PANDEM-2
PANDEMIC PREPAREDNESS AND RESPONSE

Privacy, Social & Ethical Issues Preliminary Guide

Deliverable D3.6

27 April 2021

This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement No. 883285

PANDEM-2

Privacy, Social & Ethical issues Preliminary Guide

Document date: 27 April 2021
Document version: 1.0
Deliverable No: 3.6

Full Name	Short Name	Beneficiary Number	Role
NATIONAL UNIVERSITY OF IRELAND GALWAY	NUIG	1	Coordinator
FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V	FRAUNHOFER	2	Beneficiary
UNIVERSITE CATHOLIQUE DE LOUVAIN	UCL	3	Beneficiary
PINTAIL LTD	PT	4	Beneficiary
FOLKHALSOMYNDIGHETEN	FOHM	5	Beneficiary
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	RIVM	6	Beneficiary
CARR COMMUNICATIONS LIMITED	CARR	7	Beneficiary
TERVEYDEN JA HYVINVOINNIN LAITOS	THL	8	Beneficiary
INSTITUTUL NATIONAL DE SANATATE PUBLICA	NIPH	9	Beneficiary
ROBERT KOCH-INSTITUT	RKI	10	Beneficiary
STICHTING KATHOLIEKE UNIVERSITEIT	RUNMC	11	Beneficiary
CLARISOFT TECHNOLOGIES ROM SRL	CLARISOFT	12	Beneficiary
OSTERREICHISCHES ROTES KREUZ	ORK	13	Beneficiary
EPICONCEPT	EPIC	14	Beneficiary
INSTITUTO NACIONAL DE EMERGÊNCIA MÉDICA	INEM	15	Beneficiary
TRILATERAL RESEARCH LTD	TRI	16	Beneficiary
ISTITUTO PER L'INTERSCAMBIO SCIENTIFICO	ISI	17	Beneficiary
ASSOCIAZIONE DELLA CROCE ROSSA ITALIANA	ITRC	18	Beneficiary
INSTITUTO NACIONAL DE SAUDE DR. RICARDO JORGE	INSA	19	Beneficiary

Privacy, Social & Ethical Issues Preliminary Guide

1 Executive Summary

In PANDEM-2 Task 3.5 partner TRI will conduct a comprehensive privacy, social and ethical impact assessment (PIA+) of the PANDEM-2 database, situational awareness and pandemic planning dashboard (data protection is subsumed under a privacy approach). The PIA+ will act as a tool to ensure that the project takes a privacy-by-design approach and will include a process for building GDPR compliance and demonstrating accountability. The PIA+ will be iterative across all phases of the project: 1) design and development of the database and tools, and 2) demonstrations/testing. It is conducted in partnership with the end-users and technical developers. There will be three PIA+ conducted throughout the course of the PANDEM-2 project and they will be distinguished as follows: D3.6 is PIA+_v1, D3.7 is PIA+_v2, and D3.8 is PIA+_v3. As a whole it will proceed with the following steps:

1) Analyse architecture and intended data flows and the potential privacy, social, and ethical impacts associated
2) Consult with relevant project stakeholders and external stakeholders (e.g., technical experts, lawyers, civil servants, privacy advocates, citizens, human rights experts as well as others) via a workshop scheduled for Month 9 to test and validate the analysis in step 1 and suggest additional issues for consideration. External stakeholders will be recruited through other H2020 projects and/or through the cross-sectional network developed in WP6
3) Identify privacy, social and ethical risks and technical/operational solutions and mitigation measures. This step will include input from Task 2.1 on the legal issues identified and Task 4.2 on the social, ethical and legal issues in pandemic preparedness planning
4) Suggest measures to ensure European legislative compliance (data protection as well as others)
5) Formulate recommendations and work with project partners to implement them.

Deliverable 3.6 (D3.6) is the first iteration of the PIA+ (PIA+_v1). Therefore, it is a preliminary guide. **The objective of this deliverable is to identify potential ethical, privacy and data protection opportunities and issues early in the project to help partners become aware of their importance so that they can be addressed in full throughout the project.** This process will be reflected in the subsequent iterations of the PIA+, i.e. D3.7 (PIA+_ v2) at M18 and D3.8 (PIA+_v3) at M24).

2 Introduction & Background

2.1 Overview of PANDEM-2

The aim of the PANDEM-2 project is to implement novel concepts and IT systems to improve European countries capacity for pandemic preparedness and response. PANDEM-2 will facilitate and demonstrate the capture and integration of pandemic-relevant data from numerous sources, including participatory surveillance systems (e.g. Influenzanet) and social media (e.g. twitter, reddit). This data will be accessible and analysed via an online dashboard, designed and built to support the specific needs of pandemic managers (public health agencies responsible for pandemics), hospital managers and first responders in Europe. The PANDEM-2 dashboard will also facilitate predictive modelling of infection rate and spread, and impact on resource management and mapping of workforce capacity. Overall, the PANDEM-2 project will assist the relevant authorities to make rapid, evidence-based decisions in response to a pandemic and supply them with the resources to communicate these decisions effectively to citizens of European countries.

2.2 Overview of a Privacy, Social & Ethical Impact Assessment

This document has been produced by Trilateral Research Ltd (TRI), a partner on the consortium of the PANDEM-2 project. It provides an overview to the privacy, social and ethical parameters that may need to be taken into account as the consortium develops its technical solutions in a privacy-by-design manner. Privacy-by-design encourages a proactive approach of including privacy considerations at the outset of design and development of a new technology rather than waiting for risks to materialise after its use.

A Privacy Impact Assessment (PIA) is a process that can be used to adopt this approach and includes all relevant stakeholders to collaboratively develop tools and methods to minimize potential risks. The **aims of conducting a Privacy Impact Assessment are** better privacy protection, increased transparency of personal information processing technologies (with special attention paid to surveillance systems) and increased accountability. Extending the scope of a PIA to include further ethical and social considerations such as dignity and autonomy, we developed the Privacy, Social and Ethical Impact Assessment (PIA+). A PIA+ is a continuous process that begins in the very early stage of a project and continues to the deployment of the product or service. The PIA+ process contributes to informed decision-making and protection of societal concerns[1], while minimising the privacy and ethical harms for individuals, organisations and society. Under a TRI approach, a PIA+ incorporates a systematic process to mapping information flows, mapping and assessing risks, and providing a set of recommendations for technology developers to take into account during the design stage of a system. Furthermore, a PIA+ is an iterative and interactive process that can revisit steps and will run throughout the lifecycle of a project. The steps might differ in sequence or take place concurrently. The process is adjusted to the specific needs of each project as it evolves.

