Chapter 5

Protect

Contents

Main take-aways 104
5.1 Ethics and data protection 105
5.2 Ethical review process 107
5.3 Processing personal data 113
5.3.1 Diversity in data protection 120
5.4 Informed consent 125
5.5 Anonymisation 133
5.6 Copyright 140
5.6.1 Diversity in copyright 143
5.7 Adapt your DMP: part 5 153
Sources and further reading 154

Main authors of this chapter

Scott Summers, UK Data Archive

Libby Bishop, UK Data Archive

CITATION

CESSDA Training Team (2017 - 2019). CESSDA Data Management Expert Guide. Bergen, Norway: CESSDA ERIC. DOI: 10.5281/zenodo.3820473

Retrieved from https://www.cessda.eu/DMGuide

LICENCE

Introduction

This part of the tour guide focuses on key legal and ethical considerations in creating shareable data.

We begin by clarifying the different legal requirements of the European Union Member States, and the impact of the General Data Protection Regulation (GDPR) on research data management. Subsequently, we will show you how sharing personal data can often be accomplished by using a combination of obtaining informed consent, data anonymisation and regulating data access. The supporting role of ethical review in managing your legal and ethical obligations is also highlighted in this chapter.

DISCLAIMER: ***This chapter is based on European and country-specific laws and codes of research ethics. Any guidance and advice within this module do not constitute legal advice. Professional legal advice should be sought where you are unsure of the legal requirements placed upon you by law when conducting your research.***

Main take-aways

After completing this chapter you should:

- Be aware of your legal and ethical obligations towards participants and be informed of the different legal requirements of EU Member States;
- Understand how protecting your data properly protects you against violating laws and promises made to participants;
- Understand the impact of the General Data Protection Regulation (GDPR; European Union, 2016a);
- Understand how a combination of informed consent, anonymisation and access controls allows you to create shareable personal data;
- Be able to define what elements should be integrated into a consent form;
- Be able to apply anonymisation techniques to your data;
- Be able to answer the DMP questions which are listed at the end of this chapter and adapt your own DMP.

5.1 Ethics and data protection

When collecting, using and sharing research data, ethical considerations and legal obligations guide the way.

Ethics are an integral part of a research project, from the conceptual stage of the research proposal to the end of a research project. Within the EU the RESPECT project has drawn up professional and ethical guidelines (Institute for Employment Studies, 2004) for conducting socio-economic research. The RESPECT Code of Practice is based on three main guidelines:

1. Upholding scientific standards

Researchers should always seek to take account of all the relevant evidence and present their research without omission, misrepresentation or deception.

This means in practice that researchers should ensure that when they are formulating their research questions, designing surveys, questionnaires or interviews they do not predetermine or prejudice the outcome through their choice of questions or actions.

2. Compliance with the law

Researchers need to ensure that they are aware of all the relevant national and international laws that may affect their research project. With collaborative projects which cross legal borders, this may involve various laws. Ones of particular relevance (and to be aware of) will be in regards to data protection and intellectual property. These will be discussed in more depth in this chapter.

3. Avoidance of social and personal harm

Researchers should aim to avoid or minimise social harm to groups or individuals when conducting their research projects. This means that the research project should be designed responsibly and consider participants throughout. For example, participation in the research project should be voluntary and on the basis of fully informed consent.

Depending on the type of data you collect you will have to deal with different laws. Whereas Intellectual Property legislation applies to all data, the collection of personal data has its own laws to adhere to. Importantly, since 25 May 2018, the General Data Protection Regulation (GDPR; European Union, 2016a) applies to any EU researcher or researcher in the European Economic Area (EEA) who collects personal data about a citizen of any country, anywhere in the world, as well as any researcher worldwide who collects personal data on EU citizens.

Archiving and publishing personal data

Recap: What are personal data?

If you collect research data that enables you to identify a person, then this is classified as personal data. Within the General Data Protection Regulation (GDPR, European Union, 2016a) personal data is defined as any information relating to an identified or identifiable natural person known as ‘a data subject’. It is further specified that an identifiable natural person is someone who can be identified, either directly or indirectly, by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. Personal data can include a variety of information, such as names, address, phone number and IP addresses.

The GDPR applies only to the data of living persons. Data which do not count as personal data do not fall under data protection legislation, though there may still be ethical reasons for protecting this information.

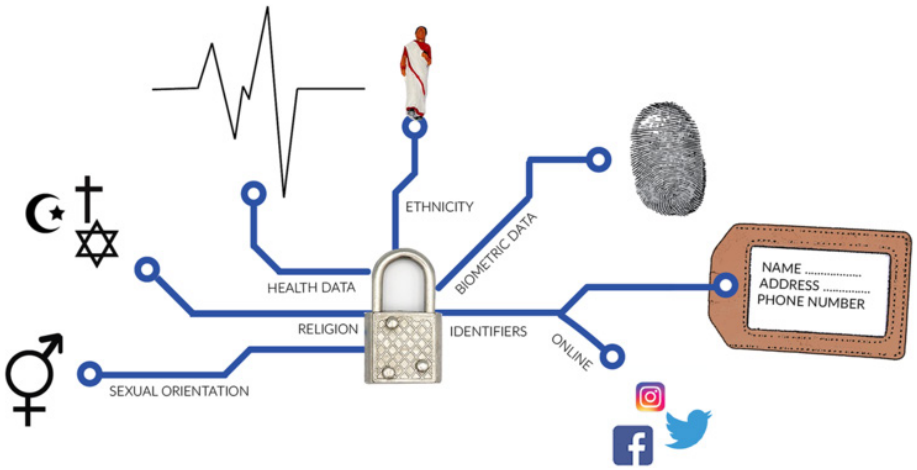
Sensitive personal data

Certain personal data are considered particularly sensitive and thus require specific protection when they reveal information that may create important risks for the fundamental rights and freedoms of the involved individual. Examples of sensitive personal data include data revealing religious affiliation, sexual orientation, or racial or ethnic origin. Within the GDPR the following categories are defined as 'special categories of personal data':

- Racial or ethnic origin;
- Political opinions;
- Religious or philosophical beliefs;
- Trade union membership;
- Genetic data;
- Biometric data;
- Data concerning health;
- Data concerning a natural person's sex life or sexual orientation.

There are other data which may contain sensitive information which do not fall under the special categories of personal data but should still be treated as such, including, for example, confidential business data and secret data concerning state security.

Many research funders and journals expect or require data sharing (i.e., data to be made available in a data repository). Especially for (sensitive) personal data, there may be a perceived tension between data sharing and data protection. In the coming paragraphs, we will show how a combination of gaining consent, anonymising data, gaining clarity over who owns the copyright to your data and controlling access to data can enable the ethical and legal sharing of data.



First, we will get you started on the topic of ethical review. Starting with an ethical self-assessment will help you identify the key ethical and legal issues in your study beforehand, which will maximise your data's value whilst protecting your participants.

5.2 Ethical review process

Ethical review is about helping you as a researcher to think through the ethical issues surrounding your research. The principles of good research practice encourage you to consider the wider consequences of your research and engage with the interests of your participants.

Ethics review by a Research Ethics Committee (REC) is typically required when (sensitive) personal data are being collected. The role of a REC is to protect the safety, rights, and well-being of research participants and to promote ethically sound research. Among other duties, this involves ensuring that research complies with national and international data protection laws regarding the use of personal information collected in research.

Ethical self-assessment

Regardless whether there is a formal requirement, we recommend you to perform an ethical self-assessment. The type of questions which are generally to be answered in an ethical review is shown in the illustration below. These questions are derived from the Ethical guidelines for research by the Norwegian National Research Ethics Committees (n.d.)

- **Question 1: The project's aim and method**
  Could the project's aims and methods come into conflict with commonly recognised values? Could carrying out the project involve risk of injury to people, animals, or nature to an extent that should not be neglected? If so, are the persons involved aware of the risk?
- **Question 2: Research involving identifiable persons**
  Does your research involve personal data collection and/or processing? If so, will informed consent be obtained from the participants? Will personal information be sufficiently anonymised in order to ensure adequate privacy protection?
- **Question 3: Whistle-blowing**
  If a project employee develops serious doubts regarding ethical aspects of the project, will he or she be allowed to present his or her worries to an independent consultative body? Is this option made known in advance?

Ethical review in H2020

Since FP7 (the European Union's Research and Innovation funding programme for 2007-2013; European Commission, 2013)) and its successor Horizon 2020 (running from 2014-2020; European Commission, n.d.) the EU has started to require ethical review. We have used the H2020 ethical guidelines (European Commission, n.d.) to get you acquainted with the steps which may be taken in an H2020 ethical review process. Do note that step four will be very rare.

1. Ethical self-assessment

The first step when applying for funding under the H2020 scheme is for the applicants to perform an ethics self-assessment (European Commission (2016), pages 16 and 17) to submit with their research proposal. This entails completing an ethical checklist about how you will protect your participant's personal data and involves considering questions around how the data will be collected and stored securely and safely, how the data will be retained, and whether any of the data will be transferred to any non-EU countries.

2. Ethical screening

The ethical screening process takes place during the scientific evaluation of the proposal or soon after it is considered for funding. It takes into account the ethical self-assessment conducted by the researcher. If an ethical issue is identified the ethical aspects of the proposals objectives, methodology, and potential impact will be considered by ethical experts.

3. Ethical assessment

In limited cases, an ethical assessment may need to be undertaken, which involves an in-depth analysis of the ethical issues of the proposal. The conclusions of the ethical screening are also taken into account. This typically happens in cases where there will be severe intervention on humans.

4. Ethics check

During the ethical screening or ethical assessment, the experts identify the projects that need an Ethics Check to be executed during the course of the research project. In case of substantial breach of ethical principles, research integrity or relevant legislation, the Commission can afterwards carry out an Ethics Audit. The checks and audits can result in an amendment of the grant agreement.

European diversity in ethical review

Ethical guidelines for research involving people are often issued by professional bodies, host institutions, and funding organisations. Therefore, these rules and guidelines will differ from country-to-country as well as from research funder to research funder. This wide variation in requirements for ethical review across countries is challenging, especially for multi-national research projects. Usually, when working in more than one country, the strictest regulations typically apply. It is also good practice to engage with any local regimes, where possible.

Below we list examples of local diversity in ethical review. Also see the online version of this guide.

Croatia

According to the Act on Scientific Activity and Higher Education, the Croatian Parliament appoints the Committee for Ethics in Science and Higher Education which shall promote ethical principles and values in science and higher education, business and public relations, and in the application of advanced technologies and environmental protection. The Committee adopted the Code of Ethics determining principles of ethics in higher education, the publication of results, relations among scientists, teachers and other participants in the process of science and teaching, procedures and activities related to market competition, as well as relations to the public and the media.

By the same law, higher education institutions, scientific research institutes and other scientific research organisations may, in accordance with the statute, establish their own ethics committees and adopt their own codes of ethics, which must comply with the Code of Ethics of the Committee for Ethics. For example, Faculty of Humanities and Social Sciences Department of Sociology and Department of Psychology have formed their own committees and published guidelines and procedures on how and why researchers and students should submit their research proposal for ethical review. In their work, they follow national and international professional codes of ethics in addition to general ethical principles. In the case of research on children, applicants are advised to familiarize themselves with the Code of Ethics for Research on Children (the new version is soon to be published).

The Croatian Science Foundation, the major funder of basic, applied and developmental research adopted the Code of Ethics of the Croatian Science Foundation. This Code of Ethics contains a set of principles in the area of scientific integrity and scientific ethics that serve as guidelines for professional activities and public actions of all Foundation's employees, members of the Foundation's bodies and boards, evaluators and beneficiaries of the Foundation's funds, as well as other researchers whose work is connected with the Foundation's activities. The Code is based on

the European Code of Conduct for Research Integrity, which establishes best scientific practice on the principles of scientific integrity, guiding the researchers in their encounters with practical, ethical and intellectual challenges, including reliability, honesty, respect and accountability.

Czech Republic

There exist several ethical codes and standards that apply to empirical social research in the Czech Republic. The general ethical principles for research are introduced in the Ethical Framework for Research, the set of recommendations (not obligations) approved by the Czech government.

Large research organizations in the Czech Republic have their own ethical codes and committees, for example Charles University's Code of Ethics or Code of Ethics for Researchers of the Czech Academy of Sciences.

There are professional associations in different fields of social science research and humanities, e.g. Czech Sociological Association or Czech-Moravian Psychological Society. While the psychological society has defined field-specific ethical rules and maintains ethical committee, the Czech Sociological Association is lacking both specific ethical rules and ethical committee and it is often a problem to get any official expert opinion on ethical issues from this organization.

Data collection for research purposes, even the academic ones, is usually conducted by credible commercial research agencies. Such agencies are members of international and national professional organizations (SIMAR, resp. ESOMAR) and adhere to recognized standards, codes of ethics and other rules (ISO 20252 etc.). Individual researchers are often members of professional organizations (EFAMRO, WAPOR)

Germany

Ethical review of Social Science research

Research ethics has received increased attention over the past years. Besides regulations like Federal and State Data Protection Laws (Datenschutzgesetze, see the website of the Federal Commissioner for Data Protection and Freedom of Information for an overview), there are voluntary ethical statutes of organizations like the German Association of Sociology (DGS, German only), the German Association for Political Science (DVPW, German only), or the German Association for Psychology (DGP, German only).

