OSTRAVSKÁ UNIVERZITA

Guide to Good Research Practice

EUROPEAN UNION
European Structural and Investment Funds
Operational Programme Research,
Development and Education

MINISTRY OF EDUCATION,
YOUTH AND SPORTS

Content

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Introduction

The University of Ostrava (UO) strives to maintain high standards of precision and integrity in all aspects of research, according to the European Code of Research Integrity (ALLEA, 2017[1]):

- Reliability in ensuring the quality of research, which is reflected in the design of its concept, methodology, analysis, and use of resources.
- Integrity in the development, conduct of research, assessment, reporting, and communication of research in a transparent, honest, comprehensive, and impartial manner.
- Respect for colleagues, research participants, society, ecosystems, cultural heritage, and the environment.
- Responsibility for research from the initial idea to the publication of results, for its management and organization, training, supervision and guidance, and for the wider implications of research.

For this reason, the University of Ostrava[2]:

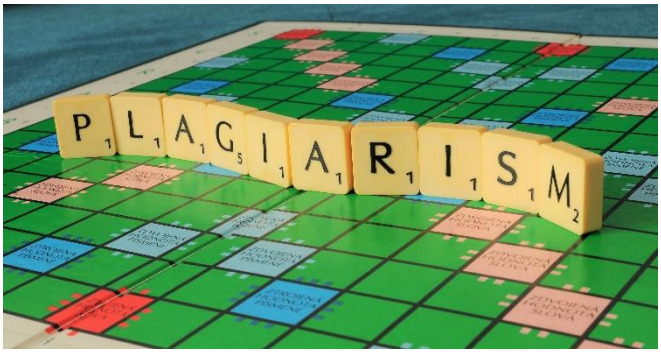
- Ensures that research is conducted in accordance with relevant ethical, legislative, and professional frameworks, requirements, and standards.
- Supports a research environment based on integrity, good governance, good practice, and supports the further development of researchers.
- Uses transparent, robust, and fair processes that address ethical research issues and possible allegations of scientific misconduct, should they arise.
- Strives to strengthen the integrity of research, and regularly and openly assesses research developments.

[1] ALLEA, 2017: The European Code of Conduct for Research Intregrity. [online] Berlin: Brandenburg Academy of Sciences and Humanities. [accessed 26 June2019].
[2] Research Integrity Concordat. University of Sunderland.[online] [accessed 8 May 2020].

Undesirable practices in publishing

Publishing is often associated with a number of practices that are on the verge of academic ethics, or directly contradict it. The most common offences are:

- Plagiarism - publishing other people's ideas, thoughts, texts, or works of art (generally intellectual work) as your own. We can consider the conscious theft (copying) of texts as plagiarism, but more and more often, texts are also issued in the form of plagiarism for which it is not possible to trace the original author, even though it is obvious that they do not belong to the author who presents them. The boundaries of plagiarism are sometimes very blurred, and are the subject of intense debate. Detailed materials can be found at https://plagiatorstvi.vse.cz/o-projektu/.



  From the whole range, the following types of plagiarism are especially important:
    - Direct citation (a literal or word-for-word copy) of the text, without mentioning the original author and the indication of the direct citation (usually quotation marks or italics). This category may also include literal translations from another language. Sometimes, it is difficult to assess the extent to which it is a paraphrase and when it is already plagiarism, but many sources state that omitting or confusing a few words is not enough.
    - Paraphrasing a text (transcribing an idea) without mentioning the author. This type of plagiarism can also be caused by ignorance of the rules of citation, so it is very important that both students and their tutors are sufficiently familiar with the issue.

- Ghost-writing - failure to list the actual authors of the work. There can be several reasons for this breach of ethics:
    - Writing works to order (so-called contract cheating), when the real author gets paid for the work, and the client then publishes the work as his/her own (from a certain point of view, this is actually plagiarism), is a common phenomenon, especially for students, and its detection is relatively difficult. It is usually recommended to check the knowledge of the thesis during its defence (for example, the defence of diploma theses), or the supervisor continuously checks the progress of the work, and discusses the results with the student (probably the best method to detect unfair practices in the beginning).
    - Creating a spiritual work under duress. Recently, the use of doctoral students or post doctoral students to write scientific reviews for their supervisors has been discussed in scientific circles. The description of this scandal has even appeared on the pages of prestigious magazines.
    -
- Honorary authorship - attribution of authors who did not play a significant role in the writing of the text).

- Publishing in predatory journals or in predatory conference proceedings - the term "predatory journal" is understood to mean a journal that does not carry out a standard review process, and usually publishes articles, without being reviewed, for a certain financial amount. Publication in predatory journals may not always be the unethical conduct of the author. Authors may not be sufficiently informed about this risk.

In addition, some predatory journals are difficult to distinguish (for more information, see https://kuk.muni.cz/vyuka/materialy/predatori/). In addition, fictitious predatory conferences have recently appeared, which publish abstracts, and possibly proceedings, without the authors participating in the conference.

- Deliberate slicing up of scientific publications (“salami slicing”) - in academic circles, there are known cases where the authors try to divide the result of their research into as many partial outputs as possible. These practices are quite difficult to prove, and the authors may not necessarily do so with the aim of increasing the number of publications (for example, they may want to publish specific results in specialized journals).

- Falsification and fabrication of results - a very serious violation of scientific ethics, where research results are either distorted (falsified) or completely made up (fabricated).

