

**RULES AND REGULATIONS ON THE REPORTING OF VIOLATIONS  
AND FOLLOWING-UP ON SUCH REPORTS IN THE MEDICAL RESEARCH AGENCY  
(MRA)**

**Chapter 1**

**General Principles**

**§ 1**

1. These Rules and Regulations on the Reporting of Violations and Following-up on Such Reports in the Medical Research Agency (hereinafter: the Rules and Regulations) set out:
  - 1) the rules and procedures for the reporting of Violations by Whistleblowers within the framework of Internal Reports and External Reports;
  - 2) entities competent for receiving Internal Reports and taking Follow-up Actions;
  - 3) Follow-up Actions taken on Internal Reports received;
  - 4) rules for keeping the Register of Internal Reports;
  - 5) rules and measures to protect Whistleblowers.
2. Whenever the Rules and Regulations refer to:
  - 1) Agency – this shall be understood to mean the Medical Research Agency (MRA);
  - 2) Directive – this shall be understood to mean Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law;
  - 3) Follow-up Actions – shall be understood to mean the actions taken by the Agency to assess the veracity of the information contained in an Internal Report, and to counteract the Violation that is the subject of the Internal Report;
  - 4) Retaliatory Action – this shall be understood to mean a direct or indirect act or omission that is caused by an Internal Report, External Report or Public Disclosure and that violates or is likely to violate the rights of the Whistleblower, or causes or is likely to cause harm to the Whistleblower, including the unwarranted initiation of proceedings against the Whistleblower;
  - 5) Work-Related Context – this shall be understood to mean past, present, or future activities related to the performance of work under an employment or other legal relationship underlying the provision of work or services, or the performance of functions in or for the Agency, in the course of which information has been obtained of the Violation and the possibility of retaliation exists;
  - 6) Violation – this shall be understood to mean an act or omission contrary to the law, internal regulations or ethical standards applicable to the Agency, or an act or omission intended to circumvent those regulations, standards or the law;

- 7) Public Authority – this shall be understood to mean the chief and central government administration bodies, field government administration bodies, bodies of local government units, other state bodies and other entities performing, by law, tasks in the field of public administration, competent to undertake Follow-up Actions in the areas indicated in Article 3(1) of the Act;
  - 8) Employee Processing the Report – this shall be understood to mean the Report Officer, Data Protection Officer, Anti-Fraud Officer, Information Security Management System (ISMS) Officer appointed by the President of the Agency, or the Report Investigation Committee taking Follow-up Actions;
  - 9) President of the Agency – this shall be understood to mean the President of the Agency or a person authorised by the President;
  - 10) Register of Internal Reports – this shall be understood to mean the register kept by the Agency of Internal Reports received;
  - 11) Whistleblower – this shall be understood to mean an individual submitting an Internal Report, External Report or Public Disclosure in a Work-Related Context within the meaning of Article 4 of the Act, as well as an applicant or beneficiary in competitions organised by the Agency, and other individuals who may influence the Agency's activities or who may be influenced by the Agency's activities;
  - 12) Public Disclosure – this shall be understood to mean disclosing the information about the Violation of the law to the public;
  - 13) Act – the Act of 14 June 2024 on the protection of whistleblowers;
  - 14) Internal Report – this shall be understood to mean an oral or written communication by the Whistleblower to the Agency of information, including reasonable suspicion, concerning an actual or potential Violation that has occurred or is likely to occur at the Agency or concerning an attempt to conceal a Violation;
  - 15) External Report – this shall be understood to mean an oral or written communication by the Whistleblower, to the Ombudsman or a Public Authority, of a Violation of the law.
3. In matters not covered by the Rules and Regulations, the provisions of the Act and the Directive shall apply.

