Treatment of Research Data at Masaryk University
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     by Right of Database Maker
The goal of this material is to inform scientific workers about:

(1) how to proceed when collecting, gathering and processing research data,
(2) how to protect the data via intellectual property rights.
Treatment of Research Data

Research data represent all the data scientific workers acquire for the purposes of a particular research project. The law comes to the process of collection, gathering and processing of research data in the following aspects:

Legal Regulations Applicable to Research Data fixed in Tangible Medium

These mainly deal with the issue of biological material, its sampling and storage, storage of other research samples, treatment of chemical substances, waste liquidation, etc. This document does not address this issue in detail.

Advisory services in the given area are provided by lawyers of the respective economic unit or by the Legal Department of the Rector’s Office.

Legal Regulations Applicable to Research Data

Mainly following issues are concerned:

I. Personal Data Protection

Contact person in charge of personal data protection is the Manager for Internal Administration RNDr. JUDr. Vladimír Šmíd, CSc.: http://is.muni.cz/osoba/smid?lang=en

II. Legally-Ethical Aspects of the Research

Contact institution regarding legally-ethical aspects of research are ethical committees of the particular economic units.

III. Classified Information Protection

Contact person regarding classified information is JUDr. Naděžda Horynová: http://is.muni.cz/osoba/horynova?lang=en

Research Data and Intellectual Property Protection

IV. Research data, if it forms a database, could be protected by special rights of the maker of the database

Contact persons regarding legal protection of databases are lawyers of the Technology Transfer Office:

or Mgr. Václav Stupka:
Personal Data Protection
The area of personal data protection has to be addressed in biomedical and behavioural research. The law regulates it via Act no. 101/2000 Coll. on the Protection of Personal Data and Amendment to Some Related Acts. The respective state administration body is The Office for Personal Data Protection to which the notification of personal data processing is submitted (https://www.uoou.cz/en/).

In the area of personal data protection Masaryk University has adopted the MU Directive no. 3/2010 Personal Data Protection at MU: https://is.muni.cz/auth/do/rect/normy/smernicerektora/Smernice_rektora_3-2010.pdf.

The contact person for personal data protection is the Manager of Internal Administration RNDr. JUDr. Vladimír Šmíd, CSc. http://is.muni.cz/osoba/smid?lang=en
**Personal Data**

Any information regarding a determined or a determinable data subject.

*It could be a name, an address, a telephone number, information about education, jobs, family status, and salary (basically, it could be any data, including information about shoe size or hair colour).*

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**Sensitive Personal Data**

Personal data which is more strongly protected due to its character.

*It concerns information about nationality, race or ethnical origin, political attitudes, membership in trade unions, religion and philosophical beliefs, criminal conviction, health condition and sexual life, genetic and biometric data enabling full identification or authentication of the respective persons.*

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**Data Subject**

A natural person to whom personal data relates.

*A data subject cannot be a legal entity (a business company, institution or municipality). It is not important whether he/she is a citizen of the Czech Republic, a foreigner, a child or an adult, a legally competent or incompetent person. All these natural persons are data subjects. However, a dead person cannot be a data subject.*
Administrator

A subject who determines the purpose and means of personal data processing and who processes the data and is responsible for it.

*Masaryk University always has to be the administrator of personal data if the processing of the personal data is done by its scientific workers for purposes of meeting of his/her working obligations. Masaryk University shall not be the administrator if the scientific worker processes the personal data only for his/her personal needs (e.g. collection of personal data on Facebook, contact data in his/her mobile phone, etc.)*

Processor

A subject authorized by an administrator or by a special legislation to processes personal data.

*It can be an external company contracted by Masaryk University for personal data processing. If individual economic units make agreements concerning personal data processing with each other, it is only a division of responsibility within Masaryk University. The entire Masaryk University is the administrator and the processor of the data.*
Personal Data Processing

Operations or sets of operations which the administrator and the processor systematically perform with personal data (collection, storing, making them accessible, changes thereof, etc.)

*Personal data processing is, for instance, their gathering in a form of filled-in forms (in a paper form or online on the Internet), subsequent processing and data indexing, making databases with personal data, mining databases containing non-anonymized data, etc.*

Consent to Personal Data Processing

By such consent the data subject gives permission to the administrator to process particular personal data for specific purposes for a certain period of time. The consent does not have to be written, however the administrator must prove its existence. Therefore it is recommended that the consent is granted in writing.

