for better ethical assessment.
- Researchers at all levels, including principal investigators, research collaborators, biorisk and biosafety officers, and all other relevant players, need to engage to consider dual use implications.

Institutions

- Have a responsibility to provide support to their researchers through institutional bioethics committees, security advisory groups, biosafety/biorisk management teams, etc.
- Training opportunities and material should be made available for staff and new hires, to help them understand dual-use potential risks, and to provide them with tools to assess their projects properly.
- Institutions also need to establish processes that researchers can refer to when they have identified dual-use risks in a particular research project.

Funding bodies

- Funding of research can be from national and/or international agencies and from public and/or private funds
- Have a responsibility to conduct formal assessment of submitted research proposals and to request further information from projects with identified potential dual-use risks.
- If submitters do not propose mitigation measures, the inherent risk of proposals should be evaluated thoroughly before funding the project is considered.

Publishing bodies

- Have a responsibility to follow-up and inquire with any submitting authors that have declared dual-use risks or components associated with the results they wish to publish.
- Journals should have dual-use research experts on editorial staff/editorial board and as part of the peer-review processes to properly address concerns.
- Expert reviewers could evaluate all research projects, even those that have no declared dual-use aspects but that might still pose dual-use risks.

Policy makers

- Need to develop legislation, when appropriate.
- With the quick pace of scientific advancement, regulators, both at national and international level, need to make sure legislation is not obsolete by the time of enforcement and thus must be advised by practitioners to have a clear direction of travel.

IDENTIFICATION OF RISKS

Once stakeholders are made aware of their responsibilities, they are informed and better equipped to identify dual-use risks in their respective areas. Identifying dual-use risks requires a continuous evaluation of the research project and is best assessed by those conducting the practical research themselves. Researchers are aware of the expected results from their projects and can best identify unexpected outcomes that could pose a dual-use threat.

The identification of dual-use risks goes back to a list of experiments and toxic agents listed in a US report of the National Research Council in 2003 (also known as the Fink Report[14], **Box 2**). This influenced the formulation of many codes of conduct including the Tianjin guidelines[15] and various lists and definitions. None, however, will be all-encompassing and allow for the identification of dual-use risks in all research projects, but the following resources could help narrow down areas and agents of potential risk and could be used as a baseline.

Box 2. Fink report with a list of experiments and toxic agents considered of dual-use.

7 Experiments

1. Enhance the harmful consequences of the agent or toxin?
2. Disrupt immunity or the effectiveness of an immunization against the agent or toxin?
3. Confer to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies?
4. Increase the stability, transmissibility, or ability to disseminate the agent or toxin?
5. Alter the host range or tropism of the agent or toxin?
6. Enhance the susceptibility of a host population to the agent or toxin?
7. Generate or reconstitute an eradicated or extinct agent or toxin or will synthetic biology techniques be used to construct a pathogen, toxin, or potentially harmful product?

15 Agents and Toxins

1. Avian influenza virus (highly pathogenic)
2. *Bacillus anthracis*
3. Botulinum neurotoxin (For purposes of this Policy, there are no exempt quantities of botulinum neurotoxin. Research involving any quantity of botulinum neurotoxin should be evaluated for DURC potential.)
4. *Burkholderia mallei*
5. *Burkholderia pseudomallei*
6. Ebola virus
7. Foot-and-mouth disease virus
8. *Francisella tularensis*
9. Marburg virus
10. Reconstructed 1918 Influenza virus
11. Rinderpest virus
12. Toxin-producing strains of Clostridium botulinum
13. Variola major virus
14. Variola minor virus
15. *Yersinia pestis*

The Australia Group[16] is an informal group of 42 countries[17], including the European Union, established in 1985 that seek to ensure export controls measures to prevent the development of chemical and biological weapons. They provide a list[18] of human, animal and plant pathogens, as well as toxins that fall under export control measures.

The Netherlands Biosecurity Office[19] as part of the National Institute for Public Health and the Environment (RIVM), and a valuable EVA partner, has put together a comprehensive list[20] of human, animal and plant pathogens. The list provides biosafety and biosecurity classifications according to national (Dutch) legislation, the EU dual-use regulation, and the Australia group.