## **§ 2**

1. In the manner set out in the Rules and Regulations, the Whistleblower may submit an Internal Report concerning, in particular:
  - 1) public procurement;
  - 2) privacy and data protection;
  - 3) security of communication and information networks or systems and security of information;

- 4) suspected irregularities or adverse actions in competitions organised by the Agency or projects funded by the Agency;
  - 5) incidents of a corrupt nature;
  - 6) the occurrence of a risk to life, health, occupational health and safety, or the environment;
  - 7) suspected irregularities or adverse actions in the implementation of the National Recovery and Resilience Plan (RRP);
  - 8) incidents of workplace bullying or discrimination, including harassment or sexual harassment;
  - 9) the occurrence of conflicts of interest;
  - 10) Work Rules and Regulations;
  - 11) Code of Ethics.
2. In the event that the Employee Processing the Report receives a case that does not constitute a Violation, it shall be handled in accordance with the relevant internal regulations or legislation.

## **Chapter 2**

### **Rules and Procedures for Internal Reports**

#### **§ 3**

1. The Whistleblower may submit an Internal Report at their choice to:
  - 1) the Report Officer – for all Violations;
  - 2) the Data Protection Officer – regarding Violations of privacy and personal data protection;
  - 3) Anti-Fraud Officer – for suspected irregularities or adverse actions in competitions organised by the Agency or projects funded by the Agency, and in the implementation of the National Recovery and Resilience Plan;
  - 4) the ISMS Officer – with regard to Violations concerning the security of communication and information networks or systems and security of information.
2. In the event that an Internal Report concerns the Employee Processing the Report, the Whistleblower may submit an Internal Report directly to the President of the Agency. If the Employee Processing the Report has received an Internal Report that concerns them, they are obliged to forward it immediately to the President of the Agency, as far as possible without reading its contents and the details of the Whistleblower. The case is entered in the Register of Internal Reports upon completion of the Follow-up Actions.

#### **§ 4**

1. The Whistleblower may submit an Internal Report in the following form:

- 1) electronically via the application form on the Agency's website;
  - 2) electronically to the e-mail address of the Employee Processing the Report;
  - 3) by post to the registered address of the Agency, marked "confidential – to the addressee", to the relevant Employee Processing the Report;
  - 4) a delivery deposited at the Agency's premises directly to the Employee Processing the Report;
  - 5) a statement made at the Agency's premises during an in-person meeting in the presence of the Employee Processing the Report organised within 14 days of receipt of the Whistleblower's request for the meeting.
2. The contact details of the Employee Processing the Report are posted on the Agency's website.
  3. Cases referred to in the Internal Report constitute documentation which does not comprise the case file and is not subject to registration in the register of cases in accordance with the Office Instructions.
  4. The delivery referred to in paragraph 1(3) and 1(4) shall not be opened at the Agency's office or registered in the electronic document management system (EZD system). The delivery referred to in paragraph 1(3) shall be forwarded without delay directly to the Employee Processing the Report.
  5. In the case of the statement referred to in paragraph 1(5), the Employee Processing the Report with the consent of the Whistleblower shall record the content of the Internal Report in the form of a recording of the conversation or minutes.
  6. The Whistleblower may submit an Internal Report either anonymously or by providing personal or contact details. The Agency will not take any action to establish the identity of anonymous Whistleblowers.
  7. A Whistleblower who has submitted an Internal Report should not get in touch with regard to the Violation with the entity or person who is the subject of the Internal Report (i.e., was identified in the report as the entity or person who committed the Violation or with whom that entity or person is associated).

## **§ 5**

1. In order for the Internal Report to be processed efficiently and for Follow-up Actions to be effective, it is recommended that the Internal Report contains, in particular:
  - 1) data of the person/entity involved in the Violation;
  - 2) description and course of the Violation (e.g., time, place, circumstances, witnesses);
  - 3) data of the Whistleblower (unless the Internal Report is made anonymously);
  - 4) any other information that is relevant to the Violation, including possible documents;