Authorship and affiliation

Basic rules for authors of research results

- Authors must act as honestly and transparently as possible when publishing the results. The results should be made available to the public, unless they are part of a trade secret, or are subject to other specific copyrights.
- The authors make sure that the data is managed in such a way that it is possible to check the accuracy, but also that any misuse of the data is prevented.
- Authors must not improperly manipulate, falsify, or fabricate results.
- Authors must pay attention to the originality of the research, and properly cite any ideas and data reproduced, i.e. refer to all sources used, as well as previous research related to the results.
- Authors (including co-authors) assume responsibility for published texts.
- Authors truthfully and fairly state the share of individuals in a given result.
- Authors do not use previously unpublished results of their colleagues or students without their permission.
- Authors do not abuse authority and their position in the workplace in order to exert pressure to obtain the results of others.
- Authors strive to ensure that their outputs are of high quality, accessible, and cited by the scientific community. Authors should avoid purposefully circumventing review procedures, which include the purposeful establishment of their own journals, the organization of their own conferences for the sole purpose of publishing proceedings, publishing in predatory journals, and reporting papers at predatory conferences.

Authorship

The author of a scientific output is generally a researcher who has made a fundamental intellectual contribution to the research work and the completion of the output. Other persons who contributed to the results, but not in a significant way, should be mentioned in the acknowledgment. Due to the fact that the view of the contribution and the share of authors may differ, it is currently a good habit to state the degree of involvement in the research of individual authors, directly in the given publication (monograph or scientific article). It is not appropriate to state the degree of involvement in percentages (there is a devaluation of research activities, because the result cannot be related to relative values, but rather to the absolute values of the effort spent on the result); rather, it should be indicated by listing the activities in which the author participated.

The following criteria are very often stated, which a person must meet in order to be considered an author[3]:

- Significantly contributed to the conception and design of the study, data generation, or interpretation of results.
- Prepared or critically revised the manuscript with significant intellectual contribution.
- Approved the final version of the text to be published.
- Assumed responsibility for the result or its relevant part; for the correctness, accuracy, and completeness of the results of the published output (the authors often declare when sending the manuscript).

Because it is not always clear what a significant result is, we can list the main activities that are recognized as a significant share:

- Manuscript writing and its critical revision leading to a shift in analysis or interpretation of results.
- Preparation of the research concept and development of the methodology (design).
- Analysis and interpretation of results.
- Comprehensive provision of data collection, including participation in other activities (adjustments to the methodology of data collection, control and processing of data).
- Organization of a research team, but with a share in other activities (see also honorary authorship).

The list of authors should not include persons who did not participate intellectually in the creation of the result, i.e.:

- Administrative staff, technicians, and laboratory technicians who only performed routine activities which, by their nature, do not have a significant effect on the professional content of the publication.
- Workers who only provided funding (e.g. sponsors, project staff) or, where appropriate, provided appropriate research permits (e.g. nature conservation workers who allowed the collection of material, which is not common practice in Europe, but not uncommon in some other parts of the world).
- Workers involved in data collection, without requiring further scientific expertise [4].
- “Honorary authorship”, where the author is credited for formal team leadership, previous research credit on a given topic, or as an expression of gratitude. Honorary authorship is often also considered to be the authorship required from the position of a superior authority (e.g. head of department, head of clinic, student mentor, etc.), without these employees otherwise contributing to the result.

[3] ICMJE, 2019: Defining the Role of Authors and Contributors. International Committee of Medical Journal Editors. [online] accessed 15 June2019. Available from: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html.

[4] Petr M., 2017: Dobrá praxe vědeckého publikování. (Good practice in scientific publishing) [online] Masarykova univerzita. Last update 20.6.2017, [accessed 21 June2019] Available from: https://scientometrics.muni.cz/media/3057631/zasady_vedeckeho_publikovani_na_mu_cz.pdf

- Reciprocal authorship, where co-authors are credited in exchange for inclusion in their publications (as reciprocity). This phenomenon is not rare, and is considered a very unethical increase in publishing performance.

Potential unethical conduct includes the purposeful omission of some people who played a key role in the outcome. The main examples of such persons include:

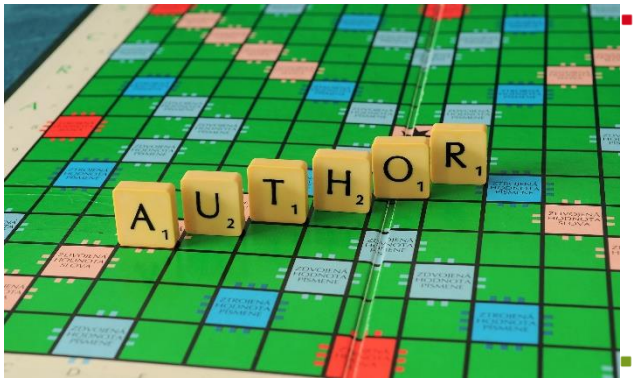
- Students who have participated in some of the main activities listed. The head of the laboratory or supervisor should give students who contributed to the results the opportunity to participate in the preparation of the manuscript, and be co-authors of the output.

- People who write an article to order, but are not listed as co-authors. In this case, it is so-called "ghost-writing", which is considered to be scientific fraud.

- Persons who were fundamentally involved in the result, but were subsequently excluded for formal reasons, or their employment was terminated.

- Persons not listed due to a potential conflict of interest (e.g. industry partners).

The order of authors is usually stated according to the intensity of their involvement in the preparation of the publication, and is decided mainly by the main author (the author with the largest share in the publication). It is generally recommended that authorship be discussed before the result is written, and the terms of co-authorship should be known to all those involved in the preparation of the output.