*The consent must cover the use of all personal data processed by the scientific worker in the given research project. Considering that the personal data could be interesting for other research projects, the researchers are recommended to apply for the so called “secondary use”, which is consent to use the data in other research projects and consent to give the personal data to third parties.*

*If the European projects require the data to be accessed for free scientific use in an anonymized form (so called “open data”), the consent must include a permission for such use.*
I would like to process personal data in research. What do I have to determine?

- **circle of data subjects**
  natural persons from whom personal data are gathered within the frame of the research project

- **purpose of personal data processing**
  for instance, scientific exploration and research activities in the area...

- **scope of personal data processing**
  for instance basic data: name and surname, address of residence, date of birth, birth ID; other connected identification data: academic titles, contact or temporary address, other possible ways to reach the data subject (telephone, e-mail, etc.); data used for statistical purposes: socioeconomic markers such as gained or ongoing education, occupation, employer, income, number of persons in household, type of living, home equipment, etc.

- **method of processing and storing personal data**
  for instance, personal data of data subjects are kept on original deeds... in computer databases... on archive media... the processing tool could be for instance an information system, a questionnaire, software for statistical data processing, database software, etc.

before initializing data gathering, standards should be chosen on the basis of which the data will be kept (namely in case the data are stored
in electronic form); according to the scope of the data one can choose to keep it in a form of a regular database, in XML and CSV formats, or via some standardized software (MS Excel, etc.); the choice of the standard influences the possibilities of statistical data processing, data transfers and especially the options of data security

- **personal data protection security**
  security measures are set in accordance with the conditions of the respective economic unit (passwords to access computers or respective information systems, limited authorization of employees for access to particular rooms, etc.)

  administrator must determine who shall have access to the data and he has to document the received technically-organizational measures for personal data protection

- **termination of personal data protection and their liquidation**
  liquidation of personal data is done for instance: by shredding the original documents, by permanent anonymization of data in computer databases; by shredding of archive data media

**Is it necessary to report personal data processing?**

Personal data protection must be reported to the Office for Personal Data Protection. The report shall be carried out according to the MU Directive no. 3/2010 – Personal Data Protection at MU by the Manager of Internal Administration **RNDr. JUDr. Vladimír Šmíd, CSc.:** [http://is.muni.cz/osoba/smid?lang=en](http://is.muni.cz/osoba/smid?lang=en)
MU is authorized to make both general reports of personal data processing and special reports of data processing in research projects to the OPDP. It is always recommended to consider whether the personal data processing in the particular research project could be included into an already existing report which MU had made in the past.

**How should I give consent to personal data processing?**

Every type of consent to personal data processing is specific because each processing has a different purpose. MU does not use standardized forms. It is recommended to follow some examples that are on the Internet and adjust them to the conditions of the particular research. The data subject must be informed about which data shall be processed, for what purpose, to which administrator he/she gives the consent and for how long. The consent is a unilateral act and could be revoked unilaterally.

**I would like to process sensitive personal data. Are there any limitations in this area?**

Sensitive data could be processed only in enumerated cases (sec. 9 of Act no. 101/2000 Coll., on Personal Data Protection). In the area of research it means that the research participant must give express consent to sensitive data processing (e.g. DNA samples, health information, sexual life, etc.); such consent shall
contain the purpose of data processing and mark the personal data to which the consent applies and the period of usage. MU must be able to prove existence of such consent for the whole period of the data processing. The consent has to include advice on the rights of the research participants regarding access to the gathered data (sec. 12 of Act no. 101/2000 Coll.) and advice on their rights in case of unauthorized usage of personal data (sec. 21 of Act no. 101/2000 Coll.).

Regarding the sampling and storing of biological materials, special legal regulations apply (Act on Healthcare Services, Act on Specific Healthcare Services, Civil Code, Act on Public Health Protection, etc.). In these cases it is necessary to handle the sampling and treatment of the biological material in cooperation with a lawyer or a secretary of the respective economic unit so that the legal regulations are followed.

**When is MU in the position of a personal data processor?**

Generally, it could be cases when MU provides some services (usually commercial) to external subjects in which personal data is processed. In such case MU is obligated to make a written agreement on personal data processing with the administrator which shall include information about the scope, purpose and duration of the processing and guarantees concerning personal data protection securing.
Is it of any importance how the research data are used, shared or made accessible?

If the research data containing personal data are expected to be used for further research (secondary use) it is necessary to bear it in mind while formulating the consent to personal data processing. The data cannot be used for further research unless the research participant gives consent to their further processing. Should such data be shared with other subjects or made accessible (e.g. online), it is most appropriate to permanently anonymize them before the transfer or publication thereof so that they are not under the regulations of the Act on Personal Data Protection because the possibility of transfer and publication would be very limited.