The German Ethics Council (Deutscher Ethikrat) publishes policy-relevant guidance on all areas of research ethics (mostly German, English Abstracts available). The German Data Forum (RatSWD) has published recommendations and teaching material on research ethics (German only). It also hosts a(n) (incomplete) list of local ethics commissions. The incompleteness (as of December 2019) is due to the fact that many individual universities are just now beginning to set up general Ethical Review Boards that handle all types of human subjects research. Finally, the Data Ethics Committee has also published a broad expertise for ethical conduct concerning the handling of research data in general under the auspices of the Federal Data Protection Commissioner (German only).

Intellectual Property Rights and data

Concerning data archiving, creators of data and documentation are treated as owning the Intellectual Property Rights of the research data. When archiving, they transfer the non-exclusive rights of use and rights of reproduction to the archive on the basis of an archive agreement. The non-exclusive rights of use comprise the right to pass data and documentation to a third-party and the right to change the format of digital objects (data files, tables, etc.) for the purpose of long-term preservation (e.g. migrating files to the latest formats). All incoming datasets are checked for possible ethical and data protection issues (voluntary consent, direct personal references, etc.).

The agency Euraxess offers an overview of German intellectual property rights.

North Macedonia

Article 14 of the Law on scientific and research work (2008) establishes a national level Ethics' board, 9 member body, 6 of which are proposed/appointed by the Intra-university conference and 3 by the Macedonian academy of sciences and arts. The main function of the board is "monitoring and evaluation of ethical principles and values in scientific work, protection of human integrity in scientific research, and ethics in professional relations among those performing scientific research".

The Board adopted an Ethical code that addresses ethical principles in: scientific work, in the publication of the results of scientific work, in the relations among researchers, in the procedures and activities related to competition, and in the relations with the public and public media.

Universities are not obliged, but they can adopt their own Ethical codes. Biggest universities have done this.

Research disciplines in which ethical behavior is of utmost importance (medicine, psychology etc.) have adopted their own Ethics codes.

The Law on personal data protection (2005) also addresses important issues that, although not explicitly, apply to ethics in scientific research.

Norway

The Norwegian National Research Ethics Committees (n.d.) are independent agencies for questions regarding research ethics and investigation of misconduct, within all subject areas. All the committees provide ethical guidelines on research ethics within the different subject areas.

The Regional Committees for Medical and Health Research Ethics (REK) must give prior approval for medical and health research projects and general research biobanks. REK may also grant exemption from the duty of confidentiality for health information used for non-medical research.

For other subjects (science, technology, social sciences, law, humanities and research on human remains) there are advisory bodies (NENT, NESH and The National Committee for Research Ethics on Human Remains) for research ethics in its subject areas which provide advice and recommendations for specific projects submitted to the committees. Obtaining advice prior to a research project is not mandatory, but researchers are encouraged to contact the committee if the project is considered to present challenges in terms of research ethics.

NSD – The Norwegian Centre for Research Data AS, as a Data Protection Service, offers research institutions an agreement to assess the processing of personal data in research projects in accordance with data protection legislation.

Serbia

Within the Ministry of Education, Science and Technological Development of the Republic of Serbia, the National Council for Scientific and Technological Development functions as the highest decision-making body. On February 21, 2018, the Council adopted a Code of Conduct for Scientific Work, which the Ethics Committee for Science takes care of. Apart from this central body, each accredited university, faculty, and institutes have an obligation to produce its own document that will regulate ethics in the scientific research of a particular institution.

Slovenia

The three main Universities in Slovenia adopted their Codes of Ethics: University of Ljubljana, University of Maribor and University of Primorska (only in Slovenian language). Committees for Ethics in Research are established on the level of faculties. For instance, Committee for Ethics in Research at the Faculty of Social Sciences (CER FSS) examines the applications for ethical assessment of research tasks and projects undertaken at the Faculty of Social Sciences involving research work that interferes with the privacy of people or engages in research involving people. The Committee discusses the applications of teachers, researchers and research associates employed at FSS, and students upon the proposal of a mentor. The Committee gives opinion on proposals of research projects that involve research work with people, using methods of humanities and social sciences.

On the national level there are National Medical Ethics Committee, Administration for Food Safety, Veterinary Sector and Plant Protection, which discuss the ethical issues of the relevant field of research, and if needed the researcher shall obtain the opinion from the relevant body or organization.

Sweden

The Act concerning the Ethical Review of Research Involving Humans (2006:460) was implemented with the purpose to protect the individual person and ensure respect for human dignity in research. It includes provisions with a requirement for ethical review of research involving living and deceased persons or biological material from humans.

In Sweden, if you are going to process personal data, and you work with research at a Swedish university or authority, you need a Data Protection Official for Research to help you ascertain that you follow the GDPR and Swedish legislation.

Research may only be approved if the risks it may entail to study participants in regard to health, safety, and personal integrity are outweighed by the scientific value. Research cannot be approved if the expected results can be reached in a way that presents fewer risks to study participants. Research may only be approved if is to be conducted by, or under the supervision of, a researcher who possesses the necessary scientific competence.

The Act includes provisions on information to study participants. Researchers are required to inform study participants of the overall plan for the research, the purpose of the research, the methods that will be used, the consequences and risks that the research may entail, the identity of the research principal, and the facts that participation is voluntary and that participants can withdraw their participation at any time. An ethical review is always required, even if study participants have given their expressed consent to the use and handling of their data.

Switzerland

In Switzerland, the legislation makes it mandatory for a research project to be evaluated by a cantonal commission when it falls within the scope of the Swiss Federal Act on Research on Human Beings (Human Research Act, HRA). The HRA's scope of application is "any project for which biological material is collected from a person or personal data related to his or her health are collected in order to respond to a scientific problem or to reuse biological material or health-related data for research purposes" (Art. 6). All researchers working on subjects related to the diseases, structure and functioning of the human body, or at least those working with personal data related to these subjects should, therefore, consult their cantonal commission to determine whether or not they are subject to the HRA. If so, they must submit their project for evaluation before any data is collected.

For research projects that do not fall within the scope of the HRA, there is no legal obligation to be evaluated by an

ethics committee. However, in some universities there are committees through which it may be mandatory to go through, depending on the type of subject being studied. Other universities offer such commissions as a service for research that requires ethics validation in order to meet the increasing demands of funders, publishers, fields, disciplines, etc.

United Kingdom

In the UK, some form of ethical review is required for most research involving human participants, personal (sensitive) data or controversial methodologies (e.g., covert research). Funders, universities, journals, or other bodies may make these requirements. The major funder of social research in the UK, the ESRC, requires reviews to be completed prior to the start of research (but not when submitting a proposal) (ESRC, 2017a). On their website guidance is offered (ESRC, 2017a).

Most institutions offer a graduated review system of review, ranging from a self-assessment checklist to a light-touch review for most student and low-risk projects, to comprehensive review at the institutional level. This flowchart (Economic and Social Research Council, n.d.) helps in deciding what type of ethical review your project needs. Furthermore, the case studies (ESRC, 2017b) may help you in gaining a picture of the ethical dilemma's which may arise during your own research project.

Expert tips

TIP 1. Educate your REC

RECs may be informed and supportive of efforts to share data. However, there is great variation, and some oppose data sharing, fearing (mistakenly) that sharing data violates participants' confidentiality. As a researcher, you may need to ensure that your REC is fully informed on these subjects. At a minimum, REC members should know that:

- Many research funders and journals expect or require data publication (i.e., data to be made available in an archive or repository);
- Consent forms should allow for participants to opt in or opt out of data sharing, whilst also protecting their confidentiality (see 'Informed consent');
- Data protection laws only apply to personal data, but they do not apply to anonymised data;
- Identifiable information may be exempt from data sharing;
- A combination of gaining consent, anonymising data and controlling access to data can enable the ethical and legal sharing of data; even sensitive data can be shared if suitable procedures and precautions are taken, as is done at major data repositories.

Tip 2. Finding RECs

Find the REC at your own institution or have a look at The European Network of Research Ethics Committees - EURECis (EUREC, n.d.) - which brings together already existing national Research Ethics Committees (RECs) associations, networks or comparable initiatives on the European level.

5.3 Processing personal data

Since 25 May 2018, the General Data Protection Regulation (GDPR, European Union, 2016a) applies to any EU researcher or researcher in the European Economic Area (EEA) who collects personal data and any researcher worldwide who collects personal data on EU citizens. The GDPR applies only to the data of living persons. Data which do not count as personal data do not fall under data protection legislation, though there may still be ethical reasons for protecting this information.

The GPDR (General Data Protection Regulation, Chapter 2, Article 5) prescribes that you should adhere to the following six principles when processing personal data:

I. Process lawfully, fairly and transparently

The participant is informed of what will be done with the data and data processing should be done accordingly.

II. Keep to the original purpose

Data should be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes.

III. Minimise data size

Personal data that are collected should be adequate, relevant and limited to what is necessary.

IV. Uphold accuracy

Personal data should be accurate and, where necessary kept up to date. Every reasonable step must be taken to ensure that personal data that are inaccurate are erased or rectified without delay.

V. Remove data which are not used

Personal data should be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed.

VI. Ensure data integrity and confidentiality

Personal data are processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures.

The research exemption

The GDPR contains an exemption which entails that some of the principles above are slightly different when you collect and process personal data for research purposes. This is called the 'research exemption'.

> *Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subjected to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner | General Data Protection Regulation, Article 89.*

In practice, this means that Principle II. and V. are less strict. Further processing of personal data for the purposes of archiving, scientific or historical research purposes and statistical purposes is not considered to be incompatible with the initial purposes of data collection, even when this purpose was not expressly mentioned earlier.

Also, personal data may be stored for longer periods for such purposes. In all cases, appropriate technical and organisational measures should be taken to safeguard the rights and freedoms of the participants in your research, such as data minimisation and pseudonymisation.

Legal Basis

Personal data can only be processed when there is a valid legal basis to do so. The GDPR recognises six bases (grounds):

- consent of the data subject
- necessary for the performance of a contract
- legal obligation placed upon the data controller
- necessary to protect the vital interests of the data subject
- carried out in the public interest or in the exercise of official authority (public task)
- legitimate interest pursued by the data controller

In research, the three most applicable bases for processing personal data are consent, public interest (public task) or legitimate interest. For each research project, if personal data will be collected and processed, the most appropriate legal basis needs to be decided and recorded (and should not be changed at a later date). The UK Data Service has published examples of where a legal basis may be applied in research.

GDPR in practice

When you start a research project that involves collecting information from people, for example via a survey or interviews, then consider whether or not you willcollect personal data.If not, then data protection legislation does not apply. If you will collect personal data, then:

- determine who will be the data controller (possibly your institution)
- decide which legal basis will apply
- if collaborative partners need access to personal data, then make sure agreements are in place
- consider whether a Data Protection Impact Assessment is needed (see details on this in the GDPR Questions and Answers below)
- communicate to research participants how personal data collected about them will be used, stored, processed, transferred, who the data controller is (with their contact details), the legal ground and purpose of the processing, the period of retention and their rights; this can be done via an information sheet or a webpage (e.g. privacy notice)
- consider where to store personal data securely
- minimise the personal data to collect and pseudonymise where possible

GDPR Questions and Answers

Below are some questions and answers about how to implement the GDPR requirements in practice in a research project, resulting from 2019 CESSDA Webinar.

Q: I am a postdoc researcher doing a qualitative study, interviewing women about abusive relationships. I will use pseudonyms for each woman interviewed. Respondents may still be identifiable from the story they tell. Does this constitute personal information? If so, which legal ground should I use for this research?

A: Yes, this would constitute personal information. In this case the legal ground could be consent, which should be sought from the women participating in the study. Another aspect to keep in mind here is data collected which would allow identification of other people who may not have been asked for consent, for example partners carrying out the abuse. So you may also be processing personal data from people who have not been asked for consent. In that case, the processing ground could be public interest and the argument would be that the research has value for society. If the project allows, such partners could be made aware of the processing of their data, if this poses no risks to the participating women.

Q: I am doing an online poll survey, using Qualtrics, asking 5000 people across Europe for which political party they voted in the recent European elections, also recording their ethnicity and other demographic information. Does this qualify as processing special categories data? If so, how do I gain explicit consent for collecting this information?

A: A first consideration would be how much identifying/personal information is collected during the survey, alongside the political view and ethnicity. This helps to decide whether this classifies as special categories data. If no data is collected that allows identification of the respondents, then the GDPR will not apply. If identifying information is collected, then this qualifies as special categories data and therefore explicit consent would be needed. One way to achieve this would be through double consent, whereby consent for processing personal data collected would be asked at the beginning and the end of the questionnaire.

Qualtrics is a USA based company and thanks to negotiations by various European survey institutions, Qualtrics now only processes collected survey data in the EU for EU-based surveys. This means that Qualtrics can be used as a tool for surveys that need to comply with the GDPR.