According to the share in the publication, we usually distinguish several basic types of authors, which can be identified by order, or other indications:

- First author (also main author). For scientific articles, this is usually the author who prepares the first version of the manuscript, and is fundamentally involved in the whole research. The main author is usually mentioned in the first place. An exception is, for example, mathematical and computer science disciplines, where the order may be listed alphabetically.

- Corresponding author. In the case of multiple authors, it is usually the author who sends the article to the editorial office, and then receives and distributes comments within the review procedure. The correspondence author is often in the last place, or is listed directly in the introductory part of the output (many journals explicitly mention the correspondence author in some section of the article).

- The head of research or head of laboratory is customarily ranked last in the biological and medical sciences. This is not an honorary authorship. This author often organizes a large part of the research, participates in the preparation of the publication (major revision), and other activities. At present, the placement of the last author as a key researcher is becoming a trend in other disciplines too, however, many fields still differ significantly, and the order of authors is the subject of very intense discussions[5].

[5] https://doresearch.stanford.edu/policies/research-policy-handbook/conduct-research/academic-authorship

Dedication

In most scientific publications, it is common to dedicate the result to a specific grant programme. In dedications, the project code is usually given (not the project code in the EVID, but the project code from the database CEP – Central Evidence of the Project), possibly also the name of the project, and the grant provider:

The wording of the dedications is usually as follows:

"This study was supported by the project… *project name (project code*)… of the *name of the provider*."

It is common for dedications to be mentioned in publications in the Acknowledgements section. For SCI-indexed publications, the project codes and grant providers are nowadays also listed directly in the Web of Science database. Furthermore, the dedications must be included when entering publications into the database RIV (Register of information on results). This section also includes thanks to other collaborators who are not listed as authors (for example, students who participated in the data collection) and to reviewers.

Affiliation

In the event that the authors carry out research activities and outputs at UO, they must clearly and correctly link the published result with the University of Ostrava. In the case of incorrect affiliation, for example, authors and institutions are exposed to the risk of distorted evaluation of the institution in the national evaluation system, evaluation of universities according to international rankings and in international databases (Scopus, WoS). In general, the following rules apply to UO:

- Authors who carry out research activities and outputs at UO and publish at UO must list the University of Ostrava as their primary affiliation. This obligation also applies to short-term contracts and internships.

- The author of the result who states or should have stated the affiliation to the University of Ostrava is responsible for the correctness of the affiliation. Therefore, during the final proofreading, the author is obliged to check the correctness of the affiliation. In the event of incorrect affiliation, the subsequent correction (if possible) is arranged by the author.

- It is recommended to state the name of the university in English or in Czech (in the event of publication in Czech). The name of the university and faculties is stated according to Appendix 1 of the UO Statute, the names of the departments according to the official names listed on the UO website.

- The form of affiliation should be as follows (if the publisher allows it): workplace, faculty, institution, address. If the full wording of the affiliation is not allowed, then priority is given to the institution (University of Ostrava) and the address of the faculty.

  An example of affiliation:
  Department of Biology and Ecology, Faculty of Science, University of Ostrava, Chittussiho 10, Ostrava.

- In the case of a double affiliation, both affiliations must be listed as two separate addresses. A merged form of affiliation is considered erroneous.
  An erroneous affiliation:
  Josef Novák[1]
  [1]Department of Physiology, University of Ostrava and Faculty Hospital Ostrava.

  A correct affiliation:
  Josef Novák[1,2]
  [1]Department of Physiology, Faculty of Medicine, University of Ostrava, ...
  [2]Faculty Hospital Ostrava, ...

  PUBL:
  In PUBL, it is necessary to state the author's affiliation for only one UO workplace. In the case of two workplaces of one author, it is necessary to solve this fact individually (within one faculty, for example, state only the faculty). In the case of two affiliations to two institutions, it is possible to report the same author as domestic, with the assignment of a workplace and, at the same time, a foreign one (however, the citation will be incorrect, and it is necessary to subsequently modify it).

Work with biological material

Biological material and work with such is subject to a number of specific legislative and safety measures for work in biological laboratories, work with protected plants and animals, genetically modified organisms, and especially when working with human material, which is presented in a separate chapter. Due to a number of exceptions and the breadth of the issue, it is not possible to list all of the principles that result from the legislation. Therefore, at the beginning, we present a basic list of legislation, and then summaries of the most important rules.

Overview of basic legislative requirements[6]

Laboratory work safety:

- Act No. 258/2000 Coll., as amended, on the protection of public health;
- Act No. 309/2006 Coll., as amended, which regulates other requirements for safety and health at work in labour relations and on ensuring safety and health at work or the provision of services outside labour relations (Act on ensuring other safety conditions and occupational health);
- Government Regulation No. 101/2005 Coll., as amended, on more detailed requirements for the workplace and working environment;
- Government Regulation No. 361/2007 Coll., as amended, which lays down the conditions for protecting the health of employees at work;
- Government Regulation No. 201/2010 Coll., as amended, which stipulates the method of registration, reporting and sending the accident record, the model of the accident record, and the range of bodies and institutions to which the work accident is reported and the accident record is sent;
- Government Regulation No. 495/2001 Coll., as amended, which stipulates the scope of provision of personal protective equipment, washing, cleaning, and disinfecting agents;
- Government Regulation No. 378/2001 Coll., as amended, which lays down more detailed requirements for the safe operation and use of machines, technical equipment, devices, and tools;
- Government Regulation No. 11/2002 Coll., as amended, which stipulates the appearance and location of safety signs, and the introduction of signals;
- Decree No. 50/1978 Coll. - professional competence in electrical engineering.

