Data protection offences constitute the official offence based on information about potential violation of law.

16.5 Governance

(i) At least in the biomedical sciences research involving human participants usually is subject to ethical review by research ethics committees or similar bodies. Data protection, however, not only affects the biomedical sciences, but potentially all fields of research. Are you aware of any committees (e.g. research ethics committees, ethical review boards) or agencies (e.g. national research funding agencies, national security agencies) in your country that review data protection issues in research projects? If yes, are reviews mandatory and governed by specific guidelines or regulations? Do you know which aspects of data protection review bodies focus on? Are reviews only conducted before the actual research starts or is the research process monitored as well?

In the Republic of Latvia, the Data State Inspectorate is the only body with powers to run the case related to personal data protection issues.

(ii) What instruments (e.g. ethics self-assessments at the proposal stage), if any, do research funding agencies and other research supporting bodies in your country use to promote data protection in ICT R&I? Do they facilitate the use of these instruments or data protection impact assessments by providing tools (software or other), templates or guidelines?

Requested information is not available.

(iii) Are there any national regulations or procedures that specify what to consider when ICT R&I involves defence technology, dual use technology or is affected by embargoes? If yes, who are the bodies responsible for monitoring and enforcement? Are there any tools researchers and innovators working on security-sensitive technologies can use in order to protect against industrial espionage and other confidentiality breaches?

This field is regulated by national regulation. Ministry of Defence and instructions authority of Ministry such as Latvian State Security Service are responsible monitoring and enforcement in this field. Detailed information is not available.

17 Lithuania

Danguolė Morkūnienė (State Data Protection Inspectorate)

17.1 Informed consent

17.1.1 General Regulatory Framework

Regulation	Link	Type of regulation	Brief description and scope

Republic of Lithuania Law on Ethics of Biomedical Research	https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/76582f93e9c811e59b76f36d7fa634f8?jfwid=-gs204ij9y law in English https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.101629/asr?positionInSearchResults=0&searchModelUUID=03702bb3-7041-45a4-aa11-a23401f119d2 law in Lithuanian	Hard law	This law set forth ethical requirements for biomedical research, terms and conditions of processing of human biological samples and managing personal health information for the purposes of biomedical research and activities of biobanks, terms and conditions of issuance of approvals to conduct biomedical research, supervision of conducting of biomedical research and liability of sponsors of biomedical research and investigators for damage resulting from the subject's health impairment or death.
Decree of the Ministry of Health on the Detailed Requirements for the Content of a Person's Consent to Participate in Biomedical Research and for the Information about the Biomedical Research as well as a Procedure for Giving and Withdrawing the Consent	https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/b9895bf0ba3811e5be9bf78e07ed6470/asr?positionInSearchResults=0&searchModelUUID=8a55d841-b719-46be-b2c7-b7d537a531b4	Hard law	This law determines requirements for the content of a person's consent to participate in biomedical research, and for the information about the biomedical research as well as a procedure for giving and withdrawing the consent.

Main regulatory tools addressing data protection issues and informed consent in Lithuania

(i) The GDRP does not apply to purely personal or household activity. Is there any provision under national law for the protection of these data categories?

The Civil Code of the Republic of Lithuania govern property relationships and personal non-property relationships related with the aforesaid relations, as well as family relationships. In the cases provided for by laws, other personal non-property

relationships shall likewise be regulated by this Code. The Civil Code of the Republic of Lithuania also regulates specific rights of natural persons, also rights to privacy and secrecy.

(ii) The GDPR does not apply to national security. Is there any national regulation covering this topic (in terms of data protection issues)?

Republic of Lithuania Law on Cyber Security establishes cyber security principles, specifies institutions which develop and implement cyber security policy, defines powers of such authorities in the field of cyber securities, and determines duties of cyber security entities as well as inter-institutional cooperation. This cooperation is also possible in the field of national security.

Republic of Lithuania Law on the Basics of National Security of Lithuania establishes the basics of ensuring the national security of Lithuania.

Law of the Republic of Lithuania on Legal Protection of Personal Data, Processed for the Purposes of Prevention, Investigation, Detection or Prosecution of Criminal Offences, or the Execution of Criminal Penalties, or National Security, or Defence establishes that "When state authority of the Republic of Lithuania process personal data for the purposes of national safety or defence, this law is applied to the extent where other laws do not determine otherwise" (see Article 1, paragraph 2).