Q: What are the GDPR rules when using administrative or register data that contain personal information?

A: If consent is not collected from the individuals when the administrative or register data are collected, then the most common legal basis for further use is public task. If consent can be sought, that would be preferable.

Q: The GDPR indicates strongly that a consent form should be easy and clear, yet I have to provide so much extra information to my interviewees now. How do I do this?

A: The best way to provide this information to participants is through an information leaflet and a consent form. You can provide the information in a written leaflet. If you are interviewing people you can explain the leaflet content also face-to-face to make sure it is people understand the content.

Q: If a researcher brings an electronic device across the border to a third country, sends an email or publishes personal data on the web, does this constitute as a data transfer?

A: An email containing personal data sent from Europe to someone in a non-European country would indeed constitute a data transfer. An electronic device containing personal data carried across the border to a third country would constitute a data transfer if the personal data will be passed on to another person. If personal data are published on the web, it depends on whether the data are stored and who can access them. If it is openly published it could be considered a data transfer.

Q: What are the data protection implications for international partnerships and research projects when non-EU countries are involved?

A: If personal data are going to be handled/processed as part of the partnership research activities within the EU, then the GDPR would apply. One solution would be that the European-based partners require their non-EU partners to have appropriate privacy/data protection measures in place and that consent is given by all subjects, irrespective of whether they are based in Europe or not. That may not always be easy or possible. However, solutions can be found such as data anonymisation, data encryption, using secure servers and partners can learn from each other. Good practice is also for all users and purposes of use of the personal data to be recorded.

Q: Does the GDPR apply to personal data, collected outside the European Economic Area (EEA) and transferred to the EEA for analysis?

A: Yes, it would, because it would be classified as personal data once stored within the EEA.

Q: Are there examples of research where using consent as legal basis for processing personal data would not be suitable?

A: Covert research is an example where consent would not be an appropriate processing ground, as asking for consent would have a negative outcome for the research. In covert research, public task would likely be the best ground. It is still important that the research adheres to ethical principles, and the researcher is open about the process used in publications.

Q: How can we comply with the GDPR when studying populations that are easily identified, for example surveys of candidates running in a general election or surveys of the members of a scientific association?

A: First, you need a legal basis for the processing of personal data. The most common legal basis for this scenario may be consent. If you gain consent from the people studied you can give information about the risk of being identified in published outcomes of the survey and ask consent on that basis. If the legal basis for processing personal data is public task, you should give information about the study to the population to make sure that they can manage their rights according to the GDPR.

Q: How is the 'right to be forgotten' applied in research settings?

A: The right to be forgotten applies in research, but is not an absolute right. Best practice is to inform participants about this right as clearly as possible and explain what it means and what it may not mean. For example, if data have been published in which people are identifiable, for example a paper containing a quote for which permission was given. Then if a participant wants to be forgotten, it would be very difficult to retract the paper. So be clear to participants about what they can do with this right and up to which point they can withdraw from research and request to be forgotten.

Q: Is a Data Protection Impact Assessment (DPIA) only required in scientific research for sensitive data concerning vulnerable subjects?

A: A DPIA is required for data processing that is likely to result in a high risk to the rights and freedoms of individuals. In practice this means if at least two of these criteria apply (examples can be found in the Data Protection Working Party 248 guidelines):

- evaluation or scoring
- automated-decision making with legal or similar significant effect
- systematic monitoring
- sensitive data
- data processed on a large scale
- datasets that have been matched or combined

- data concerning vulnerable data subjects
- innovative use or applying technological or organisational solutions
- data transfer across borders outside the European Union
- when the processing in itself prevents data subjects from exercising a right or using a service or a contract.

At the same time, a DPIA is a good learning tool. For a research project that involves the collection of personal data, a joint session of the researcher with a legal person and a technical person is very useful to establish best practices for data protection. This helps to understand context and helps to define common problems, solutions and risk mitigation measures.

Q: How are Data Protection Impact Assessments (DPIAs) being implemented across different institutions, for research?

A: If research is done as a collaboration of more than one institution, with shared responsibilities, one DPIA done by one of the institutions should be enough, and the other partner institutions should apply that same DPIA. Problems might arise when research involves institutions that are implementing a DPIA in different countries, whereby policies or requirements may vary across those countries, such as for data security, ownership of the data, different understandings on gaining consent and which legal basis to use for processing personal data.

Q: How should researchers deal properly with the GDPR in the context of open data?

A: For personal data, the open access motto "as open as possible, as closed as necessary" is important. A political or societal drive for open access and open science does not mean that individual rights granted by legislation can be overruled. Therefore, for personal data, 'as closed as necessary' is the key.

Q: What is the applicability of 'legitimate interests' in research using Artificial Intelligence (AI)?

A: The use of AI is a specific form of using personal data, and legitimate interest could be a legal basis for AI. More important is the framework provided by guidelines and recommendations of the High-Level Interest Group on AI: Ethics guidelines for trustworthy AI and Policy and investment regulation for trustworthy AI.

Q: When a US entity is a processor of pseudonymised EU citizen data and the key to re-identify the subjects exists only in the EU, so that the US entity cannot re-identify the subjects, does the GDPR apply to the US entity? Is the US entity required to sign a contract if requested by the EU entity?

A: If the US entity has no access to the key, then the data would in theory be classified as anonymous data. If the key would ever be released or the US entity would gain access to it, then the data would be defined as pseudonymised data or personal data. The organisation would need to decide whether signing a processor agreement would be best, considering the risks they wish to take.

Q: In research projects that plan to use data collected from social media platforms, how can researchers reconcile the right to privacy vs. the publicly available data?

A: Gaining consent would be the best approach when using social media data. So even for social media data in the public domain, researchers should ask the people whose social media content they mine for their consent when possible. In some cases public task could be used as legal basis.

Q: Are European countries converging or diverging in their choice of legal basis for processing personal data in research across Europe, specifically when considering whether consent or public task would be used in research?

A: The UK strongly encourages the use of public task as legal ground in research, whereas many other European countries favour consent. The UK view may pose a risk for participants' rights. We will be

able to evaluate in future how this has evolved. For the German case one can rather see a diverging trend since the Federal government left things open to be defined by the 16 Federal States. They took the chance and eight have now introduced the definition of "anonymous data" as formerly used in the German Data Protection Act. But they all see consent as a major basis for research.

Q: Should data repositories and data archives be considered as data processors or data controllers? Is archiving research data from a project part of the original processing for the research, or does it constitute a separate, further processing?

A: In most instances it is likely that data archives would be considered as data processors. However, some data archives may also be involved in undertaking research for the projects, which could lead to them being a joint controller with the research institute.

Different data archives in different countries may take a different view. Some would consider all data collections as potentially personal data and treat them as such. Only when data are considered to be fully anonymous would the GDPR no longer apply. Other archives take a two-tiered approach having certain procedures for anonymous data and other for personal data. An archive can archive personal data if there is a legal basis to do so. Liaising with the research project team is important.

Secure disposal

> *Used Phones Are Full of Previous Owners' Data: Researchers bought 20 used smartphones in four cities, and recovered thousands of photos, texts, and emails | Wadell, 2016.*

Managing your data also means thinking about how to securely dispose of confidential information. Merely hitting the "delete" button on your computer or mobile device is not enough. In fact, even formatting the hard drive or doing a factory reset can leave (portions of) confidential information in place.

There are two options for secure disposal of confidential data:

- **The physical destruction of the storage medium** (e.g. shredding of discs)
- **The use of software for secure erasing**
  There are various software options available (UK Data Service, 2017e) that can securely delete files from hard drives. For example, AxCrypt (n.d.), Eraser (2017) and WipeFile (2014) are free open source file and folder shredding utilities.

The UK Data service (2017e) points out that solid-state hard disks (SSD) and USB flash drives (memory sticks) use a different technology than hard drives. Therefore, the techniques for securely erasing files are also different. The use of manufacturer-specific software is recommended. Note, though, that especially for solid state drives and USB flash drives only physical destruction is a 100% guarantee that the data cannot be recovered.

Contact the IT department and the administration of your university or institute to find out about regulations and procedures for secure destruction of confidential data.

Organisational aspects

Data security partly depends on technological and physical protection measures. However, these measures alone are not sufficient and will not adequately protect your data if you do not also address the "human factor". This is particularly important if working collaboratively in a bigger and/or distributed team.

Protection against security breaches depends on the establishment and communication of clear rules and guidelines. Here are some points to consider when planning your data management that focus on the human/organisational dimension of data security:

Do: Invest time to draw up policies and concrete guidelines/checklists for all topics discussed in this chapter, especially:

- Passwords: minimum requirements for password strength; management/secure storage of passwords.
- Encryption: what types of data are encrypted for which purposes using which tools?
- Secure data transmission and transport.
- Secure data disposal.

Do: Restrict access to sensitive data:
Most likely, not everyone on the team needs access to all files. Determine who needs access to which types of data and handle access restrictions, e.g. with the help of passwords. In addition, create a routine to ensure you adapt authorisations in case someone leaves the team.

Do: Create awareness and keep communication going:
Errors often happen due to a lacking awareness of potential issues or threats. For example, does everyone on the team know which data is considered sensitive and why? Is everyone aware of potential risks posed by transmitting unencrypted data via email? Make sure that everyone on the team is adequately involved in discussions of data security issues and measures in place.

5.3.1 Diversity in data protection

It is one of the key responsibilities of researchers and the Project Principal Investigators to familiarise themselves with the local laws, rules and ethical requirements for their projects.

When research crosses legal and jurisdictional boundaries researchers should always seek to apply the requirements of the legislation that has the most stringent requirements of the whole project. Where this is unclear, you should obtain advice from your institute, ethical committees or qualified legal professionals.

Since 25 May 2018, the General Data Protection Regulation (GDPR; European Union, 2016a) applies to any researcher who collects data on EU citizens. One of its key aims is to harmonise laws across the EU regarding data protection legislation.

In addition to the GDPR, each EU Member State has rules on data protection and legislation that you have to familiarise yourself with if you collect personal data. Because of this, some Member States have more restrictive data protection legislation than others.

Key national legislation affecting data protection is presented in the tables below. For up-to-date information, see also the online version of this guide.

Croatia

Personal data protection is a constitutional right, in the framework of human rights and fundamental freedoms. "The safety and secrecy of personal data shall be guaranteed for everyone." (The Constitution of the Republic of Croatia, Article 37).

The Act on Implementation of General Data Protection Regulation ("Official Gazette" No. 42/18) was enacted on 25th May 2018 to ensure full implementation of the GDPR in Croatia. National legislation contains no provisions regulating the use of personal data in scientific research.

The Croatian Personal Data Protection Agency is the only independent public supervisory authority in the Republic of Croatia within the meaning of the provision of Article 51 of the General Data Protection Regulation. The Agency can be contacted by researchers for consultation services about the use of personal data in their research.

Finland

Informing participants

Under the Finnish Data Protection Act it is a requirement that when personal data are collected or processed for research that participants are informed about the purpose of the research and what will happen to their contribution [Personal Data Act (523/1999), 1999].

Potential participants must have enough information to be able to make an informed choice on whether to partake in the research or not. Before collecting personal data in Finland, researchers must fill in the 'Description of the scientific research data file'. Ethical review boards usually require this file, and research participants have the right to see it, should they wish to do so. In cases where the personal data are drawn from registers (and no consent has been asked from the participants), the description of the scientific research data file must also be sent to the Office of the Data Protection Ombudsman.

More information and advice can be found at the Finnish Social Science Data Archive (2017a). You can also contact the Office of the Data Protection Ombudsman (n.d.) directly.

Germany

Data protection in Germany is governed by the GDPR, the Federal as well the State Data Protection Acts.

There is no centralized authority for research ethics and data protection due to the federal nature of Germany. The Federal Commissioner for Data Protection and Freedom of Information is part of the Data Protection Conference (webpage in German only).

The German Data Forum (RatSWD) has published recommendations and teaching material on research ethics and data protection (webpage in German only). The Federal Data Protection Act was adapted to the GDPR in 2017.

Greece

Data protection in Greece is governed by:

-Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), known as GDPR

-Law 4624/2019 with the title "Hellenic Data Protection Authority (HDPA), measures for implementing Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data, and transposition of Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 and other provisions"

Law 2472/1997 which has been has been repealed, except for the provisions referred to expressly in Article 84 of Law 4624/2019-Law 3471/2006 on the protection of personal data and privacy in the electronic telecommunications sector

Law 3471/2006 with respect to the electronic communications sector which incorporates into the Greek law European Directive 58/2002.

The above regulatory framework sets out the obligations of those who process personal data and the respective rights of those to whom the data processing relates. The same Law also provides for the establishment of the Hellenic Data Protection Authority (HDPA) and its powers and competencies.The Hellenic Data Protection Authority (HDPA) is a constitutionally consolidated independent Authority which incorporates into the Greek law. relevant EU legislation provisions.

All relevant, official, publicly available information can be found on the HDPA website.