- 5) indication of whether the Violation has been reported to another authority (if so, when and to which authority).
2. In the case of Violations, time is often of the essence. A Whistleblower should therefore communicate the Violation as soon as possible.
3. The Whistleblower is not required to collect evidence of the circumstances of the Violation prior to making an Internal Report; however, providing evidence of the Violation will assist in assessing the validity of the Internal Report.
4. It is forbidden to provide content which is, to the knowledge of the Whistleblower, untrue, in bad faith, not related to the person's employment at the Agency, their position or the scope of their tasks carried out for the Agency, as well as to provide personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, religious affiliation, trade union membership, as well as genetic data, biometric data, data concerning health, sexuality or sexual orientation, and data concerning convictions, decisions on penalties and fines, other decisions issued in court or administrative proceedings, except where the provision of such information is required or permitted by generally applicable law, including in the case of the provision of the aforementioned data by the data subject.
5. The Employee Processing the Report may request additional information or documents from the Whistleblower, if the Whistleblower can be contacted, where this is necessary for the Follow-up Actions.

### **Chapter 3**

#### **Follow-up Actions**

##### **§ 6**

1. Every Internal Report received shall be registered in the Register of Internal Reports.
2. The Register of Internal Reports shall be the responsibility of the Report Officer.
3. The Register of Internal Reports shall contain the following data:
  - 1) case number;
  - 2) subject of the Violation;
  - 3) date of the Internal Report;
  - 4) information on the Follow-up Actions taken;
  - 5) date of case closure;
  - 6) personal data of the Whistleblower and of the reported person, necessary for the identification of those persons;
  - 7) the Whistleblower's contact address.
4. The Employee Processing the Report shall promptly and on an ongoing basis provide the Report Officer with the information necessary to maintain the Register of Internal Reports.

5. Access to the data contained in the Register of Internal Reports shall be available to the Report Officer, the Employee Processing the Report in the scope of their cases and the President of the Agency.
6. The Agency shall remain the Controller of the data contained in the Register of Internal Reports. The Register of Internal Reports data shall be retained for a period of 3 years after the end of the calendar year in which the Follow-up Actions have been completed or after the proceedings initiated by these actions have been terminated.
7. The Report Officer shall submit to the President of the Agency, annually, a report on the Internal Reports received for that period, including the data contained in the Register of Internal Reports.

## **§ 7**

1. An Internal Report shall be considered in accordance with the procedure set out in the Rules and Regulations, unless the nature and subject matter of the Internal Report justify its consideration in accordance with the procedure provided for by law or separate internal regulations, such regulations being supplementary to these Rules and Regulations and, in the event of their conflict with the Rules and Regulations, the provisions of the Rules and Regulations shall apply.
2. If the Internal Report is received by the Report Officer in the scope of Violations specified in § 2(2)–(4) and § 2(7), they shall immediately forward the case along with the information and documents obtained to the appropriate Employee Processing the Report.
3. If the Internal Report relates to Violations that fall within the competence of at least two Employees Processing the Report, they are obliged to co-operate in processing the report.
4. In case of doubt as to which employee should handle the case, the decision as to the competent employee is made by the Report Officer.
5. The Employee Processing the Report shall confirm to the Whistleblower the acceptance of the Internal Report within 7 days of its receipt, unless the Whistleblower has not provided an address to which the confirmation should be forwarded.

## **§ 8**

1. The Employee Processing the Report shall perform an initial analysis of the Internal Report to determine whether the information contained therein permits consideration of the validity of the Internal Report.
2. The Employee Processing the Report may decide not to carry out an investigation if:
  - 1) the Internal Report is manifestly unreliable or contains only the information referred to in § 5(4);
  - 2) it is impossible to obtain the information necessary for the investigation.

3. The initiation of an investigation should take place no later than 14 days after receipt of the Internal Report, unless this proves impossible for legitimate reasons, in which case it should be initiated as soon as possible.
4. As regards particularly complex cases, which require special information or considerable work, the President of the Agency may, at the request of the Employee Processing the Report, appoint by order a Report Investigation Committee. Employees and other persons designated by the President of the Agency may become members of the Report Investigation Committee. The Report Investigation Committee shall be chaired by a person designated by the President of the Agency. In matters falling within the competence of the Report Investigation Committee, its members shall remain organisationally independent and report to the President of the Agency.
5. In order to safeguard the interests of the Agency, the Employee Processing the Report may, pending the outcome of the investigation, make recommendations to organisational units to take certain actions, including in particular withholding or refraining from taking certain actions or issuing certain work orders, subject to paragraph 6.
6. A prior approval of the President of the Agency shall be required for recommendations involving disciplinary action against an employee or an associate or having financial implications for the Agency.
7. Pending the appointment of a Report Investigation Committee, the Employee Processing the Report shall take urgent action.