[1] Kloza, Van Dijk, Gellert, Böröcz, Tanas, Mantovani and Quinn, "Data Protection Impact Assessments in the European Union: complementing the new legal framework towards a more robust protection of individuals", d.pia.lab Policy Brief No. 1/2017.

2.3 Aim of this Document

The aim of the current document is to bring awareness to the consortium on the privacy, ethical and societal issues that need to be considered when developing technological solutions, while providing a preliminary understanding of these issues that are or may become active in the PANDEM-2 project. By having access to the document, partners who may not use privacy and ethical terms and concepts on a day-to-day basis can quickly and efficiently familiarise themselves with the same, thus also encouraging a better co-creational workflow.

2.4 Inputs/Dependencies of this Document

Input is the research and literature review consisting of academic books and articles, EU policies and legislation, white papers and blogs from stakeholders concerned with the ethical issues concerning pandemic planning and response. Input also includes the authors knowledge acquisition of the technologies under development by PANDEM-2 partners. There are no direct dependencies for the work in this deliverable.

2.5 Project Objectives & this Document

The objectives of PANDEM-2 include collating pandemic-related data from multiple sources to develop an extensible dashboard that will enable pandemic surveillance and situational awareness with the aim to improve pandemic preparedness and response in the EU. *Therefore, it is vital to ensure that the dashboard is legally compliant, does not transgress fundamental human rights and conforms to European societal values.* Following these set of guidelines will promote responsible research innovation.

3 Approach: Privacy, Social and Ethical Impact Assessment (PIA+)

3.1 Preliminary Methodology

Currently there is no agreed international standard for a PIA+ process. TRI will develop a **qualitative** PIA+ methodology and framework that is most suitable to PANDEM-2. It will involve (as preliminary methodology as of today):

I. Developing an understanding of the PANDEM-2 technology
II. Reviewing relevant literature, policy documents and legislation
III. Producing a preliminary (PIA+_v1) guide that will give a brief overview
IV. Mapping the information flows: this describes and maps the flows of personal data in the PANDEM-2 systems by means of a partner Ethics Questionnaire
V. Identify key ethical legal, social, and privacy risks and related harms
VI. Initiate a PIA+ workshop with key project and external stakeholder to evaluate:
    • Requirements for privacy and ethical assumptions that could impede their achievement
    • How to mitigate risk
VII. Consolidate all information and analyse the same to produce recommendations
VIII. Producing an interim (PIA+_v2) report that will outline findings from a PIA+ and it will include recommendations relating to the PANDEM-2 database and tools
IX. Completing a final (PIA+_v3) report that will summarize and present the findings of the PIA+ carried out for the PANDEM-2 project on the technical solutions and mitigation measures

4 Results

4.1 Ethical Considerations

Ethics need to be central in the PANDEM-2 design in order to achieve some of the fundamental objectives of the project, including interoperability and the building of a dashboard that can enable efficient and effective pandemic preparedness and response across European countries. In these ways, ethics is integral to the design and development of the PANDEM-2 tools.

The concept of ethics is not homogenous to all cultures and there are different understandings of ethical philosophies. This is due to moral standards used within society, or within groups in a society, being affected by historical, cultural and geographical differences. However, in brief, ethics is concerned with moral issues, values and principles, as well as normative practices that are recognized in the daily life of individuals. The European community identity is built on ethical values such as human dignity, fairness, equality and non-discrimination; these values are contained also in its many human rights documents, such as the European Charter of Fundamental Rights and Treaty on European Union.

Treaty on European Union (TEU), Article 2:

The Union is founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities. These values are common to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail.

PANDEM-2 partners should be guided by the ethos that technology cannot 'impair fundamental human rights and should contribute to the values they embody'.[2]

The following outlines several relevant ethical principles, with a particular focus on autonomy and dignity. It is by no means an exhaustive list, but it introduces principles relevant to the development of the PANDEM-2 dashboard. A detailed assessment and interim report (PIA+_v2, D3.7) will be produced in M18. Therefore, this preliminary guide will outline a broad range of ethical principles and considerations, as it would be counterintuitive to be specific at this early stage of the project when partners are still determining the details of their design approaches.

4.1.1 Autonomy

The principle of autonomy reflects individuals' ability to make decisions on their own. This is a very important principle in regard to one's personal growth, which in turn is essential for democracy as citizens have their own unique voices free from any repression. However, within pandemic planning and response, an individual's autonomy may be overlooked and overridden for the overall good of public health. Debates surrounding how and when governments are justified in curtailing individual

[2] Mordini, E., Wright, D., Wadhwa, K., De Hert, P., Mantovani, E., Thestrup, J., Van Steendam, G., D'Amico, A. & Vater, I., (2009). "Senior citizens and the ethics of e-inclusion". Ethics and Information Technology, Vol. 11 Issue 3, pp. 203–220

autonomy have garnered a great deal of scholarly attention.[3,4] Considering this potential conflict between the protection of individual autonomy and promoting the public good, there are two relevant ethical theories that ought to be considered by governments/authorities as well as project partners involved in pandemic planning and response.

First is the ethics of care, which involves understanding the needs and wants of the person cared for, identifying the person's vulnerabilities that require attention and care and accepting responsibilities engendered through relationships with others.[5] In the context of pandemics, the principle of ethics of care suggests that authorities' response to it may be motivated by care, rather than more abstract principles like equality/justice. One relatively recent suggestion from the literature is that this ethical approach justifies interfering with individual autonomy during a pandemic because governments have an obligation to care for their most vulnerable residents.[6] Although this suggestion is compelling, it remains unclear precisely how much of an individual's autonomy can be curtailed by a government even for the individual's own good or the overall wellbeing of society. PANDEM-2 partners will continue to discuss the delicate balance between care/welfare and the protection of autonomy, and a more comprehensive assessment will be included in the interim report (D3.7).