Netherlands

Research data should be stored permanently as far as possible insofar as scientists participate in research by or at the institution that has adopted the Netherlands Code of Conduct for Research Integrity (Association of Universities in the Netherlands, 2018) or discloses their research in its name, research findings and research data should be made public subsequent to completion of the research to the extent possible. Simultaneously, the institutions have the obligation to ensure permanent storage as far as possible. Upon receiving a grant from the Netherlands Organization for Scientific Research (NWO) it is important to address this in the Data Management Plan (DMP).

Norway

Project notification

In Norway, if you are going to process personal data and you work at one of the institutions that have an agreement Norwegian Centre for Research Data (NSD) as their Data Protection Services for Research then you must notify NSD about the research project. If your institution does not have an agreement with NSD, you must either notify your institution's own Data Protection Official (if they have one) or the Norwegian Data Protection Authority. A notification is not required only if the research project registers anonymous information only. However, you should note that you will still need to notify the NSD if you will be processing personal data during the project, even if the research project will publish anonymous data.

If you are a researcher employed at an institution outside Norway different rules apply: if the data controller (i.e. the responsible institution) is established in an EEA country, it is sufficient to submit a notification of the project to the relevant authorities in the country concerned. If the data controller is located in a country outside the EEA, the notification must be submitted in Norway by a Norwegian institution that undertakes the role of the data controller's representative.

Further information and advice can be sought from the NSD (n.d.) directly.

North Macedonia

In this area, research institutions are obliged to respect the general provisions of the Law on personal data protection (2005) (Official gazette of the R. Macedonia No.7/05, 103/08, 124/08, 124/10, 135/11, 43/14 and 153/15). The new law, which implements the GDPR directive of the EU, is in preparation. Anyway, research institutions have developed their own practices for the protection of personal information during the research process.

Serbia

The Government of the Republic of Serbia adopted the Law on Personal Data Protection of the Republic of Serbia, in November 2018 and its implementation Act began on August 21, 2019. The Law on Personal Data Protection puts personal data at the very top of the protection priorities and gives citizens the functional capacity to manage their privacy much better and more transparently. In essence, the Law is the final product of a general civic and political initiative that has launched a long-standing "hard-fought" process to achieve legal frameworks in which each individual would have greater protection of his or her privacy and in which institutions and companies would be given much clearer rules and procedures by which they could to process and use personal information.

The special rule applies to data processing for a purpose archiving in the public interest, scientific or historical research, and statistical purposes, as well as when it comes to the right of access to information, or in general relationship between the right to protection of personal data and freedom of expression.

Slovenia

In Slovenia, the Personal Data Protection Act (Slovene, English) is still not adopted to General Data Protection Regulation. Researchers can find some guidelines on this topic at the Information Commissioner office. For more, see Publications and Guidelines of the Slovenian Information Commissioner.

Sweden

The Swedish Ethical Review Authority is a recently restructured authority under the Ministry of Education and Research, for the protection of humans in research, research on biological material and sensitive personal data.

On their website, researchers can find information on the legal requirements that must be complied with in order for the research to be legal. The ethical rules that apply to research are based on international conventions, founded on principles for research ethics. Swedish research is covered by international law and conventions, as well as national legislation. The rules are there to make sure that individuals are not harmed or subjected to unnecessary risks when personal data och people are used for research.

The General Data Protection Regulation, GDPR, and complementary legislation includes all usage of personal information. Personal information can, according to GDPR, only be used for specific, explicitly stated, and legitimate purposes. However, even when all these criteria are met, personal information for research purposes also requires informed consent.

There are exceptions in case there is a rule that conflicts with other Swedish constitutional law, for example conflicts with The Freedom of the Press Act (SFS 1949:105), or The Fundamental Law on Freedom of Expression (SFS 1991:1469). Treatment of personal information for artistic or journalistic purposes is excepted, as well as private registers.

The SND website provides further information (in Swedish).

Switzerland

Data protection in Switzerland is both regulated at the federal and the cantonal level. At the federal level, it follows the Federal Act on Data Protection (FADP) (The Federal Council, 2014) and the Ordinance to the Federal Act on Data Protection (OFADP) (The Federal Council, 2012). Besides the FADP, each of the 26 cantons has their own cantonal data protection act. Universities are regulated by cantonal laws.

The FADP is currently under revision and should align with the GDPR. See Finsterwald (2016) for more practical information.

UK

In the UK, there is the Freedom of Information Act and a common-law tort of breach of confidence.

Freedom of Information Act

Researchers who work at a publically funded research institute or university in the UK are subject to the Freedom of Information (FOI) Act 2000. This Act provides members of the public with a right to access information held by UK public sector organisations (e.g. publically funded research institutes and universities). This means that a member of the public may make a request for access to a researcher's research data.

There have been various examples of research data being requested through the FOI Act. For example, climate change researchers at the University of East Anglia had two such requests made in early 2007. The university initially refused to release data, however after one of the requesters drafted a letter to the ICO alleging that the university was in violation of the FOI Act the university released the requested research data (Booth, 2009).

An FOI request (GOV.UK, n.d.) can come in many forms, but for it to be valid, it must come in a written form, such as an email, letter or fax. An FOI request can also come from anyone, meaning that the requester does not have to have been a participant in the research project. The information needs to be provided unless an exemption or exception allows the researcher not to disclose the information. Researchers must respond within 20 working days of receiving the request and should seek assistance from their university/research institute before disclosing any

information. This is particularly important where the FOI request requests access to data which is not that of the requester but is defined as 'personal data' under the GDPR of another 'data subject'.

Researchers working on European projects need to be aware that they will need to comply with the UK FOI Act if there is a UK public research institute or university involved in their research project.

Further guidance on FOI (ICO, n.d.a) can be sought from your research institute/university or the UK's Information Commissioner's Office (ICO, n.d.b).

Breach of confidence

In the UK, there is a common-law tort of breach of confidence. A duty of confidence arises when confidential information comes to the knowledge of a person in circumstances where it would be unfair if it were then to be disclosed to others.

Disclosure of information subject to a duty of confidentiality would constitute a breach of the duty. The duty of confidentiality is not absolute and is not protected by legal privilege, and exceptions occur. For example, where the participant has consented to the information being used in specific ways, for agreed purposes, and by certain people or where a judge requires disclosure.

This applies to information not already in the public domain. If the consent form promises confidentiality, disclosing information unlawful may constitute a breach of confidence.

5.4 Informed consent

> *The following statement has been adapted from an actual consent form: "**Any information I give will be used for research only and will not be used for any other purpose**". Consider the implications for data sharing for any data generated using this consent statement. Do you have any suggestions for alternative wording or other changes?*

Some thoughts on this statement

Some comments/reflections:

1. It is tempting to use such wording as a way of reassuring participants that their data will not be misused, but this may be overly restrictive.
2. Perhaps the data—appropriately anonymised—could be equally useful for teaching, for example.
3. In general, think very carefully about any wording that restricts – forever – uses of the data. If what you are trying to do is to build trust with participants, telling them how their data can be safely used in diverse ways is a better approach!

Informed consent is the process by which a researcher discloses appropriate information about the research so that a participant may make a voluntary, informed choice to accept or refuse to cooperate.

Normally informed consent is given before the start of the research. Gaining informed consent is crucial to meeting your legal and ethical obligations towards participants whilst simultaneously enhancing the value of your research data.

To obtain informed consent, researchers should:

- Inform participants about the purpose of the research;
- Discuss what will happen to their contribution (including the future archiving and sharing of their data);
- Indicate the steps that will be taken to safeguard their anonymity and confidentiality;
- Outline their right to withdraw from the research.

Consent needs to be freely given, informed, unambiguous, specific and by a clear affirmative action that signifies agreement to the processing of personal data.

Examples of consent forms

Sample consent forms are available in the online version of this guide:

https://www.cessda.eu/Training/Training-Resources/Library/Data-Management-Expert-Guide/5.-Protect/Informed-consent

Information sheets

Information sheets play an important role in gaining a participant's informed consent to take part in a research project. They help provide participants with the background information which is necessary to make an informed decision about whether to take part in the research project.

A good information sheet discusses the following topics:

- The purpose of the research;
- What is involved in participating in the research;

- The benefits and risks of participating in the research;
- Details of the research, e.g. the funding source, sponsoring institution, name of project, contact details for researchers and how to file a complaint;
- The procedures for withdrawing from the research project;
- The planned usage of the data during the research, dissemination, storage, publishing and archiving of the data;
- The strategies for assuring ethical use of the data;
- The procedures for safeguarding personal information, maintaining confidentiality and anonymising data, particularly in relation to data archiving, sharing and reuse.

Examples of information sheets

Sample information sheets are available in the online version of this guide.

Gaining informed consent for data archiving and sharing

Gaining informed consent for data sharing is seen as 'one more small step' to gaining consent from participants to partake in your research project. As a researcher, you will already be acutely aware of the need to fully inform your participants about:

- What taking part in your research project will involve;
- How you will disseminate information from the project through publications or presentations;
- The impact taking part may have on them.

By adding the discussion of data sharing and archiving you permit the participant to make an informed decision. This empowers them and puts them in charge of choosing whether they wish for their contribution to your research project – and their data – to be available for use in future research projects.

Granular consent

The best way to achieve informed consent for data sharing is to identify and explain the possible future uses of their data and offer the participant the option to consent on a granular level. For example, in a qualitative study, this may involve allowing the participant to consent to data sharing of the anonymised transcripts, the non-anonymised audio recordings and the photographs.

Below, an example of what granular consent for data sharing could look like on a consent form is detailed.

The interviews will be archived at ..... and disseminated so other researchers can reuse this information for research and learning purposes:	
I agree to the non-anonymised audio recording of my interview being archived and disseminated for reuse	yes/no
I agree to the anonymised transcript of my interview being archived and disseminated for reuse	yes/no
I agree to any photographs of me taken during interview being archived and disseminated for reuse	yes/no

Approaches to informed consent

Consent can be gained from participants in written or oral form, one-off or continuously throughout the research project, retrospectively or not at all. The form of consent sought will depend on the project. In the accordion below the details and considerations of all three are stated.

Written or verbal consent

Choice	Advantages	Disadvantages
Written consent	» More solid legal ground, e.g. participant has agreed to disclose confidential info; » Often required by Ethics Committees; » Offers more protection for researchers (as they have written documentation of consent).	» Not possible in some cases: infirm, illegal activities; » May scare people from participating (or have them think that they cannot withdraw their consent).
Verbal consent	» Best if recorded.	» Can be difficult to make all issues clear verbally; » Possibly greater risks for researchers (in regards to adequately proving participant consent).

Written consent is typically seen as the preferred form of the two options, where possible because the participant can be given detailed written information which can then be explained to them to ensure they fully understand what they are consenting to.

One-off or process consent

Choice	Advantages	Disadvantages
One-off consent is where the participant is asked to consent to taking part in the research project only once. This would typically be at the beginning of the project before the data is collected, but could also happen at the end of the first interview.	» Simple; » Least hassle to participants.	» Research outputs not known in advance; » Participants will not know all info they will contribute.
Process consent is where the participant's consent is requested continuously throughout the research project. For example, this may be before the first interview then after each subsequent follow up interview.	» Ensures 'active' consent	» May not get all consent needed before losing contact; » Repetitive, can annoy participants.

Retrospective consent

In cases where consent was not sought at the point of research, it may be possible to gain retrospective consent from the participants for the depositing of the data in a repository. However, if participants cannot be traced, depositing the data in a repository will need to be assessed on a case-by-case basis to identify whether it is appropriate to share it. This assessment will need to consider various factors such as the nature of the project, the consent sought, the questions asked and the anonymisation levels utilised.

On the UK Data Service (2017b) website you can read a case study on gaining retrospective consent from a 30-month research project concerning the 2001 foot and mouth disease epidemic in the UK. A standing panel of 54 local people from North Cumbria produced more than 3,000 weekly diaries about the impact of the crisis and the process of regeneration.

Expert tips

TIP 1. Documenting consent

The GDPR requires that researchers document consent if consent is the legal basis for processing personal data. An obvious way to do this is by using written consent forms. If that is not possible in the research, then verbal consent discussions and agreements can be audio-recorded if the participants agree. Or the consent process and wording used can be written out in detail.

TIP 2. Delivering informed consent in the best way possible

Researchers should consider the participant's needs, understanding and the best way to gain informed consent. This may, for example, require pictures to be used instead of lots of text – to make it clear and easy for the participant to understand – or for the consent form to be translated into the participant's native language.

TIP 3. Consent for surveys

For surveys, where personal identifiers such as people's names are not collected or are easily removed from the data file, written consent is often not gathered. Instead, the information sheet given to participants or the survey introduction state that consent for the data being used for specified purposes is implied from participating in the survey, with a clause stating that an individual's responses would not be used in any way that would allow their identification. It is therefore vital that the information sheet provides details about plans for data sharing. This information should include where the data will be deposited and the potential future uses of the data.

TIP 4. Research without consent

There are circumstances where no form of consent can be obtained for research, e.g when the researcher collects the information from sources other than the persons themselves or when the data were already collected for another purpose. These situations are exceptional and will need case-by-case review and clear arguments before that research can be conducted. In jurisdictions which have Research Ethics Committees (REC), researchers will need to satisfy the requirements of these research ethics review boards. E.g. in Norway, NSD or the Norwegian Data Protection Authority would need to be informed and permit the research. A Notification form (NSD, n.d.c) listing the reasons why gaining informed consent isn't possible should be handed in.