Chemicals and chemical substances:

- Act No. 350/2011 Coll., on Chemical Substances and Chemical Mixtures, and on Amendments to Certain Acts (Chemical Act);
- Act No. 224/2015 Coll., on the prevention of serious accidents caused by selected hazardous chemical substances or chemical mixtures, and on the amendment of Act No. 634/2004 Coll., on administrative fees, as amended (the Act on the Prevention of Serious Accidents);
- Act No. 120/2002 Coll., on the conditions for placing biocidal products and active substances on the market, and amending certain related acts;
- Act No. 324/2016 Coll., on Biocidal Products and Active Substances, and on the Amendment of Certain Related Acts (the Biocides Act);
- Decree of the Ministry of the Environment No. 10/2002 Coll., as amended, which lays down a list of hazardous chemical substances that may pose a serious risk to human health and the environment;
- Czech technical standard ČSN 650201 - flammable liquids.

Genetically modified organisms:

- Act No. 78/2004 Coll., on the handling of genetically modified organisms and genetic products;

[6] More here: Veterinary and related legislation https://cit.vfu.cz/vetleg/CD/prehled.html

- Decree No. 209/2004 Coll., on more detailed conditions for the handling of genetically modified organisms and genetic products.

Nature and landscape protection:

- Act No. 114/1992 Coll., on nature and landscape protection, as amended;
- Decree No. 166/2005 Coll., which implements certain provisions of Act No. 114/1992 Coll., on nature and landscape protection, as amended, in connection with the creation of the NATURA 2000 system;
- Decree No. 395/1992 Coll., which implements certain provisions of the Act of the Czech National Council No. 114/1992 Coll., on nature and landscape protection;
- Decree No. 152/2006 Coll., on a deviating procedure for the protection of birds, and an exception to the basic protective conditions of specially protected bird species for their marking;
- Act No. 115/2000 Coll., on the provision of compensation for damage caused by selected specially protected animals;
- Red lists of endangered species of the Czech Republic (current edition);
- The IUCN Red List (also the Red List of Threatened Species) is issued every two years by the International Union for Conservation of Nature (IUCN).

Protection of human health:

- Decree No. 490/2000 Coll., on the scope of knowledge and other conditions for obtaining professional competence in certain fields of public health protection;
- Decree No. 428/2004 Coll., on the acquisition of professional competence for the handling of hazardous chemical substances and chemical preparations classified as being highly toxic.

EU regulations:

- Council Regulation (ES) No. 1/2005 on the protection of animals during transport and related operations, and amending Directives 64/432/EHS and 93/119/ES and Regulation (ES) No. 1255/97;
- Council Regulation (ES) No 1099/2009 on the protection of animals at the time of killing.

Work in a biological laboratory

Each laboratory has its own operating rules, the purpose of which is to set hygienic requirements, the observance of which by employees, students, and other persons present forms the basis for the safe operation of the facility. It is a basic internal document, with which each of the persons present must be demonstrably acquainted. The operating rules should specify:

- Health & Safety at work;
- contact person;
- training of staff and students, and the maintenance of training records;
- technical conditions of laboratory operation;
- work with hazardous substances (chemicals, etc.);
- general principles of minimizing the risk of infection (disinfection, sterilization, etc.);
- protective equipment;
- first aid kit;
- disposal of waste and hazardous substances (rules for hazardous waste management);
- fire protection.

Before starting work in the laboratory, the worker (or student) must know:

- the operating rules of the laboratory;
- the rules of access to the laboratory, and have official access (+ contact person in case of specific laboratory security);
- his/her workplace where he/she will move about, and the material(s) he/she may use;
- the operation and functions of the devices which he/she can and will use and, where appropriate, the authorized person who will train him/her;
- about ensuring the purchase of materials and financing of the operation, consumables, aids, and possible services (this is especially important if there are more teams working in the laboratory, participating in the financing of the operation).

After each end of the work process (unless otherwise specified in the operating rules):

- proper cleaning and disinfection of the work surface(s), any laboratory aids, and devices must be carried out immediately, depending on the nature of the laboratory (virucide, ethanol, chloramine);
- when archiving samples, all samples must be visibly marked and placed in a place reserved for that purpose;
- all laboratory staff are required to apply these instructions in full.

Safety when working with biological material

Biological material is understood to mean material of human or animal origin, which may contain the causative agent of the infection (causative agent of highly virulent infection or multidrug-resistant strains in pure culture), micro-organisms (e.g. fungi, bacteria, viruses), and partially plant material covered by specific legislation. The risk of transmitting infection is, for example, inhalation of an infectious aerosol, contamination of the mouth, swallowing, contamination of the skin and mucous membranes, or injury from a sharp contaminated object. General principles of safety when working with biological material, especially for medical workplaces, are set out in the Decree of the Ministry of Health No. 306/2012 Coll.

In general, occupational safety depends on the nature of the biological material, and may be specified in the operating rules, but among the basic rules are the following:

- Any material of biological origin should be considered potentially infectious.
- The basic rules of working with non-pathogenic microorganisms should be the same as working with pathogens.
- Receipt and processing of biological material must be performed in a part of the laboratory reserved for this purpose.
- Reception workers are obliged to use personal protective equipment (gloves, protective clothing).