## **§ 9**

1. The Employee Processing the Report shall conduct the investigation with due diligence, in an impartial and fair manner.
2. The purpose of the investigation is to gather all possible information and evidence in the case, evaluate them and, as far as possible, confirm or exclude the occurrence of the Violation, as well as determine the extent of any possible damage to and potential financial or image loss of the Agency.
3. In the course of the investigation, the Employee Processing the Report is entitled in particular to:
  - 1) have access to the paper and electronic official correspondence and documentation of the Agency necessary for the clarification of the case;
  - 2) make copies of documents;
  - 3) accept statements;
  - 4) hear witnesses;
  - 5) hear the employee who is the subject of the Internal Report.

4. Subject to the provisions of generally applicable law, organisational units are obliged to cooperate with the Employee Processing the Report in the course of the investigation, in particular to provide explanations or statements, make available and take copies of documents, prepare analyses of the issue (e.g., compilations or data extracts) in the forms and at the times specified by the Employee Processing the Report.

## **§ 10**

1. At the end of the investigation, the Employee Processing the Report shall issue an opinion on the validity of the Internal Report. In the case of substantiated reports, the Employee Processing the Report shall make recommendations to the organisational units to take corrective or disciplinary action against the employee or associate who committed the Violation and recommendations to take preventive action to eliminate similar Violations in the future, subject to paragraph 2.
2. A prior approval of the President of the Agency shall be required for recommendations involving disciplinary action against an employee or an associate or having financial implications for the Agency.
3. In the recommendations referred to in paragraph 1, the following should be taken into account:
  - 1) the nature and scale of the Violation;
  - 2) the applicability of the Agency's existing control mechanisms;
  - 3) a description of the Violation risk mitigation actions to be implemented and the level of risk to be achieved once the actions have been implemented;
  - 4) necessary resources if the activities will require additional resources.
4. Corrective or preventive action may concern in particular:
  - 1) initiating compensation procedures;
  - 2) making organisational or staff changes;
  - 3) making changes to internal regulations;
  - 4) conducting training or information campaigns;
  - 5) notifying the relevant legal protection authorities (e.g., Central Anti-Corruption Bureau (CBA), Police, public prosecutor's office);
  - 6) making changes to the planning of internal control tasks or the risk analysis process.
5. Disciplinary actions consist of imposing sanctions arising from, as appropriate from the Work Rules and Regulations, the Labour Code, a civil-law contract or the Civil Code.

## **§ 11**

1. The Employee Processing the Report shall provide the Whistleblower with feedback on the case without delay, but no later than 3 months after confirming the receipt of the Internal



Report or, if no confirmation is provided, within 3 months after the expiry of 7 days from making the Internal Report, provided that contact can be made with the Whistleblower.

2. The feedback referred to in paragraph 1 shall include, in particular, information on planned or taken Follow-up Actions and the grounds for such actions.
3. All actions taken by the Employee Processing the Report shall be recorded in writing or electronically, in particular in the form of an official note or records, subject to § 4(5).
4. Organisational units are obliged to notify the Employee Processing the Report immediately of their intention to take up or not to take up the individual recommendations communicated to them by the Employee Processing the Report, and then, in each case, of their implementation or non-implementation, respectively, providing a justification. If an organisational unit does not agree with the recommendation of the Employee Processing the Report and the recommendation was not previously accepted by the President of the Agency, the President of the Agency shall decide whether to implement the recommendation.
5. In the event of a Violation within the scope referred to in § 2(1)(11), the Agency shall also forward the information to the Coordinating Authority for the National Recovery and Resilience Plan following a separate procedure, including in connection with the preparation of the management declaration before sending the application for payment to the European Commission.