European diversity in informed consent

Apart from being good scientific practice, in some countries gaining informed consent is mandated by law. Below, a consent requirement comparison for several European countries is given.

An up-to-date version of this comparison is also available in the online version of this guide.

Croatia

National legislation

The Act on Implementation of General Data Protection Regulation does not regulate consent for scientific research, only for conditions applicable to child's consent in relation to information society services, and to the processing of genetic and biometric data.

Consent required to conduct research?

Depends on circumstances/In accordance with GDPR.

Verbal or written consent?

Either is permitted/In accordance with GDPR (i.e., the controller must be able to prove the consent).

One-off or process consent?

No/in accordance with GDPR (easy with exceptions for academics - but not one-off).

Czech Republic

National legislation

Act No. 110/2019 Coll. on personal data processing

Consent required to conduct research?

Depends on circumstances/In accordance with GDPR.

Verbal or written consent?

Either is permitted/In accordance with GDPR (i.e., the controller must be able to prove the consent).

One-off or process consent?

No/in accordance with GDPR (easy with exceptions for academics - but not one-off).

Germany

National legislation

Data Protection Act(s); e.g. Federal Data Protection Act

Consent required to conduct research?

If personal data is collected, stored, or processed.

Verbal or written consent?

Written, but exceptions permissible (e.g. in cases where written consent would hamper the research or where other important reasons prevent obtaining written consent).

One-off or process consent?

Not defined.

Netherlands

National legislation

GDPR National implementation act (Dutch only).

Consent required to conduct research?

Depends on circumstances/In accordance with GDPR.

Verbal or written consent?

Either is permitted/In accordance with GDPR (i.e., the controller must be able to prove the consent).

One-off or process consent?

No/in accordance with GDPR (easy with exceptions for academics - but not one-off).

North Macedonia

National legislation

Law on personal data protection (art. 6, 8 and 2)

Consent required to conduct research?

Yes, article 6 of the Law on personal data protection.

Verbal or written consent?

Not defined. Both verbal and written consent possible.

One-off or process consent?

Not defined.

Norway

National legislation

Personal Data Act (Norwegian only). Information in English (2019).

Consent required to conduct research?

As a main rule yes, but there are exceptions for research.

Verbal or written consent?

Both allowed.

One-off or process consent?

Not defined, but in practice often process consent in long-term research.

Serbia

National legislation

Law on Personal Data Protection of the Republic of Serbia.

Consent required to conduct research?

Yes, but there are exceptions for research.

Verbal or written consent?

Both allowed (but preferably written).

One-off or process consent?

Not defined.

Slovenia

National legislation

New Data Protection Act is being processed.

Sweden

National legislation

Ethical Review (in Swedish only).

Consent required to conduct research?

Yes, if research is carried out on humans, biological material, or sensitive personal data.

Verbal or written consent?

Written consent is required.

One-off or process consent?

One-off.

Switzerland

National legislation

Federal Data Protection Act.

Consent required to conduct research?

The Federal Data Protection Act requires consent for any processing of personal data.

Verbal or written consent?

When a research project falls within the scope of the Swiss Federal Act on Research on Human Beings (Human Research Act, HRA) and its ordinance (Human research Ordinance, HRO), consent must be explicit and written. The persons concerned (e.g. research participants) must receive comprehensible oral and written information on (HRA,

Art. 16):

- the nature, purpose, and duration of, and procedure for, the research project;
- the foreseeable risks and burdens;
- the expected benefits of the research project, in particular for themselves or for other people;
- the measures taken to protect the personal data collected; and
- their rights,

and on (HRO, Art. 8):

- the effort involved and the obligations arising from participation;
- their right to withhold or to revoke their consent without giving reasons;
- the consequences of revoking consent to further use of the biological material and personal data collected up to this point;
- their right to receive information at any time in response to further questions;
- their right to be informed of results concerning their health, and their right to forgo such information or to designate a person who is to take this decision for them;
- the measures envisaged to cover any damage arising from the research project, including the procedure in the event of a claim;
- the main sources of financing for the research project; and
- other points relevant to their decision on participation.

Procedures and modalities of consent, however, vary according to the risks entailed by the data collection methods. More precisely, projects considered "low risk" (category A), such as those based on observation and questionnaires, benefit from a lighter informed consent approach:

- the information may be given to the participants in successive stages and in a form other than text (HRO, Art. 8);
- consent may be given and documented in a form other than written form (oral consent), provided that the research project is carried out with adults capable of discernment (Art. 9);
- the possibility of using personal health-related data even after the revocation of consent, provided that the data are anonymised (Art. 10).

Despite these exceptions, researchers are never exempt from the obligation to inform participants in advance of the conditions and objectives of the project (Art. 8), and to guarantee the protection of personal data collected and/or used (Art. 5).

United Kingdom

National legislation

There is no legislative requirement for consent to be sought from participants. However, many funders, RECs, and ethics guidance bodies require it.

Consent required to conduct research?

No.

Verbal or written consent?

Either is permitted.

One-off or process consent?

Either is permitted.

5.5 Anonymisation

> *I am collecting data on asylum seekers' and refugees' experiences of forced labour. These participants can be considered 'doubly vulnerable'. We want to share these data. How should we protect our participant's anonymity?*

A possible approach

Consider:

- not recording any official identifying data (e.g. Home Office numbers);
- letting participants choose their own pseudonyms (which should not be disclosive in any way);
- password-protecting interviewee contact details;
- not connecting pseudonyms to these password protected interviewee contact details.

Read more about the ethical considerations of this real-life project at the site of the Economic and Social Research Council (ESRC, 2017c).

The best way to protect your participant's privacy may be not to collect certain identifiable information at all. The second best is anonymisation which allows data to be shared whilst protecting participant's personal information. Anonymisation should be considered in the context of the whole project and how it can be utilised alongside, informed consent and access controls. For example, if a participant consents to their data being shared then the use of anonymisation may not be required.

Personal data can be disclosed through two categories of identifiers.

- **Direct identifiers** are ones like the participant's name, address, or telephone numbers that specifically identify them;
- **Indirect identifiers** are ones that when they are placed with other information could also reveal an individual, for example, by cross-referencing occupation, salary, age, and location.

Anonymisation versus pseudonimisation

Pseudonymisation and anonymisation are two distinct terms which fall under different categories in the General Data Protection Regulation (GDPR; European Union, 2016a). Whereas anonymisation irreversibly destroys any way of identifying the data subject, in theory, pseudonymisation allows to re-identify the data subject with additional information.

The GDPR defines pseudonimisation as "the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information". To pseudonymise a dataset "the additional information must be kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person". Directly identifying data is held separately and securely from processed data to ensure non-attribution.

Anonymous data is data that cannot identify individuals in the dataset in any way. Neither directly through name or social security number, indirectly through background variables, nor through a list of names or through an encryption formula and code/scrambling key.

Anonymisation methods

When anonymising, data identifiers need to be removed, generalised, aggregated or distorted. Below, best practices for anonymising quantitative and qualitative data are given.

Quantitative data

Best practices for anonymising quantitative data:

- This may involve removing or aggregating variables or reducing the precision or detailed textual meaning of a variable;
- Aggregate or reduce the precision of a variable such as age or place of residence. As a general rule, report the lowest level of geo-referencing that will not potentially breach respondent confidentiality;
- Generalise the meaning of a detailed text variable by replacing potentially disclosive free-text responses with more general text;
- Restrict the upper or lower ranges of a continuous variable to hide outliers if the values for certain individuals are unusual or atypical within the wider group researched.

Qualitative data

Best practices for anonymising qualitative data:

- Using pseudonyms or generic descriptors to edit identifying information, rather than blanking-out that information;
- Plan anonymisation at the time of transcription or initial write-up, (longitudinal studies may be an exception if relationships between waves of interviews need special attention for harmonised editing);
- Use pseudonyms or replacements that are consistent throughout the research team and the project. For example, using the same pseudonyms in publications and follow-up research;
- Use 'search and replace' techniques carefully so that unintended changes are not made, and misspelt words are not missed;
- Identify replacements in text clearly, for example with [brackets] or using XML tags such as <seg>word to be anonymised</seg>;
- Create an anonymisation log (also known as a de-anonymisation key) of all replacements, aggregations or removals made and store such a log securely and separately from the anonymised data files.

Example: anonymisation methods in Finland

An example of anonymisation methods is available in the online version of this guide.

Expert tips

1. Data access controls

In situations where (sensitive) personal data are not fully anonymised, data can still be archived and shared by regulating or limiting access to the data. Access controls can permit control down to an individual file level, meaning that mixed levels of access control can be applied to a data collection. You will learn more about choosing the appropriate data access category for your data files in the chapter on archiving and publishing data (see 'Access categories').

2. Irreversible anonymisation

In some countries, anonymisation needs to be irreversible and the original data deleted. Be sure to check the national requirements.

3. Anonymisation tools

The UK Data Archive (n.d.b.) has developed a Text anonymisation helper tool (downloads in a .zip file) with how to install instructions via Wiki. It is an add-on MS Word macro for aiding anonymisation of qualitative data.

4. Reading tip

In this factsheet by OpenAIRE (2017) you are guided in how to balance open access and data protection and advised on what to do when anonymisation isn't possible.

Case study

In a research study on investigating how couples manage their households during recessions (Gush and Laury, 2015), finding the right balance between confidentiality and usefulness of the data was a real challenge (UK Data Service, 2017c). Archiving challenges with this project were to anonymise the data and apply optimal access conditions.

Careful judgement was required to apply the level of anonymisation most appropriate for this particular data. The research team members went through the transcripts and removed certain types of identifying data such as names, places of work, and geographic areas. Regarding access conditions, it was decided to make the data available using a Special Licence (UK Data Service, 2017d; see 'Licensing your data' for other possible licences). Under this kind of licence, a potential user is required not only to register with the UK Data Service, but also to complete a detailed application form and agree to additional restrictions on data handling and usage. The use of the Special Licence then made it possible to apply a minimal level of anonymisation, thus reducing the loss of data quality.

A practice in anonymising qualitative data

Follow the steps to see whether you recognise direct and indirect identifiers in an interview transcript and whether you know how to deal with them accordingly.

Step 1. Read the study background.

Mr Tom Jeavons, aged 63, was suffering from metastatic cancer resulting from a primary site in the bladder. His wife, Sue (58), had been his main carer for many months as he struggled with severe pain, anxiety and other symptoms. Eventually, she received support from the hospice at home team, based at their nearby hospice – St Barbara. 11 days before his death, he was admitted to their inpatient unit, where he died. The case was identified by the staff there as a "critical case", involving palliative sedation and the difficulties staff experienced in controlling his complex symptoms. Other interviews carried out were with the hospice consultant, Dr Jane O'Connor and three nurses: Elaine McDonald, Claire Smith, and Mark Ferguson. Mr and Mrs Jeavons' GP, Dr Paul Hyde, was also interviewed which added a different medical perspective, making this an unusual case.

Central themes in all of the interviews were his intractable and distressing symptoms and the repeated requests from Mr Jeavons for euthanasia. His wife mentions earlier discussions with Mr Jeavons about the possibility of going to a Dignitas clinic, but he was already too ill to travel. She also expresses how concerned she was about what Mr Jeavons's adult children might witness when he was dying in the hospice.

Source: Data collection by Seymour (2010-2012).

Step 2. Read the transcript and uncover direct and indirect identifiers

Read through the interview script and consider what anonymisation would be needed before archiving this transcript for future sharing.

TRANSCRIPT SYMBOLS	
INT	Interviewer
RESP	Respondent
[?]	Unintelligible

INT: So, really, it's as I said to you: I want you to tell me what you can remember about Mr Jeavons' care in the last week of his life … or about Mr Jeavons in the last week of his life.

RESP: Yeah, erm, 11 days, Tom was in St Barbara's Hospice for the last 11 days of his life so…

INT: So if you'd like to talk about that period…

RESP: Yeah.

INT: …that'd be great.

RESP: Prior to him going in, and we was coping with his care at home, but then he was becoming less and less mobile: he couldn't go to the toilet; he had a frame, and everything that you added in that was, it was a step to help him but a downward step to the end of how he could cope. We had a Bariatric bed brought into the other room but he insisted in sleeping in his chair. We had St Barbara's here and, erm, the GP, and, er, we also had him assessed at home as to whether or not we could care for him completely at home. And Tom was about 20-something stone, so he wasn't easy to manoeuvre and, and the one thing that concerned me was the fact that, erm, they needed four people to move him, you know, if he wanted to go to the toilet or if he wanted to go on a bedpan or anything, and we had the bed in there – which he wouldn't sleep in. And, erm, basically the, logistically trying to be able to do everything for him and keep him comfortable, we'd have to wait for an on-call four nurses – could be in the middle of the night – and, and sort of the idea of being able to cope, erm, for his safety and wellbeing was, was really compromised. He didn't want to go into St Barbara's, he didn't want to die in hospital, erm, but I just felt I had to take that decision to say, erm, when the guy came out to assess him, erm, he said, 'We can do it but, you know, you've got to say what you're going to do at three o'clock on Saturday, early hours of

Saturday morning, and he wants to go on the bedpan or you need to change him or whatever.' And, and it, I had to let logic and let my heart… be ruled by my head.