Second is utilitarianism, which suggests that authorities' and PANDEM-2 partners' responses to a pandemic ought to be motivated by trying to achieve the greatest good for the greatest number. According to 19th Century British philosopher, John Stuart Mill:

"Actions are right in proportion to their tendency to promote happiness or absence of pain, and wrong insofar as they tend to produce pain or displeasure" (Mill 2001)

An action or practice is right if it leads to the best possible balance of good consequences over bad consequences for all of the parties affected. As a result, however we might define "good", we ought to act so as to produce good consequences. Applying this theory to the context of pandemic response, especially in terms of implementing lockdowns or other restrictions on freedom of movement, we can ask: *should <u>everyone</u> remain housebound to ensure a <u>limited</u> number of people do not get infected and die from an infectious disease outbreak?* **Or** *should <u>everyone</u> be allowed to live their lives as normal with the consequences of their actions potentially fatal for a <u>limited</u> number of vulnerable people?* PANDEM-2 partners will continue to discuss and consider the impact of new technologies on the health and wellbeing of all individuals in a society and reflect on how and why these new technologies might be ethically justifiable or unjustifiable from this utilitarian perspective.

4.1.2 Dignity

Dignity in ethical contexts, is defined as being worthy of respect in virtue of being human. Article 1 of the European Charter of Fundamental Rights clearly states the need for the protection and respect

[3] Mill, J.S. (1998). On Liberty. Oxford: Oxford Classics; de Marneffe, P. (1998) "Rights, Reasons, and Freedom of Association" in *Freedom of Association,* ed. Amy Gutmann. Princeton: Princeton University Press, p.145-173
[4] Waldron, J. (2012) *Dignity, Rank, and Rights.* Oxford: Oxford University Press.
[5] Held, V. (2007). *The Ethics of Care: Personal, Political, and Global*. Oxford: Oxford University Press.
[6] Baron T., *What I talk about when I talk about care: Covid-19 and variation in values* presented at a workshop ran by the Centre for Ethics and Poverty Research, University of Salzburg

of human dignity.[7] Furthermore, Article 1 of the United Nations Universal Declaration of Human Rights refers to equal treatment of humans in terms of dignity and rights.[8] This means that all humans ought to be treated equally and fairly regardless of age, gender, racial or ethnic background, disability, or any other status (this is also linked to autonomy outlined in Section 4.1.1).

Within PANDEM-2, particularly in relation to pandemic preparedness, some considerations need to be made from a societal well-being point of view. While public health addresses the control of specific diseases, it also focuses on the entire spectrum of health and wellbeing. Therefore, social restrictions during a pandemic – while essential to save lives – are likely to have a disproportionate impact on the most disadvantaged, marginalised, and vulnerable individuals/groups.[9] These restrictions may negatively impact an individual's dignity by influencing their income, employment, access to food, and encourage discrimination against them. Social restrictions that confine people to their homes for extended periods increase risk of abuse and exploitation, particularly among girls and women.[9] Further inequalities are evident in people's capacity to comply with social distancing measures, with this being most difficult for those on low incomes, in insecure employment, and in overcrowded living conditions.[9] Over the course of the PANDEM-2 project, discussions will be held with partners about how the new technologies can help identify paths to protecting people, particularly vulnerable groups, from such threats to their dignity. Given the current uncertainty around travel, the empirical methodology for these discussions cannot be specified in detail yet.

4.1.3 Other Relevant Ethical Principles

The following principles have been identified throughout the literature review on ethical principles, particularly those related to technological innovation and the provision of public services:

I. Everyone has a **right to respect for private and family life** (Article 8 of European Convention on Human Rights) and the State has an obligation to protect it. However, this is a qualified right that can be interfered with in the interest of national security, public safety, or the protection of the rights and freedom of others.

II. The technology should not infringe upon anti-discrimination principles. Under Article 21 of the European Charter of Fundamental Rights 'Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited'.[7] This goes hand-in-hand with **equality, fairness**, and **impartiality**.

III. Situations where decisions and/or measures regarding individuals as a result of the information collected about them could be seen as **discriminatory** should be analysed in detail.

[7] Charter of Fundamental Rights of the European Union *OJ C 326, 26.10.2012, p. 391–407*

[8] United Nations (2015) Universal Declaration of Human Rights (UDHR)

[9] ESRC Centre for Society & Mental Health, King's College London (2020) Impacts of social isolation among disadvantaged and vulnerable groups during public health crises

IV. The **precautionary principles** suggests that it is the responsibility of the designers/engineers that the proposed technology should not (or is very unlikely to) cause **harm**. Harm is understood as both physical and psychological.

V. The technology should not isolate users and should be **user-friendly**.

VI. The technology should be economically and socially **sustainable**.

VII. The **vulnerable groups** that may be affected by the technology should be considered. Vulnerable groups include: Children, pregnant women, elderly people, malnourished people, ethnic and gender minorities, migrants, those living with mental illness. Vulnerable people may be particularly concerned about the risks of identification or the disclosure of information.

VIII. The technology should build **trust** between users, the users and the public, and between stakeholders and the technology, so that political will not override technological potential.

IX. **Protection of personal data** goes beyond privacy and consent, but also a right to having data fairly processed.

X. PANDEM-2 design should consider how data collected (personal or otherwise) could affect issues of **liability**. Law is vague on what counts as **negligence** or what is acceptable, thus ethical design should consider these issues.

XI. The technology should strive for **beneficence**, not just better performance and should **benefit** both individuals and the community.

XII. All acts supported by the tools should be **proportionate** to the situation and need, and no more than necessary.

XIII. The technology should not deter people from exercising their legitimate rights and freedoms, best known as **chilling effect.**

4.1.4 Ethical Questions

To address the above-mentioned ethical principles, partners can pose the following ethical questions (orange box = potential ethical issues; green box = potential ethical opportunities). These questions will help motivate the topics of discussion and reflection at the PIA workshop in M9.