Name of Authority	Link	Is this an independent body?	Number of employees	Level of activity	Response to requirements, questions, etc. made by the public
State Data Protection Inspectorate	https://vdai.lrv.lt/en/	Yes[124]	32[125]	High	In 2018 State Data Protection Inspectorate provided 6298 consultations, prepared 233 public information tools, drafted 12 methodological documents, 859 complaints were received. In 2018 while performing the function of approximation of legal acts delegated to the Inspectorate, it provided its comments and proposals within its remit on 182 draft laws submitted, on 153 draft orders, on 151 draft rules of procedure for

[124] During the Schengen evaluation in 2019, experts made recommendations on strengthening independence, for example in the preparation of strategic action plans.

[125] Since 2020 6 additional positions of new employees will be created. The Supervisory Authority will have 38 foreseen positions.

					information systems and 18 registers, on 78 draft resolutions of the Government of the Republic of Lithuania and other legal acts.

Information regarding Data Protection Authority in Lithuania

(iii) Does your national legislation introduce a specific definition of "data processing for research purposes"? Does your national legislation define "research in public interest", e.g. referring to Ministerial lists of expected research, etc.?

Republic of Lithuania Law on Higher Education and Research determines, that fundamental research means experimental and/or theoretical operations which are carried out primarily to acquire new knowledge about the essence of phenomena and/or observed reality without aiming, at the time of research, to use the obtained results for a specific purpose; scientist means a researcher who has a scientific degree. According to the principle of accountability, the data controller must to implement the appropriate technical and organisational measures to ensure and be able to demonstrate that the personal data are processed in accordance with the data protection rules (see Article 24 of GDPR).

There is no definition of "public interest" in our national legislation, however, data processing in public interest is lawful if the processing has a basis in Union or Member State law. It should also be for Union or Member State law to determine whether the controller performing a task carried out in the public interest or in the exercise of official authority should be a public authority or another natural or legal person governed by public law, or, where it is in the public interest to do so, including for health purposes such as public health and social protection and the management of health care services, by private law, such as a professional association (see Recitals 45 of GDPR).

Lithuanian legislation does not introduce specific definitions "data processing for research purposes" or "research in public interest".

(iv) Does your national legislation implement Article 89 of the GDPR, introducing in particular some specific safeguards to adopt in case of data processing for research purposes?

Republic of Lithuania Law on Higher Education and Research establishes principles of research, Republic of Lithuania Law on Documents and Archives ensure the application of the legal acts of the European Union, in the sphere of regulation of the protection of individuals with regard to processing of personal data, the activities of Statistics Lithuania are regulated by the Law on Official Statistics, which consolidates the concept of official statistics and the general principles of the organization thereof, stipulates the rights and duties of respondents, defines the tasks, rights and duties of institutions managing official statistics and their liability for the violation of the law and etc.

National legislation after the entry into force of the GDPR shall not provide for additional derogations from the rights referred to in Articles 15, 16, 18 and 21 subjects of the GDPR when personal data are processed for scientific research purposes.

(v) Does your national legislation provide specific cases and safeguards for processing sensitive data beyond article 9 of the GDPR? Which cases? Which safeguards?

It should be noted that the Republic of Lithuania Law on the Rights of Patients and Compensation of the Damage to Their Health establishes the treatment of health data and requirements for their confidentiality. The rights of patients are regulated by the Constitution of the Republic of Lithuania, the Civil Code of the Republic of Lithuania and the Law on the Rights of Patients and Compensation for the Damage to Their Health. Article 11 of the Republic of Lithuania Law on the Rights of Patients and Compensation of the Damage to Their Health establishes requirements for patient participation in biomedical research and in the teaching process.

Other legislation regulating the processing of sensitive data is not relevant in this particular case.

(vi) Do you have a national (or some regional) Code(s) of Conducts or national Code of Ethics for data processing in research? Could you please summarize the content of such codes (specifying scope, suggested measures to protect individuals, prohibitions, exemptions, etc.)?

No. There is no national Code of Conduct or national Code of Ethics for data processing in research in Lithuania.