- Biological material should be supplied in single-use disposable collection containers with screw caps.

- If the biological material is in a container that is externally stained or contaminated, such a sample cannot be further processed.

- The entire collection container, including biological material, is disposed of in accordance with the relevant regulations.

Species protection and biological research

When working with organisms, it is always necessary to verify whether it is a specially protected species of the Czech Republic (Decree No. 395/1992 Coll., Lists of specially protected species). Every individual of a specially protected species in all of its developmental stages, and its habitat, is protected. Among other things, it is prohibited to collect, tear, damage, destroy, keep, cultivate, or sell specially protected species of plants and, in particular, it is prohibited to catch, keep captive, disturb, injure, or kill specially protected species.

In general, the following rules apply:

- In the case of a specially protected species, an exception to the basic conservation conditions must be obtained. The reason for granting an exemption pursuant to § 56, Paragraph 2 of Act No. 114/1992 Coll., when another public interest outweighs the interest of nature protection, or in the interest of nature protection, may be, for example, research and education.

- The need to obtain an exemption also applies to specially protected species which are subject to protection under European law.

- A written request must have the following requirements:
    - the specially protected species and the number of individuals to be researched, must be named;
    - the type of prohibited activity for which the exemption is requested ("what to do with the individuals");
    - locational and time specification of the requirement (localities, cadastre of the municipality, length of research from - to);
    - justification and demonstration that there is another public interest in the particular case that outweighs the specific interest of nature conservation, or that the exemption granted is in the interest of nature conservation;
    - identification data and designation of the administrative body to which the application is addressed, i.e. on the territory of the Protected Landscape Area outside the territory of the Šumava Protected Landscape Area, and the Labské pískovce Protected Landscape Area, if they are not military districts, and on the territory of the NPR and NPP and their protection zones, the competent nature protection authority is the Administration of Protected Landscape Areas - AOPK CR, resp. its relevant regional workplace; in the rest of the Czech Republic the competent authority is the local regional authority.

- When researching in specially protected areas, it is also necessary to obtain the necessary permits and to observe the rules of movement and behaviour in these areas.

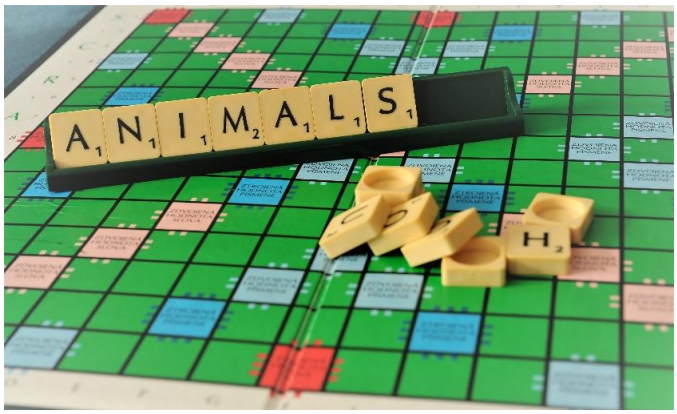
- In the case of research abroad:
    - it is necessary to study in advance the rules of the country in which the samples will be taken, and from which they will be exported, including the rules for the collection of organisms inside and outside of protected areas, the rules of export, and customs duties;

- collections must be carried out in accordance with the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (see below);
- it is necessary to find out in advance the conditions of import of live animals into the Czech Republic (State Veterinary Administration of the Czech Republic) and possible customs clearance (Customs Administration of the Czech Republic);
- specific rules apply if the species of interest is an endangered species of wild fauna or flora under CITES;
- imported geographically non-native species of plants and animals may not be introduced and released into the wild.

- The Czech Republic is a signatory to the Nagoya Protocol on Access to Genetic Resources and the Sharing of Benefits Arising from their Utilization, resulting in:
  - The Czech Republic does not restrict the sending of biological samples abroad (genetic resources from the Czech Republic may be sent), provided that other CITES type export rules, veterinary regulations, etc. are followed.
  - The Czech Republic has undertaken to comply with the rules and control the conditions set by other countries for the export of biological material from their territory. The manager of the Nagoya Protocol in the Czech Republic is the Ministry of the Environment.

Rules for working with animals

Animal manipulation is understood to mean their collection, killing, captive breeding, transport, and experiments. The Nature and Landscape Protection Act and related legislation work with the term “animal”, as an invertebrate or vertebrate. The Act on the Protection of Animals against Cruelty, which regulates the rights of animals and lays down the conditions for their handling and the purpose of which is to protect animals from cruelty, damage to their health, and their unjustified killing by humans, works with the colloquial meaning of the term “animal”.



An animal in the latter sense means any living vertebrate other than a human, including a wild animal and its independent life form, but not a foetus or embryo. The legal status of an animal, according to its relation to humans, is either “wild animal” or “animal in human care” (livestock, pet animal, experimental animal, laboratory animal, stray, or abandoned animal). Animals must be handled carefully, in accordance with Act No. 246/1992 Coll., on the protection of animals against cruelty and the relevant regulations, ensuring maximum animal welfare.

- Institutional accreditation granted by the Ministry of Agriculture of the Czech Republic in accordance with the veterinary conditions, set by the State Veterinary Administration of the Czech Republic, is required for the breeding, supply, and use of experimental animals.

- When working with animals for research purposes, it is necessary to determine whether the activity is, by definition, an experiment:
  - By law, an experiment is understood to mean any invasive or non-invasive use of an animal for experimental or other scientific purposes with a known or unknown result, or for educational purposes, which may cause pain, suffering, distress, or lasting harm to the animal, at least equivalent to needle puncture, according to normal veterinary practice.