In any case, the research participants must expressly agree with the use of their personal data and express such consent in writing.
Legally-Ethical Aspects of Research

The contact institutions regarding legally-ethical aspects of research are ethical committees of the individual economic units.
When is it necessary to deal with legally-ethical issues of the research?

Legally-ethical aspects of treatment of research data play their role in the areas of biomedical and behavioural research. These are primarily the following areas: human embryonic research, biometric research connected to sampling of biological material, animal research, research for military purposes, research on children and youth, pregnant women, the mentally retarded, ethnical and national minorities, drug addicts, delinquents, etc.

What legislation applies to these areas?

The given research areas are regulated by several legal provisions (e.g. Act no. 227/2006 Coll., on the Research on Human Embryonic Stem Cells and Related Activities and on Amendment to Some Related Acts; Act no. 246/1992 Coll. on the Protection of Animals Against Cruelty; Decree no. 207/2004 Coll. on the Protection, Breeding and Use of Experimental Animals; Act no. 296/2008 Coll. on Safeguarding the Quality and Safety of Human Tissues and Cells Intended for Human Application and on Amendments to Related Acts; Act no. 78/2004 Coll. on the Use of Genetically Modified Organisms and Genetic Products; Act no. 372/2011 Coll., on Health Services and Conditions under Which These Are Provided; Act no. 378/2007 Coll. on Pharmaceuticals and on Amendments to Some Related Acts, etc.)

In the majority of cases personal data protection has to be dealt with as well.
When do I have to pay attention to legally-ethical issues of research?

The legally-ethical issues usually have to be dealt with before submitting an application for a grant (however, the approval of the Ethical Committee and other supporting documents need not be obligatory parts of the project application; e.g. in the H2020 projects these documents are required only in the negotiation stage).

Legal issues of research involve meeting the terms stipulated by legal regulations (Act on the Protection of Personal Data and the mentioned special legal regulations); ethical issues concern scientific hypotheses, methodology and originality of research within the scientific knowledge. Furthermore, there are issues of human dignity, freedom, health, quality of life and safety of persons participating in the research.

Benefits of the research for the society are assessed in the legally-ethical consideration as well as its overall contribution and potential risks. The possibility of harm to human life, health and dignity or damage to property is also considered.

In case any risks are identified during an assessment of a research project, their gravity, methods of their prevention and minimization of consequences are assessed. Also, it is assessed whether probands gave informed consents to research on human beings (be it biomedical or behavioural research) and whether such consents cover all aspects of the research and subsequent use of the research data.
**Who deals with legally-ethical issues of research at Masaryk University?**

Legally-ethical issues should be dealt with by an ethical committee of a given economic unit (if it exists). If a new method is implemented, its assessment by the committee is required by law (sec. 38 of Act no. 372/2011 Coll.); the same applies to clinical research (sec. 53 et seq. of Act no. 378/2007 Coll.; sec. 9 of Act no. 123/2000 Coll.)

**How is animal research regulated?**

Act no. 246/1992 Coll. on the Protection of Animals against Cruelty regulates protection of laboratory animals. The research using animals is assessed by professional committees. There is the Professional Committee for Securing Good Living Conditions of Laboratory Animals at MU. Information about the committee is available on the website [http://www.med.muni.cz/index.php?id=197](http://www.med.muni.cz/index.php?id=197).

**Where is the informed consent regulated?**

Legislative requirements for informing the research participants are regulated by the Convention on Human Rights and Biomedicine; in the area of biomedical research it is Act no. 372/2011 Coll., on Health Services and Conditions under Which These Are Provided; and Act no. 373/2011 Coll. on Specific Health Services.

The informed consent must be provided namely if the research is done on patients, children, healthy volunteers, foreigners, persons legally incapable
to grant consent, other persons (e.g. prisoners) and if the research works with personal data, human genetic material and biological samples.

Researchers have to get consent from all the research participants and document it.

**What does the informed consent have to contain?**

- explanation of the research purpose
- expected time of participation in the research
- description of procedures to be followed/description of medication to be tested and identification of all experimental procedures
- declaration that participation in research is voluntary
- information about who organizes and finances the research
- description of foreseeable danger, discomfort and disadvantage
- description of advantages for the research participants or other persons which could be reasonably expected from the research
- publication of suitable alternative procedures if there are any
- description of data protection, confidentiality, privacy, incl. personal data storage
- description of treatment of random findings
- if there is a risk of the research causing harm, information whether there is a possibility of financial settlement in case of damage and information about insurance of the study
- contact information of a person who can be reached in case of additional questions
- declaration offering the chance to ask questions and information about possibility to withdraw from the research
- explanation of what will happen to data or samples after termination of the research and whether the data/samples will be kept or provided to a third party for further research
- information about what will happen with the research results

The informed consent must be comprehensible for the research participants.