Nevertheless, we have not national, but some specific ethical codes in Lithuania, for example:

- Lithuanian Doctor Professional Ethics Code
- Code of Ethics of the Lithuanian Society of Obstetricians and Gynecologists
- Code of Professional Ethics of the Lithuanian Medical Association
- Code of Professional Ethics for Dentists
- Lithuanian Code of Professional Ethics for Physiotherapists
- Code of Pharmaceutical Marketing

The codes of ethics do not contain detailed or additional provisions that regulate research.

(vii) Does your national legislation give specific definitions of data processing for "statistical purposes"? Are there specific rules that apply to such data processing?

The activities of Statistics Lithuania are regulated by the Law on Official Statistics, which consolidates the concept of official statistics and the general principles of the organization thereof, stipulates the rights and duties of respondents, defines the tasks, rights and duties of institutions managing official statistics and their liability for the violation of the law. The above-mentioned law establishes requirements for the confidentiality and use of statistical data (see Article 14) and the protection of statistical data and statistical information (see Article 15).

Director General of Statistics Lithuania 5, September 2018 approved order "On the Approval of The Information Security Policy of Statistics Lithuania" which provides that, for example:

"Aware of the importance of security of the processed data and statistical information under preparation, Statistics Lithuania undertakes when drafting, disseminating, coordinating and developing national official statistics:

1. to ensure secure statistical data collection, processing and dissemination of statistical information prepared on the basis thereof;

2. to carry on activity taking into account key principles of information security – confidentiality, integrity and availability, in order to ensure information provided by respondents and interested parties;

3. to protect data of the Integrated Statistical Information System from illegal disclosure or unauthorized dissemination;" (…)

(viii) Are there any other references to data processing for research purposes in your national legislation? (e.g. duties to have a DPO, duties to perform a DPIA, duty to collect consent, etc.)

17.1.2 Rights of data subjects and data processing

(i) Are there any other references to data processing for research purposes in your national legislation? (e.g. duties to have a DPO, duties to perform a DPIA, duty to collect consent, etc.)

The director of the State Data Protection Inspectorate has approved the list of data processing operations subject to the requirement to perform data protection impact assessment, for example:

"1. Personal data processing is conducted for scientific or historical research purposes in at least one of the following cases:

1.1. when special categories of personal data are being processed without the data subject`s consent or personal data processing is conducted matching or combining datasets;

1.2. when data of under-age persons are processed;

1.3. when the personal identification number is processed."

Article 5(2)(4) of the Republic of Lithuania Law on Ethics of Biomedical Research determines, that biomedical research may be conducted only if a person's consent to participate in research (with the exception of the cases referred to in Article 7(5) and (11) of this Law) has been obtained or, when biomedical research is conducted on the human biological samples and health information processed in a biobank – a person's consent to biobanking has been obtained.

(ii) Are there any special requirements regarding informed consent at the national level?

No.
It should be noted that Article 6 of the Republic of Lithuania Law on Ethics of Biomedical Research sets requirements for the protection of vulnerable subjects.

(iii) Are there any special requirements regarding data processing at the national level?

Yes. The Republic of Lithuania Law on Protection of Personal Data (Since the entry into force of Law No. XIII-1426 (16 July 2018) sets special requirements regarding data processing:

Article 3. Peculiarities of Processing of Personal Identification Number

1. Personal identification number can be processed when any of the conditions for the processing of personal data referred to in Article 6 (1) of Regulation (EU) 2016/679 are lawful.

2. It is prohibited to publish the personal identification number.

3. It is prohibited to process personal identification number for purposes of direct marketing.

Article 4. Processing of Personal Data and Freedom of Expression and Information

When personal data is processed for journalistic or academic, artistic or literary purposes, Articles 8, 12 to 23, 25, 30, 33 to 39, 41 to 50, 88 to 91 of Regulation (EU) No. 2016/679 shall not apply.

Article 5. Peculiarities of the Processing of Personal Data in Relation to the Employment Context

1. It is prohibited to process personal data of a candidate to perform duties or carry out work functions, or personal data of an employee relating to convictions and criminal offenses, unless such personal data are necessary to verify that a person meets the requirements established in laws and regulations in force to perform his duties or functions.