- An experiment is also understood to mean any course of action which has, or may lead to, the animal being born or hatched, or to the creation and maintenance of a genetically modified animal line in such a state.
- Live cephalopods are also considered to be experimental animals.
- Killing an animal solely for the use of its organs or tissue is not considered an experiment.
- Furthermore, an activity with the main purpose of identifying the animal and an activity that is unlikely to cause pain, suffering, distress, or lasting harm to the animal of at least equivalent pain, suffering, distress, or lasting harm caused by needle puncture, according to good veterinary practice, is not considered to be an experiment.

- Experiments on animals may only take place where necessary, under the conditions laid down by law. The experiments may only be performed by professionally qualified persons, or persons under their direction.

- Any experiment with animals must therefore be carried out in accordance with the above-mentioned legislation.

- Every animal experiment must be conducted as part of an approved experimental project. Completed applications for approval of the experimental project are approved by the Ministry of Agriculture, or the established commission of the institution for ethical treatment of animals.

- Contact for breeding, supply, and use of experimental animals at Faculty of Science of UO: lukas.choleva@osu.cz

Working with Genetically Modified Organisms (GMO)

Genetically modified organisms (GMOs) are microorganisms, animals, and plants that have altered genetic material by the use of genetic engineering. The work must be carried out in accordance with the legal regulations of work with GMOs, and training in work with GMOs (see other useful links, at the end of the chapter, contact: tereza.sevcikova@osu.cz).

Laboratory waste management

Laboratory waste includes components of various physical, chemical, and biological materials. Most require special handling and special disposal, due to specific health risks. Particularly risky is the so-called “hazardous waste”, which can pose infectious or toxic risks, i.e. which contains viable micro-organisms or their toxins and other infectious agents with sufficient virulence in a concentration known or suspected to cause disease in humans or other living organisms.

The following general rules apply to laboratory waste:

- Hazardous waste is stored in marked, separate, covered, sealable, impermeable, and mechanically resistant packaging, preferably combustible, without the need for further handling of waste.

- Sharp waste (so called “sharps”) is stored in marked, combustible, strong-walled, impermeable, and leak-proof packaging.

- Waste collection before its final disposal in a reserved enclosed space is possible for a maximum of 3 days.

- Storage of hazardous waste is possible for 1 month in a freezer or refrigerated room at a maximum temperature of 8°C.

Other useful links

- *State Veterinary Administration of the Czech Republic*
- *Ministry of Agriculture of the Czech Republic – Animal Protection*
- *BOZPprofi* – professional portal focused on Health & Safety at Work
- https://www.mzp.cz/cz/nagojsky_protokol
- *GMO* Ministry for the Environment

Safety and legislation in human research

Safety in human research (excluding clinical research)

If adult legally capable persons are included in the research, written consent to participate in the research is obtained from them in advance. These persons are always truthfully informed about the focus of the research, the approaches used, and the handling of the obtained data (collection, storage, shredding, manner, and form of presentation of results).

If the research includes persons under the age of 18 and/or people with limited autonomy, it is necessary to discuss the research plan with the relevant *Research Ethics Committee*, which decides whether the proposed procedures comply with ethical rules. Furthermore, before starting the research itself, it is necessary to obtain written consent to participate in the research from this person and his/her legal representative or guardian (see Act No. 89/2012 Coll., Civil Code).

The persons involved have the right to withdraw from this research at any time during the research (in this case, the partial data already obtained from the research will be excluded and shredded). An exception is for anonymized questionnaire surveys (in paper or e-form), where the very nature of the research tool no longer allows the respondent to be found.

Personal and sensitive data collected (see Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46 / ES (General Regulation on the protection of personal data)) are always anonymized in the presentation of research results, so as not to lead to the identification of persons involved in the research. Also, when handling such (processing, archiving and shredding), this data is secured against misuse or theft.

The presentation of research results is governed by ethical rules, especially the emphasis is on human dignity and non-stigmatization of disadvantaged people or groups. In the event of ethical dilemmas, the author may submit the created text for assessment to the relevant ethics committee for research, for comment.

Basic principles of good clinical practice/research

Clinical research refers to research performed on people (healthy or sick), with the aim of developing new diagnostic methods, drugs, treatments, validating medical devices, improving knowledge about diseases, or improving patient care. It is usually preceded by so-called “preclinical studies” (which are often performed on cell cultures, tissues, or animals). Clinical trials in the Czech Republic are regulated by the Act on Medicinal Products, No. 378/1997 Coll., and are subject to approval by the State Office for Drug Control (SÚKL), and at least one ethics committee. Clinical research is performed in healthcare facilities, and must follow the rules of the institution/facility.

In general, the following principles apply:

- Clinical trials/research must comply with the law, good clinical practice, and ethical principles, based on the Declaration of Helsinki.

- Before starting a clinical trial, the foreseeable risks and disadvantages must be compared with the expected benefits for society and the individual subjects of the trial (the benefits must clearly outweigh and justify the risk).

- The most important aspects prevailing over scientific and societal interests are human rights, safety, and the health of the subjects.

- In the case of product testing, the available clinical and non-clinical information should be sufficient to justify the proposed evaluation.

- A scientifically sound, accurate, and detailed protocol (including changes or deviations in the trial) must be kept of the clinical trial.