Similar lists are also available from other countries, including the approved list of biological agents[21] from the UK's Advisory Committee on Dangerous Pathogens.
EVA members in the European Union are subject to the export controls established under the EU dual-use regulation (EU) 2021/821[22], to be read with the Commission Recommendation (EU) 2021/1700[23]. It is important to note that in this context, "dual use" is used in a much broader sense, as it refers to any item including software and technology, even an email, which can be used for both civil and military purposes. It includes items that can be used for the design, development, production or use of nuclear, chemical or biological weapons, or their means of delivery. The regulation includes a list that consists of dual-use goods, with 10 categories, among which in category 1 are: materials, chemicals, microorganisms and toxins (e.g. human and animal pathogens and toxins, genetic elements and genetically modified organisms). As a consequence, it overlaps with the more restricted use of the term we apply elsewhere in this document when referring to research with viruses and virus-derived materials. The regulation establishes a EU regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items. **The export of dual-use goods to countries outside the EU requires a license.** There are also some exemptions such as for information that is already in the public domain, and for basic scientific research, or the minimum necessary information for patent applications. Basic research is defined as experimental or theoretical work undertaken principally to acquire new knowledge of the fundamental principles of phenomena or observable facts, not primarily directed towards a specific practical aim or objective.

ASSESSMENT OF RISKS

Risk assessment should be conducted throughout the research lifecycle and needs to consider both intentional and unintentional misuse of research outcomes. Another aspect to consider is the possible ecological, economical and societal consequences of the misuse of either knowledge/technology or materials. One way to assess risks in a research project is to use the Dual-Use Quickscan[24], a tool developed by The Netherlands Biosecurity Office that aims at to enhance awareness about DURC among researchers and help them screen their research projects for potential dual-use aspects. It is an open access tool composed of 15 questions divided into 3 themes (i.e. biological agent information, knowledge and technology about the biological agent and consequences of misuse). Questions were created by reviewing available literature from various national and international fora. Examples and clarifications are provided for the user. It is an anonymous online questionnaire that provides a PDF overview of the results once completed. The survey should be filled out by those conducting laboratory research activities and working with parts or products of, or knowledge about microorganisms. The tool should be used regularly in coordination with the biorisk management advisor and depending on the nature of the research and/or previous dual-use assessments. The results of the survey will only reflect the current situation but throughout the research lifecycle this could change depending on the outcomes.

MITIGATION MEASURES

Research projects with identified dual-use risks do not necessarily need to be stopped immediately. They have to be assessed individually and evaluated to see if those risks can be mitigated through biosafety or biosecurity programmes. Mitigation strategies should be commensurate with the level of risk and include physical, operational and security measures that should be implemented, monitored and enforced by the individual organization. Some examples of risk mitigation measures could be: using a less virulent strain or an attenuated virus, alternative model systems or restricting the sharing of specific information and results that could be misused. An example is given in Case Study 2. In some instances, however, research projects with identified dual-use risks might still be conducted if the outcomes they are expected to provide will have significant societal, ecological and economic implications, such as Case Study 3.

CASE STUDY 2

Project that required mitigation measures

A post-doctoral scientist wanted to conduct GoF experiments with an avirulent Ebola virus strain as part of a study investigating molecular determinants of virulence. The scientist designed GoF experiments on forecasted, but not validated, LoF experiments. The project was flagged as having potential DURC implications and was reviewed by the institutional DURC committee. After careful consideration and thorough discussions between the researcher and DURC committee, the committee proposed that LoF experiments be conducted first, to validate predicted outcomes, before any GoF experiments be conducted. Close collaboration between the different stakeholders (i.e. biorisk expert, project partners, facility leadership and researcher) was needed to assess, address and find mitigation measures to the proposed project. Only having predicted LoF results did not justify the execution of GoF experiments as the uncertainty of dual-use risks was too high.