2. The data controller may collect personal data relating to qualifications, professional skills and specific characteristics of a candidate applying to perform duties or work functions from a former employer, by informing the candidate in advance and from the existing employer – only with a consent of the candidate.

3. When processing video and/or audio data in the workplace and at the controller's premises or in the areas where its staff is employed, and processing personal data related to the monitoring of employees' behaviour, location or movement, these employees shall be informed of such processing of their personal data by signing or other means that prove the fact of informing providing the information referred to in Article 13 (1) and (2) of Regulation (EU) 2016/679.

4. The provisions of this Article shall also apply to the processing of personal data of individuals who work on the basis of legal relations equal to the employment relations specified in Law on Employment of the Republic of Lithuania and personal data of candidates applying to work on these grounds.

Article 6. The age of the Child to Give a Consent who is Offered with Services of Information Society

When information society services are directly offered to a child, the processing of the child's personal data is legal if consent is given by a child older than 14 years of age in accordance with Article 6 (1) (a) of Regulation (EU) 2016/679."

(iv) Are there any special requirements to exercise data subject's rights (right of access, correction, deletion of personal data)?

No.

It should be noted that Article 4 of the Republic of Lithuania Law on Protection of Personal Data (Since the entry into force of Law No. XIII-1426 (16 July 2018) determines which articles do not apply when personal data are processed for journalistic or academic, artistic or literary purposes:

"Article 4. Processing of Personal Data and Freedom of Expression and Information

When personal data is processed for journalistic or academic, artistic or literary purposes, Articles 8, 12 to 23, 25, 30, 33 to 39, 41 to 50, 88 to 91 of Regulation (EU) No. 2016/679 shall not apply."

17.1.3 Minor sensitive data and other additional categories of data

(i) Are there additional rules beyond the ones enforced by the GDPR for processing special categories of personal data (e.g. sensitive data or data of legal persons/entities)?

(ii) Are there any special rules when processing personal data of children? At what age can a minor provide consent according to your regulation?

Yes.

There is additional rule about the age of the Child to Give a Consent who is Offered with Services of Information Society. This rule set in Article 6 of The Republic of Lithuania Law on Protection of Personal Data: "When information society services are directly offered to a child, the processing of the child's personal data is legal if consent is given by a child older than 14 years of age in accordance with Article 6 (1) (a) of Regulation (EU) 2016/679".

Decree of Ministry of Health and Ministry of Social Affairs on the Procedure for a Minor's Participation in Biomedical Research, No. V-235/A1-83 (2016) (available only in Lithuanian) establishes that a child younger than 12 who can understand the information shall be informed orally about the biomedical research. A child younger than 12 may also be presented with a consent form for participation in biomedical research. Its text is adapted to the child.

For a child older than 12, information is provided orally and in a consent form for biomedical research.

The opinion of a child younger than 12 is described in biomedical research documents. One of the child's representatives confirms by signature that the child's opinion has been heard.

If a child older than 12 understands the information provided to them and agrees to participate in biomedical research, he shall sign a consent form for participation in biomedical research.

If a child older than 12 understands the information provided to him and agrees to participate in the biomedical research but cannot, for objective reasons, read or sign the child's consent form, the child's opinion shall be heard orally and noted in the research documentation.

(iii) Are there other vulnerable individuals identified in your national legislation?

Yes. Article 5 of The Republic of Lithuania Law on Protection of Personal Data found particularities of employees' data processing.

Article 6 of the Republic of Lithuania Law on Ethics of Biomedical Research sets requirements for the protection of vulnerable subjects.

17.1.4 Deceased individuals and personal data

(i) As recital 27 clarifies, the GDPR does not apply to deceased individuals. However, some countries provide people with the right to have all their personal

data deleted once they pass away. Some others empower their close relatives to do the same. In some others, these data cannot be used at all without an explicit judicial mandate. What is the situation in your country?

Provisions about deceased individuals are in The Republic of Lithuania Law of Civil Code. Deceased individual's information processing depends on the situation (e.g. inheritance and etc.).

17.1.5 Accountability and Data Protection Impact Assessment

(i) Does your national regulation introduce further provisions related to general accountability? Any particular requirements? Any specific procedures?

The national legislation does not have any additional provisions or particular requirements related to the general accountability principle.