To avoid violations of an individual's autonomy and dignity during data collection events organised within the project, researchers and partners can ask themselves:

- Does the person have a meaningful choice to participate in the collection of data/study/interview/etc.? Can they opt out?
- Might he/she feel coerced or compelled and how can I identify and eliminate the circumstances leading to feeling coerced or compelled?
- Have all subjects been provided all relevant information, and do they understand the information provided?

When developed, researchers and partners can ask themselves: Will the tool:

- Infringe on individual's freedom of movement or association?
- Reduce an individual's ability to make their own decisions, to what extent?

The following are presented as opportunities that partners can ask themselves:

- Can the technology promote an individual's dignity and autonomy (e.g. perhaps by allowing the individual to perform tasks or make decisions they otherwise could not)?
- Can the technology provide increased information to individuals thereby strengthening informed consent?
- Can the technology promote equality among different sexes, genders, races, religions, and other backgrounds?
- Can the technology benefit users' wellbeing, or benefit the community?
- Can the technology reach out to include oft-excluded segments of the population?
- Can the technology especially benefit vulnerable groups and individuals?
- Can the technology provide reliable and accurate information that will instil trust in an authority/organisation/government?

4.2 Privacy Considerations

Privacy can be seen as an umbrella term that safeguards many ethical and societal values that are conceptually distinct but still related in various ways. Privacy should not be seen just as an individual right but as a key principle that enables society to flourish.[10] Related to autonomy, the European Convention of Human Rights relates privacy to "respect for private and family life, home and communications". Privacy enables a private space to freely develop our personality and belief systems based on which we make our choices.[11]

To ensure that, the PANDEM-2 project identifies all contexts in which privacy might be relevant for its tools; it is important to note that privacy can take on different meanings in different contexts,[12] and that we can distinguish the following seven types of privacy[13] :

i. **Privacy of the person** is defined as the right to keep body functions and body characteristics private.
ii. **Privacy of behaviour and action** refers to the ability of the individual to behave and do as (s)he like without being monitored.
iii. **Privacy of communication** relates to interception of communications such as recording and access to e-mail messages.
iv. **Privacy of data and image** involves the right of the individual to exercise control over personal data, rather than such data being available to organisations and others by default.
v. **Privacy of thoughts and feelings** refers to the individual's right not to share his or her thoughts and feelings or not to have these revealed.
vi. **Privacy of location and space** encompasses the right of the individual to freely move about in public, or semi-public space, without being monitored or tracked.
vii. **Privacy of association** refers to the right of the individual to associate with others without being monitored.[14]

Note that for all kind of privacy concerns, informed consent is necessary. This means that the PANDEM-2 user needs to be informed on what kind of data will be collected, how they will be processed and stored and what the potential risks might be. The users need to provide their consent prior to any data collection. As outlined in the Grant Agreement, PANDEM-2 will involve personal data collection and/or processing, especially in regard to contact details and opinions of those participating in the interviews, focus groups, demonstrations and validations. Furthermore, the project will involve social media mining and analysis. However, it will not involve the collection and/or processing of sensitive personal data. Therefore, it is important to define personal data and sensitive personal data, and differentiate between them:

[10] https://teachprivacy.com/what-is-privacy/
[11] PRESCIENT project Deliverable 1, [Online] file:///Users/Trilateral/Desktop/PRESCIENT-D1---final.pdf
[12] Nissenbaum, H 2009, Privacy in context: Technology, policy and the integrity of social life, Stanford University Press
[13] Finn, R, D Wright, and M Freidewald 2013, European Data Protection: Coming of Age. S. Gutwirth et al. (eds.). Dordrecht: Springer.
[14] Kroener, Inga, and David Wright (2015). "Privacy Impact Assessment Policy Issues" in Artemi Rallo Lombarte and Rosario Garcia Mahamut (eds.) Hacia Un Nuevo Derecho Europeo De Protección De Datos. Towards A New European Data Protection Regime, Tirant lo Blanch, Valencia.

Personal Data

Any information relating to an identified or identifiable natural person. In particular 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

This is a wide and inclusive definition. Processing of personal data is any activity performed on personal data (such as collecting, storing or organising it).

Sensitive Personal Data

Data on racial or ethnic origin, political or religious beliefs, and health. This type of data requires extra protection because the abuse of personal data in these categories is likely to lead to harmful consequences.

4.2.1 The General Data Protection Regulation (GDPR)

Privacy and data protection are also protected by legal frameworks and specific standardized guidelines. However, it is important to make a distinction here between data protection and privacy. Even though data protection covers aspects of privacy, it does not fully cover all seven aspects of privacy as presented above, which is why a PIA+ is required in the PANDEM-2 project. Furthermore, in terms of data protection, it is necessary that all partners comply with the General Data Protection Regulation 2016/679 (GDPR)[15], which outlines how an individual's personal data should be safeguarded in the European Union. Note that the GDPR only applies to data that is associated with an "identified or identifiable natural person" (Art. 29 WP, 2007). Data that is effectively anonymised is not subject to the Regulation. Overall, the aim of the GDPR is to safeguard an individual's privacy through data protection.

GDPR is particularly important in the PANDEM-2 project as tools development will be informed by personal data from workshops, interviews, focus groups, as well as data from social media mining. Therefore, under the GDPR, data should be collected, processed and stored lawfully (Article 6). This is done when:

- The individual whom the personal data is about has consented to the processing.
- The processing is necessary in relation to a contract which the individual has entered into.
- The processing is necessary to protect the individual's "vital interests". This condition only applies in cases of life or death, such as where an individual's medical history is disclosed to a hospital's A&E department treating them after a serious road accident.

[15] 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) (Text with EEA relevance) *OJ L 119, 4.5.2016, p. 1–88*

Please note that this is a selection of the legal bases that could potentially be used in the PANDEM-2 project. The purposes and the legal base for the processing must be decided in advance (before the start of the processing activities) and cannot be modified in the course of the processing.