CASE STUDY 3

Approved project despite identified dual-use risks

A research proposal was submitted to investigate whether a naturally occurring low pathogenic strain of avian influenza had the potential of becoming highly pathogenic. The researcher proposed experiments using theoretical methods that would drive the strain to mutate towards a highly pathogenic phenotype under specific conditions. The results would provide information on the combination of mutations required to convert the low pathogenic strain into a highly pathogenic version and whether these combinations could occur naturally. Although the experiments contained dual-use risk components, the potential societal, economic and environmental benefits of these results were found justifiable to move forwards with the project. The results from such experiments would provide data to biosecurity decision makers in the region on how to prepare and respond to circulating avian influenza strains and the development of more informed predictive measures.

REVIEW

The responsibility for the identification, assessment and management of dual-use risks rests with the relevant stakeholders and reflects their individual areas of expertise. We have superimposed each stakeholder, in what we believe, are each of the steps in the DURC strategy cycle where their input is needed (**Figure 4**). For example, for DURC awareness, all stakeholders need to have a basic understanding of dual-use risks, what it means and what it entails. Whereas for the identification and assessment of dual-use risks, researchers and their institutions are the main stakeholders, as they are the ones conducting and supporting the research. On the other hand, a review of appropriate mitigation measures requires collaboration and integration of views and risk perceptions from all stakeholders as efforts to mitigate dual-use risks can be best addressed and considered in a more comprehensive approach. Dual-use risks can arise at any time of the research lifecycle, even when they are not expected! Therefore, a continuous assessment of research projects and review of applicable mitigation measures is necessary and a fundamental element of good scientific practice.