(ii) Are data protection impact assessments requirements specified by your national regulation? Any particular requirements? Any specific procedures?

Director of State Data Protection Inspectorate 14, March 2019 adopted order "ON THE APPROVAL OF THE LIST of DATA PROCESSING OPERATIONs SUBJECT TO THE REQUIREMENT TO PERFORM DATA PROTECTION IMPACT ASSESSMENT".

(iii) Any specific reference to data processing in research?

DPIA list in Lithuanian is available in this reference: https://www.e-tar.lt/portal/lt/legalAct/abb01940465511e9a221b04854b985af.

Republic of Lithuania Law on Ethics of Biomedical Research in Lithuanian you can find in this reference:

https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/7aa28cc261bb11e5b316b7e07d98304b

Republic of Lithuania Law on Ethics of Biomedical Research in English you can find in this reference:

https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/76582f93e9c811e59b76f36d7fa634f8?jfwid=-gs204ij9y

17.2 Commercialization of data

17.2.1 General Regulatory Framework

Regulation	Link (English version if possible be)	Type of regulation (	Brief description and scope
General data protection regulation (GDPR)	https://eur-lex.europa.eu/eli/reg/2016/679/oj	Hard law	Any kind of personal data can be processed only according to the requirements of GDPR (for example, article 5, 6, 9, 32, etc.)

Main regulatory tools addressing data commercialization in Lithuania

17.2.2 Practice

(i) In practice, does your country allow contracts based on exchange of personal data for services (for instance, to gain access to an app)?

In Lithuania, it is neither allowed nor forbidden. Service providers must ensure GDPR requirements. To be emphasized the importance of following the regulation of GDPR. So any exchange of personal data may be processed, including provision for other person only if at least one of the basis for lawful processing, which is set in Articles 6 or 9 of GDPR, can be met and only if all the principles for processing, which are set in Article 5 of GDPR, are followed and applied.

It should be noted that where suspected or inferred conditions might tend to make individuals more vulnerable (e.g. through cognitive impairment) it is entirely incompatible with human rights obligations to permit profiling or targeted marketing of such vulnerable persons

(ii) Do you know if these practices are routinely performed?

The State Data Protection Inspectorate has received only a few complaints about such potentially unlawful processing. Inspectorate does not have the data whether such activity is happening routinely but The State Data Protection Inspectorate is informed that it happens from time to time.

(iii) Does your country have any specific regulation on the remuneration of data subjects if profit is made out of their data?

No such regulation is known.

There were proposals from politicians to regulate the remuneration of data subjects if profit is made out of their data. There are no real draft laws.

(iv) Do you have any particular national regulation on the secondary use of data?

Yes, “Law of the Republic of Lithuania on the Right to Obtain Information From State and Municipal Institutions and Agencies” (link) but it cannot be used for secondary use of personal data (as GDPR must be followed for this), for or of copyright or related rights of third parties or sui generis rights of database author, etc. (see Part 2 of Article 2).

Article 5 (1) (b) of GDPR establishes, that “Personal data shall be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation')”. So GDRP is applied when research involves secondary use of personal data.

(v) Do you have any specific protection for metadata or non-personal data in your country?

There is no special protection, but metadata or non-personal data are processed in accordance with this legislation:

1. Information Resource Management Law of the Republic of Lithuania (https://www.e-tar.lt/portal/lt/legalAct/TAR.85C510BA700A)

2. Description of general requirements for electronic information security (https://www.e-tar.lt/portal/lt/legalAct/TAR.FC952AC6A109/asr)
3. Technical Requirements for Electronic Information Security of State Registers (Cadastres), other Registers, State Information Systems and other Information Systems (https://www.e-tar.lt/portal/lt/legalAct/TAR.5DFE39DEAB5A
4. Law of the Republic of Lithuania on electronic communication (https://www.e-tar.lt/portal/lt/legalAct/TAR.82D8168D3049/asr)
5. Etc.

17.2.3 Nature of Data

(i) How does your country classify data? Is it a product/commodity/good or service? Do you have an additional construct for data?

Lithuania does not classify personal data as good or service or product, etc. We consider it only as person's right to private life which is guaranteed to be protected by law

(ii) Except for the Sui Generis Right on the protection of databases, do you have a legislation protecting data in your country (e.g. like copyright)?