- When consent is used as a legal basis for the processing, all criteria that render it valid under the GDPR (Art. 4 (11), Art. 7) should be met. Consent should be able to be withdrawn at any time.
- Relationships between the stakeholders should be thought out, in particular who determines the purposes and the means of the processing.
- Individuals whose data is being processed should be aware of the processing activities, as well as the exact type of data that is being collected from and/ or about them and the purpose for which the processing takes place.
- Data should only be collected for a specific, pre-determined purpose and no further processing, incompatible with the original purpose, is allowed.
- Only the minimum amount of data should be collected.
- Data should not be stored longer than necessary. The retention period should be proportional to the purpose of the processing.
- Security of data stored or otherwise processed should be ensured (through both technical and non-technical measures).
- Data collected and stored should be accurate and up to date.
- The anonymity of the data subject should be protected.
- How the technology will affect 3rd parties who may not be able to consent to the technology needs to be considered.
- Compliance with the GDPR should be able to be demonstrated (through documentation).
- Individuals whose data is being processed should be informed about their data protection rights and should be facilitated when exercising them. These include the:
  - Right to information
  - Right to access data
  - Right to rectify data
  - Right to erasure ('right to be forgotten')
  - Right to restrict processing
  - Right to data portability[16]
  - Right to object to processing

Individuals also have the right to lodge a complaint about data processing with a supervisory body. To protect those rights, the GDPR empowers independent supervisory bodies (sometimes also called **Data Protection** Authorities or Information Commissioners) to oversee compliance with the GDPR and to promote awareness of GDPR obligations and rights. These bodies work together as the European Data Protection Board. The GDPR also introduces significant penalties for non-compliance. Supervisory bodies can carry out investigations, issue warnings and reprimands to controllers, and impose fines up to €20 million or 4% of worldwide turnover for serious infringements of the GDPR.

[16] The right for data subjects to obtain that a data controller holds on them in a structured, commonly used and machine-readable format

4.2.2 Privacy Risks and Potential Mitigation Steps

Potential data protection risks associated with the PANDEM-2 project and tools include:

- Collection & processing of data (will any data contain personal information): Traditional (practitioner, hospital, laboratory) and non-traditional (school/work absenteeism, environmental data, airline flight path data, social media, pharmacy sales, etc.) data sources (*Task 2.1*)
- Compliance with social media data protection regulations & the GDPR: Social media mining (*Task 2.3*) and social media listening (*Task 5.3*) - (e.g. real-time tweets (Twitter), social media posts (e.g., Reddit) or stored data)
- Authorised access to data (public/private) beyond the lifecycle of the project: Integration of the identified data sources into a database and development of analytic tools to generate key indicators (*Task 2.4*/ *Task 3.1*), which will feed into the dashboard (*Task 3.2*) and situational awareness tools (*Task 3.3*)
- Laboratory data anonymisation & location of data: Identification and mapping of laboratory data for pandemic detection and monitoring including Next Generation Sequencing (NGS) (*Task 2.5*)
- Agreement/Contract outlining scope of work with PANDEM-2 data: External (outside the project) access to this data via secured-access APIs (*Task 3.4*)
- Security and on-going management of dashboard beyond the lifecycle of the project: Suite of pandemic planning tools developed in WP4, which use data-derived tools and resources previously mentioned in WP2 and WP3

Steps that partners can follow to eliminate/reduce data protection risks, and that TRI will undertake to monitor or address these risks:

1. When collecting personal data ensure the individual is aware of what is being collected, that they consent to what data is obtained, that the data collected is relevant and limited to the purpose of the research project (Data Minimisation) and that the data is stored securely.
2. TRI will contribute to the Data Management Plan (D2.1), which will be completed by M6. Partners should frequently refer to this.
3. A questionnaire (Appendix 7.1) asking about partners' plans for data collection, and information sheet (Appendix 7.2) and consent sheet (Appendix 7.3) templates have been circulated for WP8 Ethics requirements. These documents will allow TRI to identify any potential data protection risks. In addition, the templates for information and consent sheets ensure that partners are GDPR compliant when collecting data from human subjects.
4. When conducting social media mining from Twitter, partners should be aware of the following:
    - Twitter developer's agreement https://developer.twitter.com/en/developer-terms/agreement
    - Mining data from Twitter is necessary to have a Twitter developer account

- Standard Twitter API returns only 1% of the volume of the tweets. This means that only a tiny portion of users is represented and the portion of tweets with accurate geo-location is subsequently limited
- Developers should comply with what they reported to Twitter in the application or inform Twitter if the scope of their analysis changed
- Standard Twitter API does not allow to crawl tweets older than 7 days
- Several limitations on the rate and quantity of tweets you can get
- Tools used to overcome these Twitter API limitations are illegal
- Tweets crawled by a developer are owned by the developer and should be stored in a secure storage system.
- Sharing of tweets (text + user information) is not allowed by Twitter. However, sharing pseudo-anonymised tweets is possible (for instance, masking the username or any information that could lead back to the user) - The safest and most common way is sharing only the tweet id of the tweet.
- Sharing of aggregated Twitter data or processed indicators is possible.
- It is not explicitly possible to accurately obtain demographic information from the users on Twitter. If some of this information is available, they are self-declared, and developers and analysts should be aware of this. Some level of inference is possible but to perform with care.
- Be aware of profiling risks from social media. For instance, there are ML models to infer gender, age, socio-economic status from Twitter data. These are often biased or make their inference based on stereotypes. If you use such models, make sure to understand the data they are trained on (make sure, for instance, that profile pictures are not used to infer the gender of a user etc.).
- Some Twitter users are protected, and data cannot and should not be crawled from them.

5. When conducting social media mining from Reddit, partners should be aware of the following:
   - Refer to the following links for more details on T&Cs of Reddit API:
     - https://docs.google.com/forms/d/e/1FAIpQLSezNdDNK1-P8mspSbmtC2r86Ee9ZRbC66u929cG2GX0T9UMyw/viewform
     - https://www.reddit.com/wiki/api
   - Reddit has less strict regulations and obtaining a developer account is straightforward and doesn't require Reddit approval.
   - However, if the intended use is commercial, approval is required (from their website: "If your intended usage is commercial, you'll need approval from us''
   - Use of the API is considered "commercial" if you are earning money from it, including, but not limited to in-app advertising, in-app purchases or you intend to learn from the data and repackage for sale. Open-source use is generally considered non-commercial.")