- The clinical trial protocol (including changes or deviations in procedures) should be submitted to the ethics committee of the relevant institution, or its component (Faculty of Medicine of UO, possibly FNO, etc.) and approved (agreed to, recommended) by this committee before the start of the clinical trial.

- In the case of clinical trials, the qualified physician is always responsible for the medical care provided and the medical decisions concerning the subjects of the evaluation.

- All persons involved in conducting a clinical trial/research should have the appropriate qualifications (education, work experience, and general experience) to perform the respective tasks.

- Each subject participating in a clinical research must provide voluntary informed consent prior to participating in the clinical trial.

- During a clinical trial, all information on the course of the trial must be recorded, processed, and stored so that accurate reporting, evaluation, and verification may be achieved. This rule applies to all record types, regardless of the type of data carrier used.

- Confidential records, through which the subjects can be identified, must be protected in a way that respects privacy and the principle of confidentiality in accordance with the law.

- In the case of medicinal products that are being evaluated in clinical trials, the manufacture, handling, and storage must comply with the relevant guidelines of good manufacturing practice (always available from the relevant institutions). The use of drugs must be in accordance with an approved protocol.

- Quality assurance procedures must be in place for those aspects that are necessary to ensure the protection of the subjects of evaluation and the reliability of the results.

The evaluation of clinical research, in which UO employees participate, cannot be approved by the Ethics Committee for Research at UO, but by the ethics committees of the relevant medical facilities. The examiner may be present at the meeting (but may not vote, even if he/she is a permanent member of the EC).

The Commission must have the following composition:

- min. 5 members with relevant qualifications and experience;
- min. 1 member without medical education or professional scientific qualifications (must always vote);
- min. 1 member without an employment relationship with the founder/organiser (must always vote).

The examining physician who provides the clinical research has the following responsibilities, from the point of view of medical care:

- Decides on any medical matters in the study.
- Provides medical care in the case of adverse events of subjects (including the occurrence of clinically relevant laboratory values).
- Informs the subject in the case of further complications (e.g. concomitant illness).
- If the subject withdraws from the study, he/she must make an effort to find out the reasons.
- Informs the attending physician about the subject's participation in the clinical research.

A protocol is an essential part of a clinical research/trial, and any deviation from the protocol must be explained and described by the sponsor of the clinical trial, and approved by the ethics committee.

The protocol must contain the following information:

- basic description of the clinical trial (general information);
- the purpose and objectives of the clinical trial;
- clinical research methodology and schedule;
- rules for the selection and exclusion of subjects for evaluation;
- medical treatment of the subjects of evaluation and adverse events;
- prohibited, permitted, and rescue medication;
- assessment of effectiveness;
- safety assessment;
- statistics;
- access to source documentation (reports, tables, examination records, diaries, etc.);
- quality control and assurance;
- ethical aspects;

- data collection and storage, data publishing;
- finance and insurance.

The following rights must always be exercised for subjects in clinical research:

- participation in clinical research must be completely voluntary (consent is confirmed by the subject in writing - so-called “informed consent”);
- the subject may withdraw from the study at any time, and continue treatment with commonly available drugs/procedures;
- the subject has the opportunity to ask the investigator or other team members, before and during the study, for any information about the study, procedures, and treatment.

Informed consent shall be drawn up in two originals (for the subject and for the examiner), with the examiner being responsible for the following particulars:

- signing and dating of the consent document by the subject before any procedure in the study;
- recording the process in the source documentation;
- the signature of the medical doctor who led the discussion;
- ensuring that the subject of evaluation is fully informed;
- ensuring sufficient time to study and answer any questions;
- the subject is not affected or forced to enter the study.

Documentation and data protection

Introduction to open access to scientific information (Open Access)

Due to the rapid development of science, the availability of scientific information is a key condition for the development of not only individual scientific disciplines, but also public services. Availability brings a number of benefits (see below), and leads to faster and more efficient implementation of innovations. Promoting an open access to information policy is a priority for many research support providers and major research institutions, so this policy has already been included in the terms of the 7th Framework Programme and the programme Horizon 2020, and can be expected to be increasingly pursued and implemented.

In 2014, the Government Council for Science, Research and Innovation (RVVI) issued a recommendation "Open Access to published results of publicly funded research", and subsequently a document"*National strategy for Open Access in the Czech Republic to scientific information for the years 2017–2020*" was created, which further develops the principles of the National Policy for Research, Development, and Innovation for the years 2016–2020.

The document defines open access as follows:

Open access to the results of publicly funded research (hereinafter referred to as "OA" or "open access") is understood to mean the provision of free and unrestricted online access to the end user for scientific information, with the possibility of further re-use of this information. It ensures the dissemination of science and the exchange of knowledge, promotes innovation, and maximizes the benefits of science, while fully respecting the rule of law, in particular, copyright and industrial property rights. For the purposes of this strategy, "scientific information" is understood to mean scientific publications and research data.[7]

The starting point for the "open access" policy is the following resources and initiatives:

- Budapest Open Access Initiative – 2002;
- Bethesda Statement on Open Access Publishing – 2003;
- Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities – 2003;
- European Research Council open access rules – 2007 (revised 2013);
- Amsterdam Call for Action on Open Science (2016);
- Coalition-S (2019);
- OA rules in the EU Horizon 2020 programme.

The main benefits of open access are:

- faster dissemination of information and feedback;
- visibility for researchers and institutions;
- higher citations - more significant impact on research;
- contribution to the evaluation of research and development results;
- an increase in the likelihood of plagiarism, which, on the other hand, is easier to detect;
- ability to track the number of visits and downloads for each document.

