



## Dual use potential of life sciences research

Code of conduct for risk assessment and risk mitigation

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- 1 Introduction
- 2 Basic principles
- 3 Criteria for assessing the dual use potential of research projects and their results
- 4 Evaluation of research projects regarding their dual use potential
- 5 Developing awareness of the dual use problem

### 1 Introduction

Research and development in the life sciences have crucially contributed to today's progress and improvement of living conditions. At the same time, findings in the life sciences often run the risk of being misused to the detriment of society and environment. This "double applicability" of scientific findings is described as the "dual use dilemma".

The potential for misuse of scientific findings is especially obvious for research on pathogenic microorganisms and toxins: on the one hand, research results regarding transmissibility, pathogenesis and genomics of pathogenic biological agents are indispensable to prevent the agents' spread and proliferation and to enable or improve the treatment of infection and exposure to toxins. On the other hand, these results can also potentially be misused to cause harm to humans, animals or plants.

It is therefore necessary for institutions dealing with pathogens and toxins – such as the Robert Koch Institute (RKI) – to establish a code of conduct which

- on the one hand, preserves freedom of research that benefits society and
- on the other hand, prevents the distribution of information and research results that could harm society and the environment.

### 2 Basic principles

At the RKI, the code of conduct to prevent or rather minimize dual use risks follows these principles:

- Progress in medicine and health protection is impossible without the life sciences. Therefore, it is inherently necessary to conduct research – particularly in the field of pathogenic and highly pathogenic agents and toxins – and to publish the results.
- Research projects must be reviewed with regard to their potential for misuse.
- Any potential for misuse of a research project will be minimized as far as possible by responsible design and execution of the project as well as by application of a responsible publication policy. In doing so, one must balance the necessity to do research with safety/security requirements.
- Research results will be published only if the potential benefit of the disclosed information surpasses the risks involved.
- The scientist/work-group leader in charge (hereafter: project leader) is primarily responsible for his/her research project. It is his/her responsibility to acquire the knowledge necessary to assess his/her research work and to monitor the current relevant publications. He/she must heighten the awareness of his/her staff accordingly and provide further training. In addition, the heads of units and departments are also responsible together with the RKI itself as the institution with overall responsibility.
- This responsibility forms the basis for effectively preventing or minimizing potential risks, not least by preserving and reinforcing the confidence that the public has in the RKI as a public health research institute.

- It is essential that all scientists and the entire RKI explore the dual use dilemma as well as develop awareness of the problem. The dual use topic must therefore be included in ongoing education seminars and the further qualification of scientists.

### 3 Criteria for assessing the dual use potential of research projects and their results

Findings and research results in the field of life sciences harbor the potential - to varying degrees - of being misused. The context and misapplication however, is difficult to predict.

In particular, research activities have a dual use potential, when their results, products or technologies, according to the current state of the art, can be applied directly by third parties who aim to endanger public order, public health or the environment.

Usually these involve research activities that demonstrate ways or provide products or technologies

- to achieve transmissibility of microorganisms or to enhance their infectiousness,
- to increase the virulence of microorganisms or toxins,
- to increase the tenacity of microorganisms or toxins,
- to facilitate the intake of toxins,
- to promote or induce the resistance of microorganisms towards therapeutic or prophylactic antimicrobial or antiviral substances,
- to enhance the capacity for spreading or for easy release or making them "weapons-grade",
- to weaken the response of the immune system against microorganisms,
- to alter the host tropism of a microorganism or a toxin,
- to increase the susceptibility of host organisms,
- to generate entirely novel pathogens or to recreate pathogens that had previously disappeared or had been repressed (eradicated/eliminated/controlled/vanished naturally),
- to alter the absorptive characteristics of a biological agent or the toxicokinetics in a manner that enhances their effect,
- to reveal methods to lower the effectiveness of medical countermeasures (vaccinations, therapeutic and prophylactic means),
- to hinder or prevent diagnostic procedures

This rule of procedure and of conduct also applies to those research projects and their results that suggest similar implications and consequences as those listed above.

In addition, the generation and storage of infectious or toxic materials in quantities considerably exceeding those necessary for conducting the proposed project or for maintaining a collection of reference stocks will be avoided. In this respect, all legal requirements and in-house provisions of the RKI must be observed.

## 4 Evaluation of research projects regarding their dual use potential

### 4.1 Timepoints of evaluation

Every research project, including those for which no formal application is made, and any collaboration, is reviewed for its dual use potential at the following time points:

- in the planning stages (e.g. when applying for the project),
- throughout the course of the project (usually before starting a new phase in the project and when interpreting the results), particularly in the case of unexpected or critical results (see criteria under section 3.),
- prior to utilization of results, i.e. usually prior to publication.