These steps will be discussed in more detail and elaborated on in the interim report (PIA+_v2).

4.3 Compliance with Laws, Regulations, Codes & Guidelines

In addition to the GDPR, partners should be mindful of standards contained in, amongst others but not limited to:

Laws & Policies protecting privacy & data protection:

- European General Data Protection Regulation
- ISO/IEC 29100:2011
- ISO/IEC 27001:2013
- Universal Declaration on Human Rights 1948
- European Convention on Human Rights 1953
- Charter of Fundamental Human Rights of the European Union 2009
- Council of Europe's Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data 1980
- Asia-Pacific Economic Cooperation (APEC) Privacy Framework 2015

Laws & Policies on Public Health

- **Decision No 1082/2013/EU on Cross-Border Threats to Health**
  To improve preparedness and strengthen capacity for a coordinated response to health emergencies across the EU.

- **International Health Regulations (2005) (IHR)**
  Provide an overarching legal framework that defines 196 countries' rights and obligations in handling public health events and emergencies that have the potential to cross borders.
  - **National Legislation**: legal, administrative and other governmental instruments that may facilitate the implementation of the IHR by States Parties. It may cover public health communication & assessments, emergency preparedness.

- **Directive 2011/24/EU on patients' rights in cross-border healthcare**
  Established the eHealth network to advance the interoperability of eHealth solutions.

- **Communication on enabling the Digital Transformation of Health and Care in the Digital Single Market (COM (2018)0233)**

  Allowing researchers and other health professionals to pool resources across the EU

TRI will base the PIA+ on the above standards and legislation, in addition to academic research concerning the ethics of public health, pandemic surveillance, and pandemic situational awareness data collection, and will guide partners through the process of adhering to elements of these standards and ethical insights. The initial task of the PIA+ have been achieved through (1) a detailed literature review of ethical principles particularly those related to technological innovation and the provision of public services; (2) the development of a series of ethical questions that partners can pose to themselves to begin to address the Ethical principles; (3) the development of an initial list of PANDEM-2 risks and potential mitigation steps in relation to the PANDEM-2 project and tools. This included the

drafting and circulation of an Ethics questionnaire (Appendix 7.1) and information sheet (Appendix 7.2) and informed consent sheet (Appendix 7.3) templates.

5 Impacts & Conclusion

This deliverable outlines a number of the privacy, ethical and societal issues that are active within the PANDEM-2 project which will inform and guide the project on matters such as privacy and GDPR compliance, as well as an individual's autonomy and dignity. This, as a *preliminary guide* (PIA+_v1), is by no means an exhaustive list of the relevant issues, and additional considerations will be reviewed, researched and addressed in future iterations of the PIA+ (D3.7 (v2) and D3.8 (v3)). Overall, this document gives the partners a brief outline of what they need to consider and comply with to ensure they are creating a dashboard using a privacy-by-design approach.

However, as highlighted above, as the project is in the early development stage a number of these issues remain nascent. These issues must continue to be addressed through research, monitoring and the collection of information (for example, from end-users during pilots). With a PIA+ workshop being conducted during M9 there should be more explicit details available on the dashboard's components and functionalities at this point. This will allow for a more in-depth PIA+ to be completed and the subsequent recommendations circulated to the consortium members.

6 Appendices

6.1 PANDEM-2 Ethics and Data Management Plan Questionnaire

Each partner is required to complete this.

PANDEM-2 Ethics and Data Management Plan Questionnaire

Integrity and proper conduct are a fundamental aspect of undertaking research. Due to the nature of its end-user focus on pandemic management and preparedness, the PANDEM-2 project will touch on issues of human research ethics. The consortium will ensure that ethical standards and guidelines within Horizon 2020[17] and European legislation will be rigorously applied, regardless of where the research will be conducted. To that end, and in order to comply with the PO requests we have put together some questions regarding data collection, exploitation, and preservation that we ask that you answer in order to complete the privacy and data protection tasks in WP3, the ethics requirements in WP8 and to inform the Data Management Plan (WP2, Task 2.6).

1. **What types of data will your WP collect, process and keep? Any sensitive data?** (*This includes technical data (logs, code, usability information), data from test subjects (logins, genomics), informant data (interviews, focus groups, workshop participants), etc.)*

2. **How will this data be collected?** (*Directly from researchers, first responders or systems? Indirectly from use of technical systems, social media? What research methods are you using--observations, interviews, survey, workshop, etc.?)*

[17] Horizon 2020 is the biggest EU Research and Innovation programme, with nearly €80 billion of funding available over 7 years (2014 to 2020). It promises more breakthroughs, discoveries and world-firsts by taking great ideas from the lab to the market. For more see: European Commission, *What is Horizon2020*, [online]: https://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020 accessed 28th July 2016

3. **What format(s) will the data be in?**

4. **If possible, state the size of the data.**

5. **Which organisation will store the data? Where?**

6. **How will you ensure it is stored securely? Please describe the technical and security measures that will be implemented to prevent unauthorised access to the data as well as the equipment used for processing data.**

7. **How long will you keep it?**

8. **Does this data need to stay in your organisation?**

9. **Can this data be shared with other project partners?**

10. **Can this data be made openly accessible after the close of the project?**

- **If yes, how will it be shared?** *(e.g. establishing copyright, creating user documentation, creating discovery metadata, selecting appropriate access to data, publishing data, or promoting data, etc.)*
- **If no, why not?**

11. **Does your organisation have a data protection officer? Please provide his/her name and contact information.**

12. **How will you identify and recruit people to participate in WP activities?** *(e.g., general public, academics, pandemic manager, advisory board/first responders, policy makers/draw on existing contact list, snowballing, recruitment through social media etc.)*

13. **Will volunteers be offered any compensation for participation? (e.g. Amazon gift card)**

14. **How will you attempt to ensure demographic, gender, and ethnic diversity among the individuals you recruit?**

15. **Describe the anonymisation/pseudonymisation techniques you intend to employ.**

16. **How will the data be processed and analysed both during and after the completion of the project?** *(e.g. entering, digitising, transcribing, and translating data, checking, validating, cleaning, or anonymising data, deriving data, describing and documenting data, managing and storing data, analysing and interpreting data, producing research outputs and citing data, etc.)*

17. **How will it be made accessible for verification and/or re-use?** *(e.g. conducting secondary analysis, undertaking follow-up research, conducting research reviews, scrutinising findings, and using data for teaching and learning, etc.)*

18. EU Member States have established their own regulations on data processing, especially concerning the processing of special categories of data (such as health data). Consequently, collecting this data may be subject to additional national legal requirements (e.g. Irish Health Research Regulations 2018), including the prior notification of regulators or data protection authorities.