INT: Mm.

RESP: So we got him into St Barbara's., and he went in on the Friday, 11 days before he died, and, erm… when, when he went in – because he couldn't move – from, from a few days before that he wasn't able to move to get to the toilet or anything and we got commodes and things like that and, you know, with having young, young girls in here, we couldn't find him somewhere that he could be private…

INT: Mm.

RESP: …and that was a bit of a problem for him, because he was a very private man in that, in that way. Erm, so we went into St Barbara's on the Friday and they decided that what they were going to do was going to fit him with a catheter. Well, unfortunately, it was so traumatic for him because all Tom's waterworks had retracted…

INT: Ah.

RESP: …so much, but there was a determination on the, on the part of the staff to try and make it easier for him to have this catheter put in. Well, it wasn't, it was counter-productive really because, erm, his son came to see his dad, and I was there, and we went out the room and this nurse had spent about an hour and a half trying to get this catheter in. They tried to do it at home, erm, and failed…

INT: Mm.

RESP: …and of course he was incredibly sensitive, incredibly tender and everything else, and everything had shrunken and retracted so far back it was nigh impossible to actually, to do it without causing him any distress.

INT: Mm.

RESP: So they left it at home but we tried to get it done, erm, in the hospital, they tried to do it, and this lady, erm, had succeeded in getting a catheter in, but he was traumatised by it – there was no other word, he was traumatised – and when myself and his son went back into the room after about an hour and a half, waiting for this thing to, to be finished, er, he actually said to me and to his son, 'Just go away and leave me alone.' And that, unfortunately, was the last time his son saw him, so, Darren lives way over in Seatown. So unfortunate his son's last memory was that. So he stuck with the catheter but the catheter didn't really feel that comfortable, and every time he passed water he was actually yelling in pain. Er, two or three days later they actually took the catheter out and just put him on a pad and, and let him just wee, because, to be honest, did it matter? You know, and to put him through it, he was traumatised with his catheter fitting, and, you know, obviously they're trying to make life easier and more comfortable, erm, but it was, as I say, it was counter-productive.

Anyway, erm… I came home, had a shower, went back in and he was a little bit calmer. Erm… before he went in, erm, he wasn't eating very much or drinking very much, because his, his requirement for food – he kept asking for, for help to die, because he'd enough – he was, he was really, there was no quality; he was in such a lot of pain; he was on such a lot of drugs, and he, he just really, there was no value to him just languishing as he was. Erm, and so it was basically decided that if, if he wanted a drink… a drink would always be there if he wanted one, but there'd be no encouragement, erm, because as, as St Barbara's said, 'We can't kill him,' you know, quite [?], 'We can't…' you know, 'There's nothing we can't… we can keep him out of pain; we can keep him calm, erm, but we can't kill him.' Erm, and I remember him saying to Dr O'Connor 'Just put the boot in, Dr O' Connor.' … 'Just put the boot…' [?], he'd had enough. Anyway … [ ] I cannot criticise the care that they gave him at St Barbara's because it was, you know, fantastic.

Step 3. Have a look at the answers to this exercise

Here you find the answer to what direct and indirect identifiers need to be anonymised. They are underlined and given a number in brackets. At the bottom of the page, you see how anonymisation can be done for each case.

TRANSCRIPT SYMBOLS	
INT	Interviewer
RESP	Respondent
[?]	Unintelligible
[ ]	Edited to maintain anonymity **[1- Added to clarify anonymisation of transcript]**

Mr Tom Jeavons **[2 - Delete and replace with [This gentleman]]**, aged 63, **[3 - Delete]** was suffering from metastatic cancer resulting from a primary site in the bladder **[4 - Delete]**. His wife, Sue **[5 - Delete]** (58), **[6 - Delete]** had been his main carer for many months as he struggled with severe pain, anxiety and other symptoms. Eventually, she received support from the hospice at home team, based at their nearby hospice – St Barbara. **[7 - Delete]** 11 days before his death, he was admitted to their inpatient unit, where he died. The case was identified by the staff there as a "critical case", involving palliative sedation and the difficulties staff experienced in controlling his complex symptoms. Other interviews carried out were with the hospice consultant, Dr Jane O'Connor **[8 - Delete]** and three nurses: Elaine McDonald, Claire Smith and Mark Ferguson **[9 - Delete]**. Mr and Mrs Jeavons' **[10 - Delete and replace with [The couple's]]** GP, Dr Paul Hyde, **[11 - Delete]** was also interviewed which added a different medical perspective, making this an unusual case.

Central themes in all of the interviews were his intractable and distressing symptoms and the repeated requests from Mr Jeavons **[12 - Delete and replace with [the patient]]** for euthanasia. His wife mentions earlier discussions with Mr Jeavons **[13 - Delete and replace with [her husband]]** about the possibility of going to a Dignitas clinic, but he was already too ill to travel. She also expresses how concerned she was about what Mr Jeavons's **[14 - Delete and replace with [his]]** adult children might witness when he was dying in the hospice.

INT: So, really, it's as I said to you: I want you to tell me what you can remember about Mr Jeavons' **[15 - Delete and replace with [your husband's]]** care in the last week of his life … or about Mr Jeavons **[16 - Delete and replace with [your husband]]** in the last week of his life.

RESP: Yeah, erm, 11 days, Tom **[17 - Delete and replace with [he]]** was in St Barbara's Hospice **[18 - Delete and replace with [the hospice]]** for the last 11 days of his life so…

INT: So if you'd like to talk about that period…

RESP: Yeah.

INT: …that'd be great.

RESP: Prior to him going in, and we was coping with his care at home, but then he was becoming less and less mobile: he couldn't go to the toilet; he had a frame, and everything that you added in that was, it was a step to help him but a downward step to the end of how he could cope. We had a Bariatric bed brought into the other room but he insisted in sleeping in his chair. We had St Barbara's **[19 - Delete and add [hospice at home]]** here and, erm, the GP, and, er, we also had him assessed at home as to whether or not we could care for him completely at home. And Tom **[20 - Delete and replace with [he]]** was about 20-something stone, so he wasn't easy to manoeuvre and, and the one thing that concerned me was the fact that, erm, they needed four people to move him, you know, if he wanted to go to the toilet or if he wanted to go on a bedpan or anything, and we had the bed in there – which he wouldn't sleep in. And, erm, basically the, logistically trying to be able to do everything for him and keep him comfortable, we'd have to wait for an on-call four nurses – could be in the middle of the night – and, and sort of the idea of being able to cope, erm, for his safety and wellbeing was, was really compromised. He didn't want to go into St Barbara's **[21 - Delete and replace with [the hospice]]** , he didn't want to die in hospital, erm, but I just felt I had to take that decision to say, erm, when the guy came out to assess him, erm, he said, 'We can do it but, you know, you've got to say what you're going to do at three o'clock on Saturday, early hours of Saturday morning, and he wants to go on the bedpan or you need to change him or whatever.' And, and it, I had to let logic and let my heart… be ruled by my head.

INT: Mm.

RESP: So we got him into St Barbara's **[22 Delete and replace with [the hospice]],** and he went in on the Friday, 11 days before he died, and, erm… when, when he went in – because he couldn't move – from, from a few days before that he wasn't able to move to get to the toilet or anything and we got commodes and things like that and,

you know, with having young, young girls in here, we couldn't find him somewhere that he could be private...

INT: Mm.

RESP: ...and that was a bit of a problem for him, because he was a very private man in that, in that way. Erm, so we went into St Barbara's **[23 Delete and replace with [the hospice]]** on the Friday and they decided that what they were going to do was going to fit him with a catheter. Well, unfortunately, it was so traumatic for him because all Tom's **[24 - Delete and replace with [his]]** waterworks had retracted...

INT: Ah.

RESP: ...so much, but there was a determination on the, on the part of the staff to try and make it easier for him to have this catheter put in. Well, it wasn't, it was counter-productive really because, erm, his son came to see his dad, and I was there, and we went out the room and this nurse had spent about an hour and a half trying to get this catheter in. They tried to do it at home, erm, and failed...

INT: Mm.

RESP: ...and of course he was incredibly sensitive, incredibly tender and everything else, and everything had shrunken and retracted so far back it was nigh impossible to actually, to do it without causing him any distress.

INT: Mm.

RESP: So they left it at home but we tried to get it done, erm, in the hospital, they tried to do it, and this lady, erm, had succeeded in getting a catheter in, but he was traumatised by it – there was no other word, he was traumatised – and when myself and his son went back into the room after about an hour and a half, waiting for this thing to, to be finished, er, he actually said to me and to his son, 'Just go away and leave me alone.' And that, unfortunately, was the last time his son saw him, so, Darren **[25 - Delete and replace with [his son]]** lives way over in Seatown **[26 - Delete and replace with [he lives some distance away]]**. So unfortunate his son's last memory was that. So he stuck with the catheter but the catheter didn't really feel that comfortable, and every time he passed water he was actually yelling in pain. Er, two or three days later they actually took the catheter out and just put him on a pad and, and let him just wee, because, to be honest, did it matter? You know, and to put him through it, he was traumatised with his catheter fitting, and, you know, obviously they're trying to make life easier and more comfortable, erm, but it was, as I say, it was counter-productive.

Anyway, erm... I came home, had a shower, went back in and he was a little bit calmer. Erm... before he went in, erm, he wasn't eating very much or drinking very much, because his, his requirement for food – he kept asking for, for help to die, because he'd enough – he was, he was really, there was no quality; he was in such a lot of pain; he was on such a lot of drugs, and he, he just really, there was no value to him just languishing as he was. Erm, and so it was basically decided that if, if he wanted a drink... a drink would always be there if he wanted one, but there'd be no encouragement, erm, because as, as St Barbara's **[27 - Delete and replace with [the hospice]]** said, 'We can't kill him,' you know, quite [?], 'We can't...' you know, 'There's nothing we can't... we can keep him out of pain; we can keep him calm, erm, but we can't kill him.' Erm, and I remember him saying to Dr O'Connor **[28 -Delete and replace with [the doctor]]** 'Just put the boot in, Dr O' Connor **[29 - Delete and replace with [doctor]]** .' ... 'Just put the boot...' [?], he'd had enough. Anyway ... [ ] I cannot criticise the care that they gave him at St Barbara's **[30 - Delete and replace with [the hospice]]** because it was, you know, fantastic.

5.6 Copyright

Copyright is an internationally recognised form of intellectual property right, which arises automatically as a result of original work such as research. It does not need to be registered to apply to a piece of work.

Copyrighted output from research could include spreadsheets (and other forms of originally selected and organised data), publications, reports and computer programs. Copyright will not cover the underlying facts, ideas or concepts, but only the particular way in which they have been expressed. The right will lie with the author of the work, or with their relevant institution—different universities will have different policies on intellectual property.

A copyrighted work cannot usually be published, reproduced, adapted or translated without the owner's permission.

Key copyright considerations for researchers

Whether you want to reuse someone else's data or if you are planning to archive and share your own, you should ask yourself who the copyright holder of the datasets is (also see 'Licensing your data'). Are you allowed to use them and in what way? Are you allowed to archive and publish them in a data repository? How do you answer the question who the copyright holder of a dataset is? Is it you, your employer, the data archive, fellow researchers? The answer depends on multiple factors, such as who had input into creating the research data, whether data were used from other datasets, and what the researcher's contract of employment stipulates.

Key copyright considerations for researchers are highlighted below:

Joint ownership

In two cases multiple copyright holders exist and joint ownership is implied:

- **Datasets created by multiple researchers**
  When data is collected, and created by multiple researchers, then multiple researchers may be listed as joint copyright holders, with all gaining and retaining intellectual property rights. Prior to archiving it is important to ensure permission for depositing data is given by all copyright holders as well as participants.
- **Derived datasets**
  The key issue with derived data is the matter of copyright ownership. Because the resulting data is derived from previously created data the permission of the original copyright holder should be sought before the data is deposited with a repository. The best practice is for researchers to try to negotiate the sharing of derived data with the data suppliers at the time of acquisition or purchase. If permission is granted then they should also be listed as a joint copyright owner.

Database rights

Database rights acknowledge the investment made by a researcher in developing a database, even in cases where this does not involve a creative aspect. The organisation, structuring of a database and the selecting of which data to include in the database are all decisions which can receive protection through copyright legislation. If you want to use (large parts of) a database you should always ask the permission of the database creator.

Provisions in a contract

Depending on the employer you might have a stipulation in your contract that any works which are created during employment are the intellectual property of the employer. But, even where contracts of employment make this statement we typically find that the employer is happy for the researcher to be listed as the copyright holder or for the employer and employee to be listed as a joint holder.

Repository copyright rules

Most repositories operate a system of not acquiring any copyright ownership in the data*. Before you deposit your data the repository will need to be informed – and confirm – who the copyright owner is.