Republic of Lithuania Law on Copyright and Related Rights (EN, it is not an official version).

(iii) Are you aware of any mechanisms to determine the value of data?

No.

17.3 Security and cybersecurity

17.3.1 General Regulatory Framework

Regulation	Link	Type of regulation (hard law, soft law…)	Brief description and scope
Cyber Security Law of the Republic of Lithuania	https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/f6958c2085dd11e495dc9901227533ee/asr In English:https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/ceb0e7b291ad11e8aa33fe8f0fea665f?jfwid=-gs204ihxw	hard law	This law establishes the principle of cyber security, the authorities responsible for the formulation and implementation of cyber security policy, the powers of these authorities, the level of cyber security, the work of cybersecurity entities, as well as inter-institutional cooperation.
National cyber security strategy	https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/94365031a53411e8aa33fe8f0f	hard law	Identifies key directions for national cyber security policies in the public and private sectors.

	ea665f?jfwid=dg8d31595		
The Critical Information Infrastructure Identification Methodology **The Description of the Organisational and Technical Requirements for cybersecurity for cybersecurity entities** **The National Cyber Incident Management Plan**	https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/e16e7761fc4b11e89b04a534c5aaf5ce	hard law	The Critical Information Infrastructure Identification Methodology describes the criteria for identifying a critical information infrastructure and the process for identifying a critical information infrastructure. The Description of the Organisational and Technical Requirements for Cybersecurity Entities sets out the organisational and technical requirements for cybersecurity entities. The National Cyber Incident Management Plan establishes cyber incident categories, cyber incident notification, cyber incident investigation and cyber incident analysis for cyber incident management.
Information Resource Management Law of the Republic of Lithuania	https://www.e-tar.lt/portal/lt/legalAct/TAR.85C510BA700A	hard law	Ensure proper development, management, use, maintenance, interoperability, planning, financing and security of state information resources.
Description of general requirements for electronic information security	https://www.e-tar.lt/portal/lt/legalAct/TAR.FC952AC6A109/asr	hard law	To create conditions for safe automatic processing of data, documents and information of state registers (cadastres) and departmental registers, information of state information systems and other information systems.
Technical Requirements for Electronic Information Security of State Registers (Cadastres), other Registers, State	https://www.e-tar.lt/portal/lt/legalAct/TAR.5DFE39DEAB5A	hard law	Establishes minimum technical requirements for electronic information security

Information Systems and other Information Systems			

Main regulatory tools addressing security and cybersecurity in Lithuania

17.3.2 Implementation of EU Law

(i) Are any particular procedures described in your national regulation?

(ii) What is the status of the implementation of the NIS directive in your country towards data protection/security of data?

(iii) The GDPR stipulates that appropriate technical and organisational measures to protect personal data must be implemented. Is this prevention reflected in your national regulation?

No, technical and organisational measures is the responsibility of the controller, but The State Data Protection Inspectorate introduced a Handbook on Security of Personal Data Processing and Risk assessments.

You can find the Handbook in this reference: https://vdai.lrv.lt/uploads/vdai/documents/files/02_%20VDAI_saugumo_priemoniu_gaires-2019-08-09.pdf

The NIS directive has been fully implemented in Lithuania.

The Law on Legal Protection of Personal Data of the Republic of Lithuania contains no provisions on data security.

17.3.3 Personal Data Breach Notification

(i) What requirements in relation to data breach notifications exist in your national regulation? Is this issue regulated in the national implementation of the NIS Directive?

The GDPR sets requirements for data breach notifications. For this reason, only the recommended data breach notification form is approved in Lithuania.

Incident notification under the NIS Directive in Lithuania is regulated by the Law on Cyber Security of the Republic of Lithuania. Reports can be sent directly by e-mail or by filling the form or by phone.

17.3.4 Supervision of cybersecurity

(i) Does a supervisory body in a narrow sense with enforcement powers exist in your country?

Yes, the National Cyber Security Centre at the Ministry of National Defence (NCSC).

(ii) Is in your country an institution like the German BSI (Bundesamt für Sicherheit in der Informationstechnik) established. The Federal Office for Information Security is the national cyber security authority of Germany. It shapes information security in digitisation through prevention, detection and reaction for government, business and society. (https://www.bsi.bund.de/EN/TheBSI/thebsi_node.html) or

something similar established? If yes, what are the competences and responsibilities?