For the Czech Republic, *National strategy for open access to scientific information* for the years 2017-2020, approved by the government, and Recommendation No. 2012/417/EU, on access to and storage of scientific information, are key.

[7] National strategy for open access to scientific information

Gold and Green Open Access

The open access system offers two basic options (paths):

- **GOLD Open Access** (gold path):
  - publishing in commercial and non-commercial peer-reviewed open access journals;
  - open access is provided by publishers (usually for a fee, paid by the authors);
  - copyright usually remains with the authors (the publishers of the journal is granted a license to publish their article), so they can continue to use the article freely, e.g. put it in an open repository;
  - journal directory - http://www.doaj.org/ (Directory of Open Access Journals).

- **GREEN Open Access** (green path):
  - self-archiving, self deposit in open repositories;
  - publishers traditionally require from authors the exclusive right to publish/make available their works; then no one else (not even the authors themselves) can publish the work without the publisher's consent; a licensing policy more friendly to these OA repositories is gradually being applied;
  - the authors provide open access to the published results by inserting their electronic version into a digital repository/storage for access and long-term preservation;
  - green OA does not provide a legal framework for licensing; use is permitted only within the limits of legal copyright restrictions;
  - the authors are limited by the conditions on the part of the publisher (whether the article can be published, which version, and under what conditions) given by the License Agreement/, Copyright Transfer Agreement;
  - publishers are divided according to the license granted to the authors (green - all versions, blue - postprint and published article, yellow - preprint, white - archiving is not supported);
  - the copyright agreement must always be reviewed so that the work can be published in a way that complies with all of the legal provisions;
  - publishers impose different periods of embargo before articles are freely available, in order to retain the benefit of a journal subscription (e.g. 6 months in science, technology, medicine; 12 months in social sciences and humanities);
  - if the publisher does not allow OA, the article may be stored in the repository in restricted mode;
  - if the providers of research grants (grant agencies, government institutions, private foundations) require the mandatory disclosure of results in the OA regime, and the publisher does not allow self-archiving, an exemption may be requested through an addendum to the contract.

Open access repositories

An up-to-date overview of available OA repositories can be found on the ROAR website – Registry of Open Access Repositories http://roar.eprints.org or OpenDOAR – Directory of Open Access Repositories http://www.opendoar.org.

Repositories may be divided into the following types:

- **institutional repositories –** the institution collects and preserves the work of its employees (preprints or postprints of published peer-reviewed articles, technical reports, student and

scientific qualification theses, etc.), institutional repositories require technical (data repository), administrative (repository management), and legislative support (e.g. measures the Rector on the obligation to store);

- **subject repositories –** are focused on a certain scientific area, e.g. *PubMed Central* http://pubmedcentral.nih.gov/ for the field of biomedicines;

- **personal pages** – lower visibility, low interoperability; it is more advantageous to create a personal professional profile within a permanently maintained scientific network, e.g. ResearchGATE https://www.researchgate.net/.

The following may be entered into OA repositories:

- *preprints*: the version of the work offered by the author to the publisher of the journal, which did not therefore undergo a review procedure and the resulting modifications;

- *postprints*: version of the work after the review procedure, with all content changes after the review procedure, but before the final linguistic and graphic adjustments made by the copyeditors of the journal;

- *publisher versions*: a finished electronic version of the work, set in the design and style of the journal; The pdf version is provided by the publisher, or the author produces it himself from the final version of the article.

DSpace appears to be one of the possible solutions for building digital libraries and institutional repositories:

- open source solutions designed primarily for academic institutions that produce scientific outputs, especially of a textual nature (scientific articles, monographs, etc.);

- the aim is to share results openly on the Internet;

- detailed information may be found on the DSpace Federation project website at http://dspace.org/;

- discussion group Dspacecz, e-mail: dspace@muni.cz.

In the Czech Republic, there are currently more and more repositories/storage banks at institutions. They are currently available at the following institutions (several repositories from the above list are OpenAIRE compliant):

- CAS (Czech Academy of Sciences)
- BUT Digital Library
- Charles University DSpace Repository
- Digital Library of the Czech Technical University in Prague
- Digital Library of the University of Pardubice
- DML-CZ (Czech Digital Mathematical Library)
- DSpace at TU in Liberec
- MU Repository
- National Repository of Grey Literature (National Technical Library)
- TBU Repository in Zlín
- UWB Digital Library in Pilsen
- DSpace Repository VSB – Technical University of Ostrava

Examples of OA policy in the Czech Republic:

Masaryk University **requires** its authors to always attach the full text (postprint or preprint) to the record of the peer-reviewed scientific result in the IS MU, and make it freely accessible, unless this is prevented by legal obstacles. Here are examples of resource links:
https://is.muni.cz/repo/1337480/cs/Svanda/Master-Claretus-Early-Didactic-Writings-on-Medicine
https://is.muni.cz/repo/1388277/cs/Sindelarova-Skupenova/Visualizing-literary-texts-in-university-language-courses

Measures related to Open Access at UO

- UO currently has limited repositories for storing final theses (Database of university qualification theses), and/or partial repositories, at some faculties.

- The PUBL database enables the storage of scientific publications. In connection with the introduction of the central storage of data on RDI results in the PUBL database, authors will be allowed to store results in this database; however, PUBL cannot currently be considered as a standard institutional repository of scientific results.

- UO recommends that authors publish the results of activities created from public funds in the OA mode.