Contributions from collaborating partners as well as the transfer of results and products to partners have to be included in the assessment. "Publication" can also mean the presentation of preliminary results and, when applicable, funding proposals. The presentation of preliminary results (e.g. talks, posters) of those projects is not required if the initial assessment has found no dual use potential and if there are no suggestions that this assessment is likely to be altered.

## 4.2 Risk assessment and risk management

1. When planning a research project the project leader (or the collaborating RKI scientist in case of collaborative projects) has to complete a checklist containing criteria for assessing dual use potential, and must include this list with the planning documents. In cases where there are no indications of dual use potential, the project leader states this conclusion with his/her signature and presents the checklist to his/her immediate superior (four-eyes principle) for his/her information. By doing so, the review is completed for the time being. Exempt from this rule are (1) a reassessment in the case that unexpected critical results emerge and (2) the final assessment prior to publication.
2. If any criterion from the list of dual use criteria is met, the project leader has to perform and document a risk/benefit analysis with regards to dual use potential.
3. During the risk/benefit analysis of dual use potential the weighing of the possible risks against the potential benefit has to be carried out and presented by the project leader. If necessary, appropriate action must be taken to ensure that the risk of misuse is minimized. If this is impossible and the possible benefits do not outweigh the possible harm, the research project will not be carried out at the RKI.
4. Otherwise the project documents together with the risk/benefit analysis and, where appropriate, the proposals for avoiding or minimizing a dual use risk have to be submitted to his/her immediate superior for decision. If the superior does not agree to the project, it will not be pursued any further.
5. If the immediate superior does agree to the project, the case file including the dual use risk/benefit analysis (and, if necessary, suggestions for risk minimization) will be presented through official channels to the head of the institute for decision.
6. In case that the head of the institute requests a consultation prior to the final decision, the head of research coordination is requested to obtain a dual use risk/benefit analysis of the proposed project in writing from three in-house experts. The head of research coordination prepares a compilation of the statements, gives a recommendation and submits it again, together with the statements obtained, to the head of the institute for decision.
7. If preliminary results of the research project indicate a possibly higher dual use potential than expected from the original dual use risk/benefit analysis, the project must be reassessed (see 1–6).
8. Upon conclusion of the research project the actual results must again be assessed with regard to their dual use potential. If the level of risk is perceived to be higher than that stated in previous dual use risk/benefit analyses, the head of the institute must be informed through official channels to allow a decision to be made regarding utilization of the results/data.
9. The intent to submit announcement for the respective manuscript, when submitted to the head of the RKI, must be accompanied by documentary evidence that an assessment with regard to possible dual use risks was performed for the research project, along with the results of this assessment.
10. Those departments which, for the time being, are exempt from having to assess the dual use potential of projects via the evaluation forms (i.e. Departments 2 and 3) are also required to assess and report projects with such a potential, following the above-mentioned criteria.

## 5 Developing awareness of the dual use problem

Sensitizing RKI members with regard to the dual use potential will take place on three levels by conducting further training.

1. A one-day seminar for scientists which will be offered several times a year. This seminar will be designed to provide applicants with such tools and guidance to help make proper decisions and enable them to assess the dual use potential of their research.
2. Provision of an online self-study tool that every scientist is obliged to work through. Evidence of this will be filed with the head of the unit.
3. One in-house seminar will be conducted each year to address the dual use topic in order to sensitize all members of RKI to the subject.

Further training will also cover the applicable laws and guidelines that all scientists are required to be familiar with and to observe (i.e. the Protection Against Infection Act, the Occupational Safety and Health Act, the Biological Agents Ordinance, the Act on Genetic Engineering, the Genetic Engineering Safety Regulations, the Council Regulation [EC] No 428/2009 of 5 May 2009 setting up a community regime for the control of exports, transfer, brokering and transit of dual use items, the so-called dual use regulation). There is a guideline for risk assessment and management of a research project with dual use potential in Appendix 4, and a guideline for risk/benefit analysis of publishing research results with dual use potential in Appendix 5 of the

article “Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information” of the “National Science Advisory Board for Biosecurity” of the United States of America. We emphasize the relevance of the Guidelines for Safeguarding Good Scientific Practice.

## Further information

- RKI Guidelines for Safeguarding Good Scientific Practice (in German)

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