What we typically see in practice is that the researcher who authors (creates) the work is listed as the copyright owner for the dataset when it is deposited in a repository. Repositories act merely as a facilitator of access to the data, with some guaranteeing to curate and provide permanent access to the data.

* However, this can differ from country-to-country and archive-to-archive. Researchers should, therefore, clarify with the repository copyright rules before depositing the data, and ideally before conducting research, so that consent forms and information sheets can inform participants accurately of who will own – and have copyright of – the data once the research project has commenced.

Case studies

In the following case studies, you can identify the potential copyright issues and state how you would address these in practice.

Case Study 1 – Copyright of Archived Data

A researcher uses International Social Survey Programme (ISSP, n.d.) data obtained from ZACAT/GESIS - Leibniz Institute for the Social Sciences in Germany. These data are freely available to registered users. The researcher incorporates some of the ISSP data within a database containing his own research data. Can this database be deposited with another archive?

Answer: Although the ISSP data are available for free to all researchers, this does not mean that the data can be published in another archive and made available to others. The data can be incorporated into a database and used for personal analysis. But, before this dataset can be deposited with another archive, permission must be sought from the owner of the original data.

Case Study 2 – Copyright of Data in the Public Domain

A researcher studies how health issues around obesity are reported in the media in the last 10 years. Freely available newspaper websites and library sources are used to obtain articles on this topic. Articles or excerpts are copied into a database and coded according to various criteria for content analysis. (i) Can the researcher use such public data without breaching copyright? (ii) Can the database be archived and shared with other researchers?

Answer: Even though the articles are publicly available, they are still under copyright. Whilst such information can be used for personal research purposes (e.g.in the UK this would be under the broad exemption of 'fair dealing'), the articles cannot be archived unless permission is obtained from the newspapers; otherwise this would breach copyright.

Case Study 3 – Copyright of Survey Questions

A researcher wishes to reuse a set of questions from an existing survey questionnaire, to compare results between the newly proposed survey and the original.

Answer: The survey questions and instruments will be copyright protected, with copyright residing with the organisation who commissioned, designed or conducted the survey (unless the original creator/ owner transfers all ownership rights). The researcher needs to contact the copyright holder directly for permission to reproduce the questionnaire text for any new use. Some questionnaires will contain measurement scales, batteries of questions or classifications. These instruments are again copyrighted. Therefore, to reproduce them the researcher will need permission.

Case Study 4 – Copyright of Interviews with Stay-at-Home Parents

A researcher interviews various stay-at-home parents about their careers and produces audio recordings and near-verbatim transcripts herself. The researcher analyses this material and offers it to a data archive. The researcher did not get signed copyright transfers for the interviewees' words. What are the rights issues surrounding this offer of data?

Answer: In this case, the stay-at-home parents hold copyright in their own recorded words, whilst the researcher holds copyright over the transcribed interviews. Quoting large extracts of the data, either in publications or by archiving the transcripts, would breach the copyright of the interviewees in their recorded words. If the researcher wants to publish large extracts of data, or archive the transcripts, they need to request permission to do so from the interviewees or request that the interviewee transfers the copyright of the interview content to the researcher, which could be achieved through the use of a Recording Agreement.

5.6.1 Diversity in copyright

Copyright legislation is created at an individual country level as there is not an international copyright law, though many countries have signed up to the Berne Convention (WIPO, 1979). For these reasons, it is important that researchers identify the relevant national copyright legislation.

The European Commission is looking to reform EU copyright law further, having published a package of reform proposals, which currently include a Directive and a Regulation. One of the aims of these reforms is to improve copyright rules on research and education.

Below we list information on national copyright legislation, what is covered, the copyright duration and the exceptions and limitations.

For updated information, also see the online version of this guide.

Croatia

National legislation

Copyright and Related Rights Act and the Act on Amendments to the Copyright and Related Rights Act (Official Gazette N°167/2003, N°79/2007, N°80/2011, N°141/2013, N°127/2014, N°62/2017, N°96/2018)

[Croatian] [English]

Duration

Article 99: "Copyright shall run for the life of the author and for 70 years after his death, irrespective of the date when the work is lawfully released, unless otherwise provided by the Copyright Act."

Article 152: "Rights of a producer of a database shall run for 15 years as from the date of the completion of the making of the database. If the database is lawfully disclosed during this period, the rights shall run for 15 years as from the first such disclosure."

What is covered

The Copyright and Related Rights Act regulates:

copyright - rights of authors in respect of their works in the literary, scientific and artistic domains; and related rights, among which the rights of producers of databases in respect of their databases might be of relevance to researchers.

Article 5: "A copyright work shall be an original intellectual creation in the literary, scientific and artistic domain, having an individual character, irrespective of the manner and form of its expression, its type, value or purpose."

Article 7: "Collections of independent works, data or other materials, such as encyclopaedias, collections of documents, anthologies, databases, and the like, which by reason of the selection or arrangement of their constituent elements constitute personal intellectual creations of their authors shall be protected as such. Databases, under this Act, shall be collections arranged according to certain system or method, the elements of which are individually accessible by electronic or other means."

Chapter 6: "Rights of producers of databases, Article 147: A database, under this Chapter of the Act, shall mean a collection of independent works, data or other materials in any form, arranged in a certain systematic or methodical way and individually accessible by electronic or other means, whereby either the obtaining, verification or presentation of is contents requires a qualitatively and/or quantitatively substantial investment in terms of resources, time and efforts engaged."

Exceptions and limitations

Unprotected creations

Article 8: "(1) The subject matter of copyright shall include expressions and not ideas, procedures, methods of operation or mathematical concepts as such. (2) The subject matter of copyright shall not include: 1. discoveries, official texts in the domain of legislation, administration, judiciary (acts, regulations, decisions, reports, minutes, judgments, standards, and the like) and other official works and their collections, disclosed for the purpose of officially informing the public; 2. news of the day and other news, having the character of mere items of press information; (3) Folk literary and artistic creations in their original form shall not be the subject matter of copyright, but their communication to the public is subject to the payment of remuneration, as for the communication to the public of protected copyright works. The remuneration shall be the revenue of the budget, and shall be used for improving the creativity in the field concerned."

Exceptions regarding rights of producers of databases

Article 150: "An authorized user of a disclosed database may, without the authorization of its producer, use the substantial parts of its contents in the case: 1. referred to in Article 149, item 1 of this Act for private use of a non-electronic database; 2. referred to in Article 149, item 1 of this Act for use intended for teaching or scientific research, provided that the source is indicated and to the extent justified by the non-commercial purpose; 3. referred to in Article 149, items 1, 2, 3, and 4 of this Act for use required for public safety, or for administrative or judicial proceedings."

Czech Republic

National legislation

Copyright Act No. 121/2000; 07/2017 (2000) (in Czech).

In English, version 01/2015: Consolidated text of Act No. 121/2000 on Copyright and Rights Related to Copyright and on Amendment to Certain Acts (the Copyright Act (Ministry of Culture Czech Republic (2000); pdf, downloads on click)).

Duration

Copyright duration varies based on the type of work. Unless stipulated otherwise, economic rights shall run for the life of the author and 70 years after his death but this is 50 years for Performer's Economic Rights, phonogram, broadcasters, and publishers. The right sui generis of the maker of the database shall run for 15 years from the making of the database.

What is covered

- Vol.I., Art.2: (1)"...shall be a literary work or any other work of art or a scientific work, which is a unique outcome of the creative activity of the author and is expressed in any objectively perceivable manner including electronic form, permanent or temporary, irrespective of its scope, purpose or significance.. A work shall be, without limitation, a literary work expressed by speech or in writing, a musical work, a dramatic work or musical-dramatical work, a choreographic work and pantomimic work , a photographic work and a work produced by a process similar to photography, an audiovisual work such as a cinematographic work, a work of fine arts such as a painting, graphic or sculptural work, an work of architecture including an urban design work, a work of applied art, and a cartographic work.
- A computer program shall also be considered a work if it is original in the sense that it is the author's own intellectual creation. A database which by the way of the selection or arrangement of its content is the author's own intellectual creation, and in which the individual parts are arranged in a systematic or methodical way and are individually accessible by electronic or other means, is a collection of works. No other criteria shall be applied to determine their eligibility for that protection. A photograph or a work produced by a process similar to photography, which are original in the sense of the first sentence, shall be protected as a photographic work.

- A work which is the outcome of the creative adaptation of another work, including its translation into another language, shall also be subject to copyright. This shall be without prejudice to the rights of the author of the adapted or translated work.
- A collection like a journal, encyclopaedia, anthology, exhibition, or any other collection of independent works or other elements that by reason of their selection and of the arrangement of the content meet the conditions set out in Paragraph 1 above, is a collection of works.
- The items that are not works hereunder, shall include, but are not limited to the theme (subject) of a work as such, the news of the day and any other fact as such, an idea, procedure, principle, method, discovery, scientific theory, mathematical and similar formula, statistical diagram and similar item as such".

Exceptions and limitations

No copyright, Art. 3: a) an official work, such as a legal regulation, decision, public charter, publicly accessible register and collection of its documents, and also any official draft of an official work and other preparatory official documentation including the official translation of such work, Chamber of Deputies and Senate publications, a memorial chronicle of a municipality (municipal chronicles), a state symbol and symbol of a municipality, and any other such works where there is public interest in their exclusion from copyright protection, b) creations of traditional folk culture, unless the real name of the author is commonly known and the works are anonymous or pseudonymous (Article 7); such works may only be used in a way that shall not detract from their value.

Finland

National legislation

Copyright Act (404/1961, amendments up to 608/2015) (2015).

Duration

Copyright shall subsist until 70 years have elapsed from the year of the author's death or from the year of death of the last surviving author.

What is covered

A person who has created a literary or artistic work shall have copyright therein, whether it be a fictional or descriptive representation in writing or speech, a musical or dramatic work, a cinematographic work, a photographic work or other work of fine art, a product of architecture, artistic handicraft, industrial art, or expressed in some other manner. Maps and other descriptive drawings or graphically or three-dimensionally executed works and computer programs shall also be considered literary works.

Exceptions and limitations

There shall be no copyright: 1) in laws and decrees; 2) in resolutions, stipulations and other documents which are published under the Act on the Statutes of Finland (188/2000) and the Act on the Regulations of Ministries and other Government Authorities (189/2000); 3) treaties, conventions and other corresponding documents containing international obligations; 4) decisions and statements issued by public authorities or other public bodies; 5) translations of documents referred to in paragraphs 1–4 made by or commissioned by public authorities or other public bodies.

The provisions of subsection 1 shall not apply to independent works contained in the documents referred to in the subsection.

Germany

National legislation

Act on copyright and related rights (2016).

Duration

Copyright expires 70 years after the author's death.

What is covered

Protected Works

Protected works in the literary, scientific and artistic domain include, in particular:

1. Literary works, such as written works, speeches, and computer programs;

2. Musical works;

3. Pantomimic works, including works of dance;

4. Artistic works, including works of architecture and of applied art and drafts of such works;

5. Photographic works, including works produced by processes similar to photography;

6. Cinematographic works, including works produced by processes similar to cinematography;

7. Illustrations of a scientific or technical nature, such as drawings, plans, maps, sketches, tables and three-dimensional representations.

Only the author's own intellectual creations constitute works within the meaning of this Act.

Collections and database works

1. Collections of works, data or other independent elements which by reason of the selection or arrangement of the elements constitute the author's own intellectual creation (collections) are protected as independent works without prejudice to an existing copyright or related right in one of the individual elements;

2. A database work within the meaning of this Act is a collection whose elements are arranged systematically or methodically and the individual elements are individually accessible by electronic or other means. A computer program (section 69a) used in the creation of the database work or to provide access to its elements does not constitute an integral part of the database work.

Exceptions and limitations

Official works

1. Acts, statutory instruments, official decrees and official notices, as well as decisions and official head notes of decisions, do not enjoy copyright protection;

2. The same applies to other official texts published in the official interest for general information purposes, subject to the proviso that the provisions concerning the prohibition of alteration and the indication of sources in section 62 (1) to (3) and section 63 (1) and (2) shall apply mutatis mutandis.

Authors in employment or service

The provisions of this subchapter shall also apply where the author has created the work in the fulfilment of obligations resulting from an employment or service relationship unless otherwise provided in accordance with the terms or nature of the employment or service relationship.

The German 'Gesetz über Urheberrecht und verwandte Schutzrechte (UrhG)' makes several exceptions when works are used in the context of research or teaching.

Greece

Law 2121/1993, as in force for copyright issues;

Law 4481/2017 for copyright collective management issues.

Duration

Copyright expires 70 years after the author's death.

What is covered

Protected Works

Protected works in the literary, scientific and artistic domain include (described in the text of the law as any original intellectual literary, artistic or scientific creation, expressed in any form), notably:

- written or oral texts,
- musical compositions with or without words,
- theatrical works accompanied or unaccompanied by music,
- choreographies and pantomimes,
- audiovisual works,
- works of fine art, including drawings, works of painting and sculpture, engravings and lithographs,
- works of architecture and photographs,
- works of applied art,
- illustrations, maps and three-dimensional works relative to geography, topography, architecture or science.