## **§ 12**

1. The Employee Processing the Report cannot be:
  - 1) a person who is a Whistleblower or a person who is the subject of an Internal Report;
  - 2) a person who is the Whistleblower's immediate superior or a person who reports directly to the Whistleblower;
  - 3) a person who is a spouse, relative – by consanguinity or affinity up to and including the second degree – of the Whistleblower or of the person who is the subject of the Internal Report, or a person who is in such a legal or factual relationship with those persons as to give rise to justified doubts as to their impartiality.
2. If, in the opinion of the Employee Processing the Report, there are circumstances that could affect their impartiality, they should exclude themselves from the case and inform the President of the Agency about this fact.
3. In the case referred to in paragraph 1 or paragraph 2:
  - 1) if necessary and possible, activities carried out with the participation of the excluded person shall be repeated;
  - 2) the President of the Agency may appoint another employee who meets the conditions of impartiality and independence to conduct the case.

**Chapter 4**  
**Confidentiality and Personal Data**

**§ 13**

1. The Report Officer and the Employee Processing the Report are obliged to maintain the confidentiality of information obtained in connection with the Internal Report.
2. Employees involved in the investigation are obliged to maintain the secrecy of information obtained in connection with the investigation.
3. The Whistleblower's personal data, which allows for the identification of the Whistleblower, shall not be disclosed to unauthorised persons, except with the Whistleblower's express consent.
4. Paragraph 3 shall not apply where disclosure is a necessary and proportionate legal obligation arising in connection with investigations carried out by Public Authorities or preliminary or judicial proceedings carried out by the courts, including for the purpose of safeguarding the rights of defence of the person who is the subject of the Internal Report.

**§ 14**

1. Access to information and documentation relating to the Internal Report and access to the personal data of the Whistleblower and the person who is the subject of the Internal Report is only available to the Report Officer, the Employee Processing the Report within the case and the President of the Agency.
2. The Report Officer and the Employee Processing the Report shall have written authorisation from the Agency to undertake certain Follow-up Actions and to process personal data.

**§ 15**

1. The processing of the personal data of the Whistleblower, the person who is the subject of the Internal Report and other persons mentioned by the Internal Report shall be carried out in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), with the exception of Article 14(2)(f) and Article 15(1)(g) in the cases specified in the Act.
2. Personal data that is not relevant for the processing of an Internal Report shall not be collected and, if accidentally collected, shall be deleted immediately. The deletion of this personal data shall take place within 14 days of the determination that it is not relevant to the case.

3. The personal data processed in connection with the acceptance of an Internal Report or the undertaking of Follow-up Actions and the documents relating to that Internal Report shall be retained for a period of 3 years after the end of the calendar year in which the External Report has been transmitted to the Public Authority competent to take the Follow-up Actions or in which the Follow-up Actions have been completed, or after the proceedings initiated by those actions have been concluded.
4. The Agency shall ensure that information is provided to Whistleblowers about the processing of their personal data in accordance with Article 13 of the General Data Protection Regulation.

## **Chapter 5**

### **External Reports**

#### **§ 16**

1. The Whistleblower may, in any case, submit an External Report without prior submission of an Internal Report to the Agency. At the same time, the Agency ensures that Whistleblowers are protected from Retaliatory Actions, that the Internal Report can be made anonymously and that the Internal Report is considered by impartial and independent persons. Accordingly, it is encouraged to refer the information about the Violation to the Agency via an Internal Report in the first instance.
2. The External Report should be made in accordance with the report acceptance procedure established by either the Ombudsman or the Public Authority.