    - **Please check the national regulations of your jurisdiction and add any derogations here:**

19. **In case the research involves profiling*, provide explanation how the data subjects will be informed of the existence of the profiling, it's possible consequences and how their fundamental rights will be safeguarded.**

*Profiling means the collection of personal data, including the automated processing of personal data, to evaluate certain things about an individual and to discriminate individuals into previously categorized groups or 'profiles'.

20. **Describe the potential dual-use implications of your research and corresponding risk-mitigation strategies.**

*Dual use means technology that could have civil and military applications.

6.2 PANDEM-2 Information Sheet Template

XXX indicates where each partner needs to add details on their specific project activity.

INFORMATION SHEET

What is this study about?

You are invited to participate in a research study being conducted by the PANDEM-2 consortium which is coordinated by NUI Galway entitled 'Pandemic Preparedness and Response (PANDEM-2). The project is funded by the European Commission under the Horizon 2020 scheme (Grant agreement number 883285). The PANDEM-2 consortium consists of 19 organisations:

PARTNER	SHORT NAME	COUNTRY
NATIONAL UNIVERSITY OF IRELAND GALWAY	NUIG	Ireland
FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V.	FINT	Germany
UNIVERSITE CATHOLIQUE DE LOUVAIN	UCL	Belgium
PINTAIL LTD	PT	Ireland
FOLKHALSOMYNDIGHETEN	FOHM	Sweden

RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU	RIVM	Netherlands
Carr Communications Limited	CARR	Ireland
TERVEYDEN JA HYVINVOINNIN LAITOS	THL	Finland
INSTITUTUL NATIONAL DE SANATATE PUBLICA	NIPH	Romania
ROBERT KOCH-INSTITUT	RKI	Germany
STICHTING KATHOLIEKE UNIVERSITEIT	RUNMC	Netherlands
CLARISOFT TECHNOLOGIES ROM SRL	CLARISOFT	Romania
OSTERREICHISCHES ROTES KREUZ	ORK	Austria
EPICONCEPT	EPIC	France
INEM	INEM	Portugal
TRILATERAL RESEARCH LTD	TRI	Ireland/UK
ISTITUTO PER L'INTERSCAMBIO SCIENTIFICO	ISI	Italy
ASSOCIAZIONE DELLA CROCE ROSSA ITALIANA	ITRC	Italy
INSTITUTO NACIONAL DE SAUDE DR. RICARDO JORGE	INSA	Portugal

About the project: The PANDEM-2 began in February 2021 and will conclude in January 2023. PANDEM-2 implements and demonstrates the most important novel concepts and IT systems to improve the capacity of European pandemic planning and response. Following the PANDEM project (with the same coordinator and many shared partners) and extensive subsequent stakeholder engagement, research and prioritisation, PANDEM-2 meets the real-world needs of public health agencies responsible for pandemics ('pandemic managers') and first responders across Europe. PANDEM-2 will enable and demonstrate the capture and integration of pandemic-relevant data from international systems, participative surveillance, laboratory (next generation sequencing) systems and social media. This data will be accessible and can be analysed via an online dashboard, designed and built to support the specific needs of pandemic managers. Additional high-priority tools for pandemic spread prediction, visual analytics and resources management, including workforce capacity mapping, will improve preparedness and planning, and enable pandemic managers to be as well positioned as possible for a pandemic when it comes

As part of the study we would like to achieve

XXX

If you agree to take part in the research, any personal information (e.g., name, contact details) that will be collected from you is for our internal processing and administrative purposes only, and to enable us to contact you if we require further information. Your details will be kept for a maximum period of 24 months following the end of the research project. Unless you prefer otherwise, we will not publish any information in reports or communications materials that would enable you to be directly or indirectly identified.

What will I be asked to do?

You will be asked to XXX

Recording

XXX

Where will the research take place take place?

The research will take place at XXX

What will you use my participation for?

Your participation will be used to provide input for us to understand:

- XXX
- XXX

Additionally, the information that you provide may be used to write articles for peer-reviewed journals and magazines, and for presentations at conferences and workshops. Unless indicated otherwise, all information that could either directly or indirectly identify you will be anonymised.

What are the potential risks of participating in research?

We do not envisage any risks to be caused by the participation.

Are there any costs?

There are no costs for participating.

Will I be paid?

We cannot pay you for participating in this research.

Storage of data

All data will be stored XXX

Observation notes and information from feedback forms will be shared with only those members of the consortium who require access for their work. This information will be retained for the lifetime of the project. After the research ends, it will be permanently and irrevocably deleted after a maximum of 5 years.

Data Protection Officer (DPO)

The DPO of our institution is: XXX

Please contact him/her for further questions.

Data Administrator

The Data Administrator of our institution is: XXX

Please contact him/her for further questions.

Legal Basis of Data Processing

The legal basis of the processing of your personal data is based on your consent, the performance of a task carried out in the public interest, and the legitimate interests of the data controller (GDPR Art. 6a, e, f).

Your rights and confidentiality

If you agree to participate in this study, please understand that your participation is voluntary (you do not have to do it). You have the right to ask questions and receive understandable answers before making any decision. You have the right to withdraw your consent or stop your participation at any time without penalty. You may leave the exercise at any time. Notes about the exercise will be taken during, but they will not include your name or any information that could identify you to others. As part of pseudonymising the interview you will be given a unique **ID number**. You will be given a unique ID number as a security measure to foster anonymity as far as possible. This allows us to collect and process data in ways that can no longer be attributed to you without the use of additional information. The record that links your ID number to you is stored separately and subject to the provisions laid out in the PANDEM-2 Data Management Plan, which follows the General Data Protection

Regulation (GDPR). All data, including audio files, will be stored on password protected computers, in a secure location at the XXX or on secure servers within EU.