**EXAMPLE OF LEGALLY-ETHICALLY VIABLE RESEARCH:**

An assistant professor at the Faculty of Social Studies plans a research project “Children Online” focusing on the behaviour of children aged 8–18 on the Internet. The research will be carried out via questionnaires and personal interviews; the researcher will look into the children’s experience with different types of risks (pornography, bullying, virtual pressure due to race, ethnicity or religion, etc.)

The key legally-ethical issues in this case concern research hypothesis, methodology (formulating questions), personal data protection and consent with personal data processing (from the children and their parents; a consent from the child is not enough because children are not fully legally competent). The researcher has to inform the probands and their parents about all important facts, i.e. what he/she is researching and why, what methods will be used, how confidentiality and safety of the data is secured. He/she should inform the participants that the research is voluntary, that they can withdraw from it anytime and it is not obligatory to answer questions they consider unpleasant. He/she shall also notify the participants and their parents where to file complaints and what will happen to the collected data after the research is terminated (i.e. whether they give consent with secondary use of the scientific data).
EXAMPLE OF LEGALLY-ETHICALLY UNVIALE RESEARCH:

Epidemiologists suggest examination of relationship between vasectomy and prostate adenocarcinoma via a case study. Men with prostate cancer confirmed by histologic examination will be asked to participate based on medical records. The control group will consist of men of the same age who do not have prostate cancer; they will be chosen randomly from a phone book. Considering that the research has to be done fast, the epidemiologists suggest that the study is carried out by means of phone interviews. The inquirers from the hired call centre will contact all eligible participants by phone and they will try to get their consents for participation in the study.

The scientists believe that the participants’ answers could be biased if they knew the exact goal of the study (the possible relationship between vasectomy and prostate cancer). The participants shall not be informed about the goal (they will only be told it is a research of risk factors for prostate diseases). Questions asked via telephone (for both groups) shall include information that will make the participants believe the research is only focused on prostate cancer (e.g. age, family status, number of children, history and time period from the vasectomy, previous and current diseases, smoking and alcohol consumption, use of other methods of fertility regulation and family anamnesis of the prostate carcinoma).

Legally-ethical aspects of such research involve these issues: access to and inspection of medical records (sec. 65 of Act no. 372/2011 Coll.), handling medical records (Regulation no. 98/2012 Coll.), transfer of such data to third parties. What also has to be assessed is the research feasibility, aptness of the used method and questions in relation to the chosen hypothesis (including usefulness of the telephonic questionnaires), absence of written consent, intentional concealing of the real purpose of the study, issue of personal data protection from the perspective of hand-over of data to employees of the call centre, etc.)

Such research would not get through the legally-ethical assessment at Masaryk University.
Protection of Classified Information
Protection of classified information is regulated by Act no. 412/2005 Coll. on the Protection of Classified Information and Security Capacity and statutory instruments thereto.

The person in charge of classified information protection at Masaryk University as per Rector's Measure no. 4/2013 is the Security Manager of MU – the head of the Office of the Rector's Inspectorate **JUDr. Naděžda Horynová:**

http://is.muni.cz/osoba/horynova?lang=en
Information in any form recorded on any data storage media marked in compliance with the Act disclosure or abuse of which could cause detriment to the interest of the Czech Republic or could be disadvantageous for this interest, and which is on the list of classified information.

*Basically, it could be any information marked by its originator as classified. For instance, it could be security project documentation, research results in the security area, etc.*

Classified information is categorized into four security levels according to harm or disadvantage it could cause to the interests of the Czech Republic:

- **Top secret:** disclosing such information to an unauthorized person could cause exceptionally grave damage to the interests of the Czech Republic,
- **Secret:** disclosing such information to an unauthorized person could cause grave damage to the interests of the Czech Republic,
- **Confidential:** disclosing such information to an unauthorized person could cause damage to the interests of the Czech Republic,
- **Restricted:** disclosing such information to an authorized person could have undesirable effects on the interests of the Czech Republic.

*Currently, only information of the security level “Restricted” can be processed at Masaryk University.*
Security Manager

The Rector shall be responsible for the protection of classified information at Masaryk University. The Rector has authorized the head of the Inspection Department of Masaryk University Rector’s Office to act as the security manager.

The security manager is in charge of unified protection of classified information; he/she cooperates with the National Security Authority (http://www.nbu.cz/en/), takes preventive measures and performs inspections in the area of protection of classified information.