NCSC is the main Lithuanian cyber security institution, responsible for unified management of cyber incidents, monitoring and control of the implementation of cyber security requirements, accreditation of information resources.

NCSC mission – to be the centre of cyber security expertise for effective cyber security incidents and a strong cyber security prevention system in the country. NCSC approved regulations provide for the following main operational goals of the institution: implement a national cyber security policy; perform the functions of the Security Service; perform the functions of the national communications protection service; perform information dissemination, research and analysis on cyber security issues. Since the year 2018 the one-stop-shop principle of the NSCS provides assistance to the state and business institutions and residents. Within the limits of its competence, the NCSC makes decisions along with the state institutions and organizations and other economic entities on the issues of state information resources and critical information infrastructure of cyber security.

Article 7 of the Republic of Lithuania Law on Cyber Security establishes NCSC competence.

(iii) How can damages caused by lack of cybersecurity be claimed (and compensated)? Are such issues sufficiently regulated in your country?

Provisions on damages are set forth in The Republic of Lithuania Law of Civil Code. It is not specified how such damage should occur. There is a need for more detailed regulation of damages. In practice, it would be difficult to prove the damage caused by inadequate cybersecurity.

The Commission on Evaluation of Damage Inflicted upon the Health of Patients under the Ministry of Health examines disputes regarding compensation of the damage made to patients. The Commission decides whether the damage was made to a patient at health care institutions and, if yes, the amount of compensation he or she must receive. It should be noted that these disputes are not related to the damage caused by the lack of cybersecurity.

17.4 Enforcement: fines and sanctions

(i) Is a crime related to data protection or cybersecurity punished by a fine or imprisonment?

It might be punished by fine or other corrective means might be imposed (like warning, reprimand, temporary or definitive limitation including a ban on processing, withdraw a certification, to order the suspension of data flows to a recipient in a third country, etc. (see Article 58 of GDPR).

Imprisonment cannot be applied for this violation.

Fines or imprisonments for crimes against privacy[126] and security of electronic data and information systems[127] are set by the Penal Code of the Republic of Lithuania for.

(ii) Are there administrative fines related to data protection issues?

Yes:

- Fines for violation of GDPR requirements are set in Article 83 of GDPR;
- Fines for violation of GDPR requirements (imposed on public institutions or authorities) are set in Article 33 of the Republic of Lithuania Law on Protection of Personal Data;
- Fines for violation of Directive (EU) 2016/680 are set in Article 49 of Law implementing the provisions of this directive (see Law of the Republic of Lithuania on legal protection of personal data, processed for the purposes of prevention, investigation, detection or prosecution of criminal offences, or the execution of criminal penalties, or national security, or defence);
- Fines for some violations of direct marketing are set in Article 83 of Code of Administrative offices of Republic of Lithuania (https://www.e-tar.lt/portal/lt/legalAct/4ebe66c0262311e5bf92d6af3f6a2e8b/asr)
- Etc.

(iii) Do data protection offences constitute an official offence or are only prosecuted by the injured party's request?

Investigation of the above-mentioned criminal offenses set in the Penal Code is initiated without the request of the injured party's request.

17.5 Governance

(i) At least in the biomedical sciences research involving human participants usually is subject to ethical review by research ethics committees or similar bodies. Data protection, however, not only affects the biomedical sciences, but potentially all fields of research. Are you aware of any committees (e.g. research ethics committees, ethical review boards) or agencies (e.g. national research funding agencies, national security agencies) in your country that review data protection issues in research projects? If yes, are reviews mandatory and governed by specific guidelines or regulations? Do you know which aspects of data protection review

[126] Article 165. Unlawful violation of a person's home immunity

Article 166. Violation of personal communications

Article 167. Unlawful collection of information about a person's private life

Article 168. Unauthorized disclosure or use of personal information

[127] Article 196. Unauthorized impact on electronic data

Article 197. Illegal impact on information system

Article 198. Unauthorized interception and use of electronic data

Article 198[1]. Illegal access to information system

Article 198[2]. Unauthorized disposal of devices, software, passwords, codes, and other data

bodies focus on? Are reviews only conducted before the actual research starts or is the research process monitored as well?