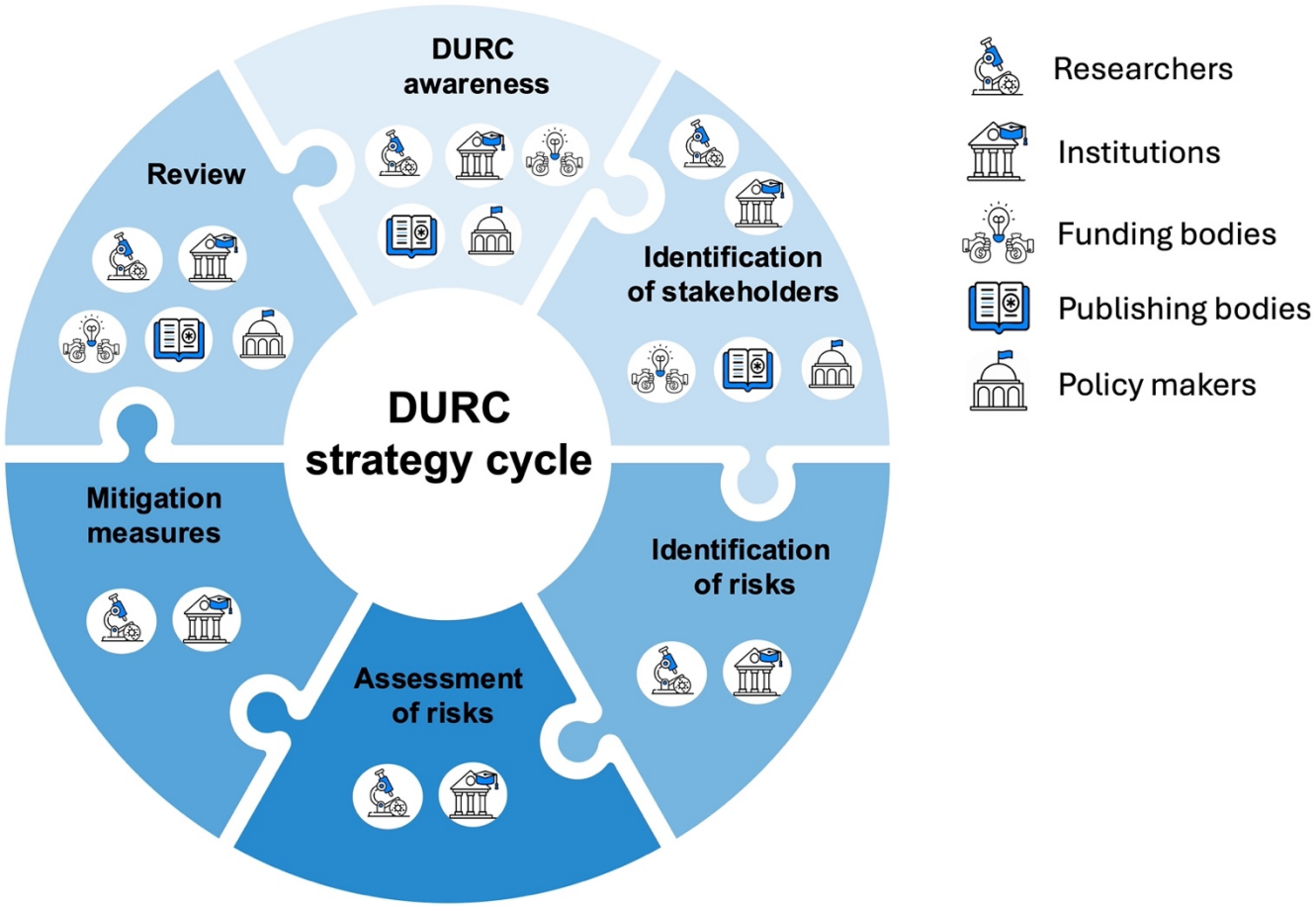


Figure 4. Modified Figure 2 with relevant stakeholders superimposed in each of the DURC strategy cycle steps.

CONCLUSIONS

Work conducted by the EVA GLOBAL consortium partners not infrequently raises the dichotomy of dual-use research. On the one hand, biological material and technologies are used to produce new scientific knowledge for the benefit of humanity and advancement of science (e.g. development of better vaccines, diagnostic kits, to understand evolution and metabolic process of harmful organisms, etc) but, on the other, pose a high potential for misuse and potentially a serious risk to human, animal and plant health and the environment. Pathogens can be used potentially as bio-weapons targeting human health or used in agroterrorism (with plant and animal pathogens). Research with high risk pathogens can therefore attract media attention and public scrutiny.'

Due to technological advances, there is a risk that dual-use research will become accessible to malicious state or non-state actors, while rapid sharing of information due to open access of data and the changing nature of scientific publication mean that dual-use information is becoming more and more broadly disseminated. Technologies that use artificial intelligence and machine learning models, as exemplified by Case Study 1, were expected to pose a risk in 5-10 years from now, but are already provoking serious concerns. There is a collective responsibility to ensure that today's sensationalist warnings of future biological catastrophes never come to pass.

This document is intended to raise awareness about dual-use research, how to identify and assess dual-use risks and ways to mitigate those risks. By no means should the identification of potential dual-use risks discourage researchers from conducting their science, as long as the risks are acceptable and adequate mitigation efforts are made. Instead, we aim to provide researchers and their institutions with links to tools and resources on how to assess those risks and find suitable corrective measures. Infectious diseeases will always represent a major threat to humanity. By enhancing awareness and providing tools and resources, we encourage our community to conduct safe, secure and responsible research, taking into consideration potential risks and thereby contribute to everyone's future well-being.

CHECKLIST for researchers

- The use of this checklist should be **in combination** with the introduction package.
- You can use this checklist before submitting your project proposal for funding or once you have obtained funding and you think the project might have dual-use risks. This checklist should help you think of potential dual-use aspects in your work.
- A research project with identified dual-use risks does not automatically have to be stopped or canceled. However, it will require a thorough assessment and implementation of adequate mitigation measures.

HAVE YOU READ THE INTRODUCTION SECTION?
The introduction package is intended to provide you with basic knowledge on dual-use research of concern.

USING BIOLOGICAL MATERIAL FOR YOUR RESEARCH?
Here is a comprehensive, but not exhaustive, list[20] of animal, human and plant material that might be regulated for dual-use purposes under various frameworks. ***But remember: your project might still have dual-use risks even if the material does not appear on a list!***

DUAL-USE QUICK SCAN
This tool[24] aims to help you assess DURC aspects in your project. The survey is composed of 15 questions divided into 3 themes: 1-11 deal with the agent itself, 12 with knowledge and technologies and 13-15 with the ecological, economical and societal consequences of use of that biological agent. Answers are yes/no/unknown and each question comes with definitions and clarifications to ensure the questions are clear, as well as literature examples. Once the survey is filled out, one gets a PDF with the overview. Make sure to share the results with your collaborators and/or your biosafety/biosecurity officer!