Personal Security

It is a type of protection of classified information. It concerns selection of natural persons who shall have access to classified information, verification of terms for their access to classified information, their education and protection.

Only natural persons who urgently need the classified information for their job or activities could get acquainted with it; they must be holders of valid Notifications or Certificates of a natural person and they must be instructed. These persons are authorized to get acquainted with the classified information up to the respective level of security. Notification of meeting the conditions to access the classified information of the “Restricted” level is issued by the security manager upon meeting the statutory conditions.
Administrative Security

It is a system of measures goal of which is to protect classified information during its creation, reception, recording, processing, transport, storing, elimination, shredding and archiving or other manipulation. It is regulated by Regulation no. 529/2005 Coll. on the Administrative Security and Registries of Classified Information.

It concerns mainly the use of administrative tools for recording classified information and for recording disposal with the classified information. The security manager is in charge of preparation, recording and authentication of the administrative tools.

Physical Security

It is a system of measures that prevents or impedes access to classified information by unauthorized persons and/or recording the access or an attempt thereof. This goal is achieved by choosing places or premises in which classified information can be kept and disposed with and which are adequately protected based on the requirements of the Act on Classified Information.

Currently, Masaryk University has premises where processing classified information of the “Restricted” level is possible. These premises are located in the economic units in which the need to dispose with the classified information comes to existence. Information of the “Restricted” level can also be kept in the central storage. If it is necessary to use classified information of a different level in research, the access to such information must be provided for instance by the contracting authority.
I would like to process classified information in my research. What do I have to do first?

The most appropriate procedure is to contact the security manager JUDr. Naděžda Horynová ([http://is.muni.cz/osoba/horynova?lang=en](http://is.muni.cz/osoba/horynova?lang=en)) and discuss with her how to proceed. Mainly, it is necessary to meet the conditions of personal security, i.e. to be a holder of a valid Notification or Certificate, depending on the security level of the information you are willing to process. Should the information be processed directly at MU, the requirements of administrative and physical security must be met as well. Presently, only information of the “Restricted” level could be processed at MU.

How does physical security work at MU?

Currently, there are several secured areas for processing and storage of classified information meeting the conditions for processing information of the “Restricted” level. These areas are located on the premises of the economic units where the need of access to the classified information comes to existence. Other economic units can also use the central storage for storing information of the “Restricted” level. If needed, a secure area can also be built in other economic units, however structural alterations and security features are relatively expensive.
How does administrative security work at MU?

Administrative security vests in keeping records of classified information, records of disposition with them and their origination. Instructions for maintaining administrative security and the necessary tools are provided by the security manager.

I would like to process classified information on a Computer. What do I have to do?

In such a case it is necessary to provide for another security measure – security of information and communication systems. The necessary assistance is provided by the Institute of Computer Science and the security manager. The information system (computer) on which the classified information is processed must meet the requirements of the law and statutory instruments.
Protection of Research Data by Right of Database Maker
Scientific data which is acquired in research projects can create a database. The database can be protected by a special right of the database maker if it is a database specific by quantity (large volume of data) or quality (internal structure of data).


The contact persons regarding protection of databases are the lawyers of the Technology Transfer Office:

**JUDr. Pavel Koukal, Ph.D.**

**Mgr. Václav Stupka**
What do the database rights protect and who is their owner?

The database rights protect the investment the maker made to create the database. If the database came to existence as a part of research done at Masaryk University, MU (or the respective economic unit) is the database maker, not the particular researcher who, de facto, made the database.

How long does the protection last and what is it based on?

The special right of the database maker is protected by the Copyright Act (sec. 88 et seq. of Act no. 121/2000 Coll.) and shall be valid for 15 years after making the database. The principle of the database right is the entitlement of the database maker to exclusively use the database and grant licenses for use thereof.

How can the database be handled?

Disposition with database data depends on what kind of data it is formed of. If it is personal data, mining of the database is limited by protection of personal data. If it is anonymized data, personal data protection does not apply to such a database and it can be used within an open infrastructure in an open-data regime or commercially.
**How do rewards for commercialization work?**

If the database is commercially used and Masaryk University gains funds in the respective year for database use, the database maker (i.e. the scientist who participated in its making) could be entitled to a rewarded from the commercialization. Details are stipulated in the MU Directive no. 10/2013 Intellectual Property at MU in sec. 23.

**How is database protection regulated at MU and who can I contact?**


License agreements regarding database mining shall be made by the head of the respective economic unit. Legal consulting regarding license agreements is provided by the Technology Transfer Office of MU (http://www.ctt.muni.cz/en/).