Only the author's own intellectual creations constitute works within the meaning of this Act.

Collections and database works

1. The term work also covers translations, adaptations, arrangements and other alterations of works or of expressions of folklore, as well as collections of works or collections of expressions of folklore or of simple facts and data, such as encyclopaedias and anthologies, provided the selection or the arrangement of their contents is original;

2. Databases which, by reason of the selection or arrangement of their contents, constitute the author's intellectual creation, are as such by copyright. The copyright protection shall not extend to the contents of databases and shall be without prejudice any rights subsisting in those contents themselves. Database is a collection of independent works, data or other, materials arranged in a systematic or methodical way and individually accessible by electronic or other means.

3. Computer programs and their preparatory design material are literary works within the meaning of the provisions on copyright protection. Protection in accordance with this Law applies to the expression in any form of a computer program. Ideas and principles which underlie any element of a computer program, including those which underlie its interfaces, are not protected under this Law. A computer program is protected if it is original in the sense that it is the author's personal intellectual creation.

Exception and Limitations

Copyright protection does not apply to:

- official texts expressive of the authority of the State, notably to legislative, administrative or judicial texts
- expressions of folklore,
- news information
- simple facts and data.

The Greek copyright law provides for several exceptions when works are used in the context of research or teaching in articles 18-28 C of law 2121/1993 - see at https://www.opi.gr/en/library/law-2121-1993#ch4.

Netherlands

National legislation

Auteurswet (2017) (in Dutch).

Duration

Copyright is in force until 70 years after the death of the author.

What is covered

The Copyright Act provides protection for works that display a certain creativity or originality.

Exceptions and limitations

Bare facts as such, citations and works produced by the official authorities do not fall under The Copyright act.

North Macedonia

National legislation

Law on copyrights and related rights (Official gazette of the R. Macedonia No. 115/10, 140/10 и 51/11).

What is covered

This law regulates the copyrights of authors over their work, among others, the rights of "....authors of data sets over their works, or related rights...", as well as the practicing and protection of copyrights and related rights (Article 1). According to this law, related rights can also be "databases and their authors". Related rights are regulated with the General provisions on related rights, especially in Part 6 - The rights of authors of databases (Article 118-122). The law includes the following aspects: definition of database authors; contents of the rights of the authors of databases; the scope of protection; rights and obligations of the legal users; restriction of the rights; and duration of the rights of authors of databases. The law also foresees the possibility of regulation of collective management of related rights.

Norway

The new Norway Copyright Act of 16.06.2018 amends the previous one drafted in 1961 (Act No. 2 of May 12, 1961) and consolidated in 2015. Information about the main normative aspects is available here.

Duration

Copyright is in force until 70 years after the death of the author.

Database rights are in force for 15 years after the year of production or after the year of the last update.

What is covered

Research data are rarely protected by copyright, but more often it may be protected by database rights.

A simple rule of thumb is that Copyright protects original works of authorship (scientific articles, books, reports, blogs) but not facts, raw data, etc. unless they are selected and arranged in an original way (cf. Lov om opphavsrett til åndsverk/2018-06-16/§2). One might think, for example, that the selection of variables or other data is unique or creative, but if your selection is motivated by rational questions or objective considerations, it is not "creative" in a copyright sense.

The Norwegian Copyright Act covers Copyright and Related Rights (Neighboring Rights), Enforcement of IP and Related Laws, IP Regulatory Body and Industrial Designs.

The Copyright owner is the author or person to whom rights have been transferred (e.g. the publisher); cf. Lov om opphavsrett til åndsverk/2018-06-16/§8.

According to §41 in Norwegian law, Database right protects databases that are the result of a substantial investment in either the obtaining, verification or presentation of its contents. This means that the investment in the creation of the contents does not give you database rights.

The database right belongs to the maker of the database, i.e. the person (natural or legal) who bears the risk of the investment. Thus, if a database is created in the course of employment, the right will belong to the employer, and not the employee(s). See Lov om opphavsrett til åndsverk/2018-06-16/§41.

Exceptions and limitations

§ 14 of the Norwegian Copyright Act states that laws, regulations, court decisions and other decisions by public authorities are not Copyright protected. The same applies to proposals, investigations and other statements relating to public authority exercise and has been issued by the public authority, publicly appointed council or selection or published by the public.

§ 1-4 of the Norwegian Copyright Act is an exception which allows the production of a copy for research purposes. This provision is relatively new and allows research institutions to apply to the Norwegian Ministry of Culture for the permission to produce copies for research purposes, for example, to cover special needs in language research. The condition is that the production of copies shall not lead to a proliferation in violation of the rights holder's interests and the copy of the product must otherwise conflict with the rights owner's own exploitation of the work.

Serbia

National legislation

The Law on Copyright and Related Rights (Official gazette of RS 104/2009, 99/2011 from 27.12.2011 and 119/2012)

Duration

Pecuniary rights shall last for the life of an author and 70 years after his/her death. The moral rights of an author shall last even after the expiration of his/her pecuniary rights. Co-authors' pecuniary rights shall expire after 70 years elapse from the death of the author that was the last to die. Pecuniary rights concerning the work whose author is unknown (anonymous work or work under a pseudonym) shall expire after 70 years elapse from the date of its disclosure. Should its author reveal his/her identity before the expiration of such term, the pecuniary right shall last the same as if its author's identity has been known since the date of its disclosure. Copyright on the collective works lasts for 70 years from the date of the legal publication of the work.

What is covered

A work of authorship, in particular: Written works (e.g. books, brochures, articles, translations, computer programs in any form of their expression, including their preparatory design material and other); Spoken works (lectures, speeches, orations, etc.); Dramatic, dramatic-musical, choreographic and pantomime works, as well as works originating from folklore; Works of music, with or without words; Films (cinema and television); Fine artworks (paintings, drawings, sketches, graphics, sculptures, etc.); Works of architecture, applied art and industrial design; Cartographic works (geographic and topographic maps); Drawings, sketches, dummies and photographs; and The direction of a theatre play (Article 2). A collection of the works of authorship, which in view of the selection and arrangement of its integral parts, meets the requirements referred to in Article 2, (an encyclopedia, collection of works, anthology, selected works, music collection, photograph collection, graphic map, exhibition and the like), shall also be deemed a work of authorship; a collection of folk literary and artistic creations, as well as a collection of documents, court decisions and similar materials, which in view of their selection and arrangement. A collection

shall also be understood to mean a database, regardless of whether it is in a mechanically or otherwise legible form, which in view of the selection and arrangement of its integral parts.

Exceptions and limitations

The protection of copyright shall not apply to general ideas, procedures and methods of operations or mathematical concepts as such, as well as concepts, principles and instructions included in a work of authorship; Laws, decrees and other regulations; Official materials of state bodies and bodies performing public functions; Official translations of regulations and official materials of state bodies and bodies performing public functions; Submissions and other documents presented in the administrative or court proceedings.

Slovenia

National Legislation

Copyright and Related Rights Act

The Act regulates: the right of authors with respect to their works of literature, science and art (copyright); the rights of performers, producers of phonograms, film producers, broadcasting organizations, publishers and makers of databases (related rights).

What is covered

As copyright works are considered in particular:

1. spoken works such as speeches, sermons, and lectures;
2. written works such as belletristic works, articles, manuals, studies, and computer programs;
3. musical works with or without words;
4. theatrical or theatrical-musical works, and works of puppetry;
5. choreographic works and works of pantomime;
6. photographic works and works produced by a process similar to photography;
7. audiovisual works;
8. works of fine art such as paintings, graphic works, and sculptures;
9. works of architecture such as sketches, plans, and built structures in the field of architecture, urban planning, and landscape architecture;
10. works of applied art and industrial design;
11. cartographic works;
12. presentations of a scientific, educational or technical nature (technical drawings, plans, sketches, tables, expert opinions, three-dimensional representations, and other works of similar nature).

Sweden

National legislation

The Act on Copyright in Literary and Artistic Works (1960:729).

Duration

Copyright of a work shall subsist until the end of the seventieth year after the year in which the author deceased. If a work has two or more authors whose contributions do not constitute independent works, the copyright shall belong to the authors jointly. In that case, copyright subsists until the end of the seventieth year after the year in which the last surviving author deceased.

What is covered

- Anyone who has created a literary or artistic work shall have copyright in that work, regardless of whether it is:
- A fictional or descriptive representation in writing or speech;
- A computer program;
- A musical or dramatic work;
- A cinematographic work;
- A photographic work or another work of fine arts;
- A work of architecture or applied art;
- A work expressed in some other manner.

Maps and other works of a descriptive nature executed as drawings, engravings, or in a three-dimensional form, shall be considered as literary works. What is prescribed in this Act concerning computer programs shall mutatis mutandis apply also to preparatory design material for computer programs. (Act 1994:190)

Exceptions and limitations

- Copyright does not subsist in:
- Laws and other regulations;
- Decisions by public authorities;
- Reports by Swedish public authorities;
- Official translations of texts mentioned under 1–3.

However, copyright subsists in works of the following kinds when they form part of the following documents: maps, works of drawing, painting or engraving, musical works or works of poetry. (Act 2000:92).

Switzerland

National legislation

Swiss Federal Act on Copyright and Related Rights (1992). The DICE project (Université de Genève, 2010) provides a useful handbook on copyright in education in Switzerland.

UK

National legislation

The Copyright, Design and Patents Act dates from 1988.

Duration

Copyright duration varies based on the type of work. For literary and artistic works it is 70 years from the end of the year of the death of creator, for sound recordings it is 50 years from date of creation and for typographical arrangements, it is 25 years from date of publication. For Crown Copyright the duration can be 50 years from the date of publication or 125 years from the date of creation.

What is covered

Original literary, dramatic, musical or artistic works, sound recordings, films, broadcasts or cable programmes or the typographical arrangement of publications.

Exceptions and limitations

The UK has created various exceptions including 'fair dealing' and 'non-commercial research and private study'.

Obstacles to the trans-European archiving and sharing of research data

Making research data as openly available as possible is a widely recognised goal. For researchers working on an interdisciplinary project involving several countries, it can be difficult to fully comprehend in which ways open access to research data can be legally obtained. European national laws still diverge.

A report from Knowledge Exchange (Knowledege Exchange, 2011) concludes that it will remain difficult to predict when particular files of research data are protected because of:

- **Diversity in copyright protection**
  Even though most research data will fail to meet the criteria for copyright protection because they are not likely to be considered as "works" (they mainly concern facts), the lack of harmonisation of the criteria for copyright protection in Europe is tricky. E.g., whereas Germany, Denmark, and the Netherlands have a relatively similar (higher) originality standard, the UK has a very low standard (skill, judgment, and labour) making it possible that collections of research data are easily granted full copyright protection.
- **Diversity in copyright owner**
  If protection applies, the right holder's consent is required for sharing the data. However, the designation of the copyright owner is also different in different jurisdictions. Although in many cases the maker of the work will be considered to be the author and therefore the right holder, only Dutch and UK law designate the employer as the right holder if the work was made in the course of employment.

Licences as a way forward

Therefore, the authors conclude that to ensure that research data can be shared and reused freely licences should always be obtained from the potential rights holders. With the right licence, researchers can waive claims to any IP rights that might apply to research data that they generate in the course of publicly funded research. In the chapter 'Archiving and publishing data' we will look into 'Data licensing'.

5.7 Adapt your DMP: part 5

This is the fifth of seven 'Adapt your DMP' sections in this tour guide.

After working on this chapter, you should be able to define your strategy in protecting the rights of your participants whilst making your data available for as full and effective use as possible for the scientific community and the public. Filling in this part of your DMP will show how you are taking legal and ethical factors into consideration and it can actually help you navigate ethical review (self-assessment or formal).

To adapt your DMP, consider the following elements and corresponding questions:

Type of data

- Are you collecting personal data or do your data in any other way require special protection?
- How is (sensitive) personal data protected during the project? (also see 'Storing your data')

Ethical review (if applicable)

- Does your project require approval by a local ethics committee?
- If so, how are your preparing for this review?
- How will possible ethical issues be taken into account, and codes of conduct followed?

Informed consent (if applicable)

- Do you require informed consent for your project? If so, how will permission be obtained?
- Are you gaining written consent from respondents to share data beyond your research?
- Did you discuss data archiving and sharing with the respondents from whom you collected the data?
- Are you adequately documenting your consent to comply with the GDPR?
- How are consent files organized and stored?

Protecting participants

- How are you going to protect the privacy of your participants?
- Are you complying with data protection legislation?
- Do you need to anonymise data, for example, to remove identifying information or personal data, during research or in preparation for sharing?

Intellectual property

- Are there IPR or copyright issues to consider?
- Have you established who owns the copyright in your data? Might there be joint copyright?
- Will permission be needed to collect/reuse the data?
- Will these rights be transferred to another organisation for data archiving?

For easy reference, we have put together a list of DMP-questions for all chapters in this tour guide. You can view and download the checklist as pdf (CESSDA, 2018a) or editable form (CESSDA, 2018b), and keep them as a reference while you are studying the contents of this guide.

Sources and further reading

Please see the online version of this guide.