## **Chapter 6**

### **Retaliatory Action Prohibition and Whistleblowers Protection Measures**

#### **§ 17**

1. The Agency shall ensure the protection of any Whistleblower who has submitted an Internal Report, an External Report or a Public Disclosure from Retaliatory Actions and the threat of carrying them out or attempt to do so, in particular consisting of:
  - 1) refusal to enter into an employment relationship or cooperation agreement;
  - 2) termination or dissolution without notice of an employment or cooperation agreement;
  - 3) overlooking the Whistleblower for training, promotion, bonuses;
  - 4) moving the Whistleblower to a less favourable position, changing their time or place of work/service provision to less favourable;
  - 5) imposing disciplinary penalties or other measures of a similar nature;
  - 6) negative performance evaluation;
  - 7) reduction in the amount of remuneration for work;

- 8) omission in the award of work-related benefits other than wages or reduction in the amount of such benefits;
  - 9) transferring the Whistleblower's existing duties to another employee;
  - 10) coercion, intimidation or exclusion;
  - 11) bullying;
  - 12) discrimination;
  - 13) unfavourable or unjust treatment;
  - 14) action to make it more difficult to find future work in a particular sector or industry on the basis of an informal or formal sectoral or industry agreement;
  - 15) causing financial loss, including economic loss or loss of income;
  - 16) infliction of other non-material damage, including damage to personal rights, in particular to the Whistleblower's good name.
2. The Whistleblower shall be protected from the time of submitting an Internal Report, External Report or Public Disclosure as set out in this Chapter, provided that the Whistleblower had reasonable grounds to believe that the information subject to the Internal Report, External Report or Public Disclosure of the Violation was true at the time of reporting and that such information constitutes Violation information, even if the Internal Report, External Report or Public Disclosure have subsequently proved to be unfounded and, in respect of a Public Disclosure, additionally after the conditions set out in section 51 of the Act have been met.
  3. The submission of an Internal Report, External Report or Public Disclosure may not give rise to liability (including disciplinary liability or damages for Violation of the rights of others or obligations under the law – e.g., defamation, violation of personal rights, business confidentiality) or disciplinary responsibility, provided that the Whistleblower had reasonable grounds to believe that the Internal Report, External Report or Public Disclosure was necessary to disclose the Violation in accordance with the Directive.

## **§ 18**

1. Anyone who has obtained the information that Retaliatory Actions are being taken, threatened or attempted against the Whistleblower or whose personal data has been unlawfully disclosed may notify the Report Officer. In the event that Retaliatory Action, threat of carrying it or attempt to do so or unauthorised disclosure of personal data has been committed by the Employee Processing the Report, it is the President of the Agency who shall be notified.
2. The perpetrators of the acts referred to in paragraph 1 may be subject to sanctions under the Work Rules and Regulations, the Civil Code or other legislation, among others,

depending on the type of legal relationship between the offender and the Agency and the seriousness of the offence.

### **§ 19**

The provisions of this chapter shall apply accordingly:

- 1) to a person who assists in making an Internal Report, External Report or Public Disclosure and whose assistance should not be disclosed;
- 2) to a person associated with the Whistleblower, i.e. a natural person who may experience Retaliatory Action, including co-workers or a person close to the Whistleblower within the meaning of Article 115 § 11 of the Act of 6 June 1997 – Penal Code;
- 3) where the Violation has been reported to the relevant institution, authority or body of the European Union following a procedure applicable to such reports.

## **Chapter 7**

### **Final Provisions**

#### **§ 20**

1. Before being allowed to work, the employee is obliged to familiarise themselves with the contents of the Rules and Regulations and to make a declaration according to the model attached as Appendix 1 to the Rules and Regulations. The statement shall be included in the employee's personal file.
2. Before taking action, the Employee Processing the Report is required to read the Rules and Regulations and make a declaration in accordance with the model attached as Appendix 2 to the Rules and Regulations.
3. The Report Officer shall review the Rules and Regulations annually and whenever the need arises, in particular due to changes in the law or the finding of inadequacy or ineffectiveness of the solutions adopted in the Rules and Regulations.
4. The Agency shall communicate the Rules and Regulations to an applicant for employment or any other legal relationship giving rise to the provision of work or services or performing functions with the commencement of recruitment or pre-contractual negotiations.