There are no committees or other entities in Lithuania that would evaluate data protection aspects before or during research, except for medical research.

Lithuanian Bioethics Committee facilitates the protection of patients' rights in the field of biomedical research, coordinates the ethical review of biomedical research projects in Lithuania as well as informs biomedical community and general public on ethical issues and moral dilemmas arising in the context of modern health care. Reviews are conducted before the actual research starts. The research process is monitored as well.

Chapter IV of the Republic of Lithuania Law on Ethics of Biomedical Research establishes supervision of conduct of biomedical research:

"2. Approvals to conduct biomedical research, with the exception of a clinical trial on a medicinal product, shall be issued by **the Lithuanian Bioethics Committee or a regional biomedical research ethics committee**. The regional biomedical research ethics committee shall issue approvals to conduct biomedical research where the biomedical research is planned to be conducted at the research sites located solely within the territory attributed to activities of the respective regional biomedical research ethics committee. An approval to conduct biomedical research planned to be conducted within the territory attributed to activities of more than one regional biomedical research ethics committee shall be issued by the Lithuanian Bioethics Committee upon receipt of conclusions of the regional biomedical research ethics committees. The institutions referred to in this paragraph shall issue approvals to conduct biomedical research on medical devices only upon receipt of a conclusion of the State Health Care Accreditation Agency under the Ministry of Health regarding conformity to the requirements for medical devices intended to be used for clinical research as specified by the Minister of Health.

3. Clinical trials on medicinal products may be conducted only subject to the issuance of a favourable opinion of the Lithuanian Bioethics Committee to conduct a clinical trial on a medicinal product and an authorisation of **the State Medicines Control Agency under the Ministry of Health**. The Lithuanian Bioethics Committee shall issue a favourable opinion to conduct a clinical trial on a medicinal product upon receipt of conclusions of regional biomedical research ethics committees, where the clinical trial on the medicinal product is planned to be conducted at the research sites located within the territory attributed to activities of an respective regional biomedical research ethics committee." (see Article 20)

However, Article 35 (1) of GDPR establishes, that "The controller *shall consult the supervisory authority prior to processing* where a data protection impact assessment under Article 35 indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk."

Article 35 (3) of GDPR establishes, that "When consulting the supervisory authority pursuant to paragraph 1, the controller shall provide the supervisory authority with:

(a) where applicable, the respective responsibilities of the controller, joint controllers and processors involved in the processing, in particular for processing within a group of undertakings;

(b) the purposes and means of the intended processing;

(c) the measures and safeguards provided to protect the rights and freedoms of data subjects pursuant to this Regulation;

(d) where applicable, the contact details of the data protection officer;

(e) the data protection impact assessment provided for in Article 35 ; and

(f) any other information requested by the supervisory authority."

The above-mentioned process ensures the fulfilment of personal data processing requirements for research. So, all research process is monitored by **the State Data Protection Inspectorate**.

(ii) What instruments (e.g. ethics self-assessments at the proposal stage), if any, do research funding agencies and other research supporting bodies in your country use to promote data protection in ICT R&I? Do they facilitate the use of these instruments or data protection impact assessments by providing tools (software or other), templates or guidelines?

Such instruments are not known.

Data protection officers or the supervisory authority (The State Data Protection Inspectorate) usually advise on data protection issues. The Lithuanian Bioethics Committee shall analyse problems of bioethics and consult state and municipal institutions, agencies and organisations on the issues of bioethics

(iii) Are there any national regulations or procedures that specify what to consider when ICT R&I involves defence technology, dual use technology or is affected by embargoes? If yes, who are the bodies responsible for monitoring and enforcement? Are there any tools researchers and innovators working on security-sensitive technologies can use in order to protect against industrial espionage and other confidentiality breaches?

There is no national specific regulations or procedures that specify what to consider when ICT R&I involves defence technology, dual use technology or is affected by embargoes. The Lithuanian Bioethics Committee shall issue approvals to conduct biomedical research and undertake ethical supervision of such research. In this case, it applies only to medical devices.

There are known cases when the authorities themselves set requirements for the processing of personal data in the context of scientific research. Such requirements are set out in a local document – the Policy.

Such tools are not known.

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