Every effort will be taken to protect your identity. You will not be identified in any report or publication of this study or its results. You can review any recording/notes that concern you should you choose to do so.

You have the right to access, update, correct and erase all personal data. As to the qualitative information that you provide us with, you have a right to withdraw the same up to the point of publishing the information in the relevant deliverable. Your researcher will inform you as to the planned publication date.

You have a right to lodge a complaint, to do so please contact the researcher or project coordinator (details below); they will in turn pass your complaint onto an independent panel.

Right to withdraw

You may withdraw your consent from this project at any time without giving a reason. You may walk away at any time. You may tell the researcher at any time that you would like to stop. Simply tell the data processor to delete your data or whether you are fine for these data to continue to be processed. You may be asked why you have decided to withdraw, but you are under no obligation to give a reason.

Sensitive information

Sensitive personal data relates to specific categories of data which are defined as data relating to a person's racial origin; political opinions or religious or other beliefs; physical or mental health; sexual life; criminal convictions or the alleged commission of an offence; trade union membership. When sensitive data is collected, it is done to be compliant with the project's non-discrimination requirements and will be fully anonymized.

Research with participants in non-EU countries

If you are from outside of the EU, we ask you to note that the personal data will be transferred to and stored in the EU/EEA.

Keeping in touch with the project

As PANDEM-2 is an innovation action, it is essential to share the high-quality results of the project with stakeholders who are likely to benefit from it. You can choose to be kept informed about the project's progress, and will thus be put on a mailing list, however this is not mandatory.

More information?

For more information on the project, please contact:

Project Coordinator
Name: Máire Connolly
Organisation: NUIG
E-mail: maire.connolly@nuigalway.ie

Researcher
Name: XXX
Organisation: XXX
E-mail: XXX

Project Manager
Name: Jessica Hughes
Organisation: NUIG
Email: jessica.hayes@nuigalway.ie

To file a complaint with your national DPO:

Name: XXX
E-mail: XXX
Tel.: XXX

6.3 PANDEM-2 Informed Consent Sheet

XXX indicates where each partner needs to add details on their specific project activity.

PANDEM-2
PANDEMIC PREPAREDNESS AND RESPONSE

CONSENT SHEET

I volunteer to participate in this research conducted by the PANDEM-2 consortium, coordinated by NUIG, entitled PANDEM-2. The PANDEM-2 consortium consists of 19 organisations:

NATIONAL UNIVERSITY OF IRELAND GALWAY
FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V.
UNIVERSITE CATHOLIQUE DE LOUVAIN
PINTAIL LTD
FOLKHALSOMYNDIGHETEN
RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU
Carr Communications Limited
TERVEYDEN JA HYVINVOINNIN LAITOS
INSTITUTUL NATIONAL DE SANATATE PUBLICA
ROBERT KOCH-INSTITUT
STICHTING KATHOLIEKE UNIVERSITEIT
CLARISOFT TECHNOLOGIES ROM SRL
OSTERREICHISCHES ROTES KREUZ
EPICONCEPT
INEM
TRILATERAL RESEARCH LTD
ISTITUTO PER L'INTERSCAMBIO SCIENTIFICO
ASSOCIAZIONE DELLA CROCE ROSSA ITALIANA
INSTITUTO NACIONAL DE SAUDE DR. RICARDO JORGE

The project is funded by the European Commission under the Horizon 2020 funding programme, grant agreement number 883285. The project began in February 2021 and will come to an end in January 2023.

By signing this form, you agree to take part in the PANDEM-2 research. The nature of the research, your involvement in it and your rights regarding your participation in the Action are explained in the Information Sheet accompanying this form.

Please place an "X in the boxes" to affirmatively consent to the following statements:

1. I confirm that I have read and understood both this form and the accompanying Information Sheet. I had the time and opportunity to ask questions as needed. ☐
2. I understand that I am free to withdraw my consent at any time without giving reason and that my participation in this project is voluntary. ☐

3. My personal data can be gathered to be used, stored and shared in the ways described on the accompanying Information Sheet. ☐
4. Data from my participation can be used to inform PANDEM-2 user requirements, develop PANDEM-2 technologies and PANDEM-2 communication. ☐
5. Data from my participation may be used to write articles for peer-reviewed journals and relevant industry magazines, for presentations at conferences and workshops. ☐
6. Data from my participation may be used in the promotion of PANDEM-2 in general. ☐

7. PANDEM-2 may take research notes or recordings of my activities as I participate in the research. ☐
8. I understand that I have the right to ask questions and receive understandable answers before making any decision. ☐

9. I understand that I have the right to decline to answer any question or to terminate my involvement at any point during the simulation exercise. ☐
10. I understand that I will not be paid for my participation. ☐
11. I consent that my personal data will be transferred to and stored in the EU/EEA. (**Applicable for research subjects outside of the EU/EEA)** ☐

12. I consent to the processing of my data. ☐

13. I understand my right to request access to any, and all, personal information that I have voluntarily provided as part of my participation, and that I may ask for that information to be rectified and/or amended if it is inaccurate, or request that all personal information that I have provided be deleted. ☐

14. I understand that the PANDEM-2 consortium intends on retaining versions of research transcripts and questionnaires for a period of up to 24 months following the completion of the project. ☐

15. I have been given a copy of this consent form. ☐

16. My PANDEM-2 ID/pseudonym number is XXX

Statement by the Researcher taking consent

I have accurately provided the information sheet to the participant and, to the best of my ability, made sure that the participant understands it. I confirm that the participant was given an opportunity to ask and get answers to questions about PANDEM-2, the research activity he/she will be involved in. I confirm that the participant has given consent freely and voluntarily.

My Signature	Researcher's signature
…….	…….
Date	Date
…….	…….

Name of researcher: XXX

Organisation: XXX

E-mail: XXX

Project Coordinator
Name: Máire Connolly

Organisation: NUIG

E-mail: maire.connolly@nuigalway.ie

National Data Protection Officer
Name: XXX

E-Mail: XXX

Tel.: XXX