OBLIGATIONS UNDER INTERNATIONAL FRAMEWORKS
If you are receiving national or international funding to conduct your research, you should abide by the rules of the country/regions providing the funds. If your research is funded from abroad, you might have to consider both your in-country obligations as well as those by those of the international funder.

If you are in the ***European Union*** *you need to consider export controls under the EU dual-use regulation (EU) 2021/821[22], look at Annex I sections 1C351-1C354.*

If you are from one of the following non-EU countries[17], you need to consider export controls under the Australia Group[16], which also includes technologies and equipment.

If you are receiving federal funding from the ***United States*** *for your project (even if you are not conducting the research in the US!) you need to abide by US laws on dual-use[12,13].*

READY TO PUBLISH YOUR RESULTS?
A statement should be considered when publishing any reseach data using material from the EVA catalogue.

CHECKLIST for institutions

- The use of this document should be **in combination** with the **introduction package and completed researcher`s checklist.**
- This document was created for research institutions to support their researchers in identifying, assessing, and mitigating dual-use risks in their research projects.
- Institutions are still responsible to support their researchers and provide them with information and guidance on how to abide by international frameworks and national regulations.

HAVE YOU AND YOUR RESEARCHER READ THE INTRODUCTION SECTION?
The introduction package is intended to provide you with basic knowledge on dual-use research of concern.

DID YOUR RESEARCHER PROVIDED YOU WITH THEIR COMPLETED "CHECKLIST FOR RESEARCHERS"?
If yes, do you have any follow-up questions, comments or concerns with their answers?

OBLIGATIONS UNDER INTERNATIONAL FRAMEWORKS
If you are receiving national or international funding to conduct your research, you should abide by the rules of the country/regions providing the funds. If your research is funded from abroad, you might have to consider both your in-country obligations as well as those of the international funder.

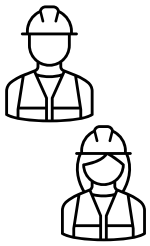
*If you are in the **European Union** you need to consider export controls under the EU dual-use regulation (EU) 2021/821[22], refer at Annex I sections 1C351-1C354.*

If you are from one of the following non-EU countries[17], you need to consider export controls under the Australia Group[16], which also includes technologies and equipment.

*If you are receiving federal funding from the **United States** for your project (even if you are not conducting the research in the US!) you need to abide by US laws on dual-use[12,13].*

DID YOUR RESEARCHER PROVIDE YOU WITH THE RESULTS OF THEIR DUAL-USE QUICK SCAN SURVEY?
The tool[24] is to be used to assess whether research projects have dual-use risks. If the majority of answers is "yes", then most likely the project has dual-use components. If it is a combination of "yes" and "unknown" answers, further discussion will be needed to clarify the project's potential dual-use risk. If all questions are answered with "no", then most likely the project does not have dual-use aspects nor implications. However, answers should be reviewed and verified by the relevant institutional body.

If DURC risks have been identified the institution needs to make sure their researchers have the resources to conduct their projects in a safe, secure and responsible way. Here we suggest a few documents on how to conduct research in an environment that considers high levels of biosafety and biosecurity.



The WHO Laboratory biosafety manual[5] published in 2020 uses a risk-and-evidence based approach to biosafety to ensure not only facilities but also work practices are relevant, proportionate and sustainable with aFigure strong emphasis on "safety culture".

The WHO Laboratory biosecurity manual[6] published in 2024 provides a more practical approach by proposing principles and measures to prevent incidents. It provides a template for institutions to assess risks and a customizable emergency response matrix in case of emergencies.

The Biorisk Management System – ISO 35001[8] is a biorisk management isonorm for laboratories. It describes requirements to establish an operational biosecurity management system and defines a process to identify, assess, control and monitor the risks associated with hazardous biological materials. This international norm is applicable to any laboratory or other organization that works with, stores, transports, and/or disposes of hazardous biological materials.

Have you provided/discussed with the researcher options for alternative methodologies?

Are mitigation measures commensurate with the initial levels of risk?

Are there any safety concerns for the staff at the Institution?

Are there any biocontainment concerns throughout all stages of the project?

Does the benefit of the work outweigh the risks?
This question needs to be discussed thoroughly with your researcher.

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