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v2.3	29/11/2024	Final version	
v2.4	23/12/2024	Final version (revised post- review). Pending Review by EC.	



#### **Executive Summary**

The aim of CHANGER (CHALLENGES AND INNOVATIVE CHANGES IN RESEARCH ETHICS REVIEWS) is to promote changes in research ethics reviews that strengthen the capacities of researchers to incorporate ethical judgements in the project design and implementation, and to support ethics committees to address new challenges posed by new technologies and new research practices. CHANGER aims to identify and discuss the challenges which are not sufficiently covered in the current review process, in order to provide innovative training to ethics review experts and researchers, and to propose innovative approaches and tools to ethics review reform and new understandings to practice ethics by design, supported by guidelines and a policy roadmap.

Within this context, Work Package 2 (WP2) had three primary objectives:

- 1. To establish a robust evidence-base regarding the challenges and approaches in research ethics reviews in light of changes in the research environment.
- 2. To identify and synthesize existing knowledge from scientific literature, other EU-funded projects, and various sources, with a focus on experiences from different scientific disciplines and ethics reviews during crisis situations, such as the COVID-19 pandemic, and to present this information in an evidence map.
- 3. To evaluate the current approaches to research ethics reviews across Europe, assessing their strengths and weaknesses in relation to new challenges, emerging players, and innovative forms of research.

This deliverable, the first under WP2, details the outcomes of the Scoping Review of challenges to ethics review in the evolving research landscape (Task 2.1) and the analysis of collected data which was further used for the development of Evidence and Gap Maps (EGMs) (Task 2.2).

In total, 756 academic articles, 65 deliverables for 46 Horizon 2020 projects and 13 deliverables from 8 Horizon Europe were included in this scoping review. We identified the most common ethical challenges across various scientific fields. Key issues include informed consent (mentioned in 119 articles), privacy (196 articles), data sharing (32 articles), security (64 articles), and transparency (47 articles), which are tightly related to technological advancements. The EGM visualizes these challenges, showing the areas where ethical concerns are most significant, such as bias and privacy in AI, informed consent, safety and regulatory gaps in biobanking, genomics and healthcare, data privacy issues in big data analytics and digital health. This deliverable lays the groundwork for creating dynamic EGMs, which will be continuously updated to keep research ethics reviews relevant and adaptive to future challenges.



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Abbreviation	Definition
AI	Artificial Intelligence
D	Deliverable
EGM	Evidence and Gap Map
EU	European Union
GPT	Generative Pretrained Transformer
КОМ	Kick-Off Meeting
LLM	Large Language Model
SyRF	Systematic Review Facility
Т	Task
WP	Work Package

## List of Terms & Abbreviations



## Introduction

CHANGER aims to foster changes in research ethics reviews, that strengthen the capacities of researchers to incorporate ethical judgements in the project design and support ethics committees to address new challenges emerging from new technologies and new research practices.

D2.1 reports on the results of a scoping review on the challenges posed by current ethics reviews in a changing research environment. In particular, it includes a systematic mapping of the scientific literature and grey sources, including EU-funded research projects and professional organizations and international resources about the challenges faced by ethics review bodies, as well as best practices, regarding new technologies, new players, new forms of collaboration and partnerships, new human rights related framework.

#### **1** Purpose and Scope

Trust in science and technology as well as the utility and acceptability of their innovative outcomes is crucially dependent on the ethical appropriateness of the research. This is the reason why research projects are submitted for ethical review. Although the existing ethics review infrastructure includes experienced members with expertise in traditional research, this is not the case for new technologies and transformative research that result in new challenges to human rights, such as digital rights. Thus, there is a clear need for Ethics Committees to evolve in order to cover this gap and to be able to support innovation while embedding new human rights. CHANGER aims to promote changes in research ethics reviews that strengthen the capacities of researchers to incorporate ethical judgements in the project design and implementation, and to support Ethics Committees to address new challenges posed by new technologies and new research practices. CHANGER will review current practices and ethics criteria, identify and discuss new challenges emerging from new technologies and from new research practices not sufficiently covered in the current review process, provide innovative training for ethics review experts and researchers, and propose innovative approaches and tools for ethics review reform and new understandings to practice ethics by design, supported by guidelines and a policy roadmap.

# 2 Approach for Work Package and Relation to other Work Packages and Deliverables

The aim of WP2 is to provide an evidence base for the challenges posed by contemporary research, and assess the capacity of existing Research Ethics Committees (RECs) to assess and monitor innovative research projects that make use of a) new technologies, including AI, big data, blockchain, gene editing, human organoids, social media research, virtual reality research, virtual worlds and the digital life; b) new players in research, including not only universities but also corporations, public and private foundations, civil society organizations, online service providers, open exchange and collaboration initiatives and platforms; and c) new forms of collaborations in research, including



collaborative research and transdisciplinary research, and an *ex ante* ethics review model and research monitoring. WP2 also includes the creation of evidence- and gap-maps, which will inform the creation of innovative approaches and tools in WP3.

#### 2.1 Methodology and Structure of the Deliverable

The study used a scoping review methodology, following the methodological approaches of the Campbell Collaboration (The Campbell Collaboration, 2020) and Joanna Briggs Institute (JBI) Review's Manual (Peters et al., 2015a). We chose to use a scoping review approach because the aim of the task was to provide an overview of the existing literature on a broader topic, identify knowledge gaps and clarify concepts, rather than a systematic review approach, which is designed to answer specific research questions using rigorous and transparent methods (Munn et al., 2018). Specific characteristics of the scoping review methodology are related to its 1) purpose, where scoping reviews aim to provide an overview or map of the existing literature on a broader topic, often to identify knowledge gaps, clarify concepts or investigate research conduct; 2) scope, where scoping reviews have more expansive inclusion criteria than systematic reviews and aim to capture a broader range of studies, often including diverse study designs, populations and interventions; 3) methodology, where both systematic and scoping reviews use rigorous and transparent methods to identify and analyse relevant literature, although scoping reviews most often do not assess methodological limitations or risks of bias of individual studies, and do not perform meta-analysis or statistical pooling; and 4) implications for practice, where in contrast to systematic reviews, scoping reviews typically do not have implications for practice, as their primary goal is to provide an overview of the existing literature rather than to inform specific decisions.

Specific search strategies were developed for literature and web searches. Following the completion of the systematic literature search, the extracted data were organized into categories based on key variables defined and agreed on by all WP2 partners. The SyRF (Systematic Review Facility, <u>https://syrf.org.uk/</u>) online platform was used for the screening process.

Given the large volume of retrieved documents for analysis, we opted to use a Large Language Model (LLM) for data extraction, implementing a methodology that included three iterations of GPT-40 text analysis: 1) a piloting phase where we tested the application programming interface (API) and refined the LLM prompts; 2) a topics extraction phase where we identified ethical and legal issues, technologies, new forms of collaborations, and frameworks/guidelines mentioned in the articles; and 3) a mapping phase involving a more detailed and refined categorization of the identified topics, mapping them to the research articles and grey literature.

The collected evidence base was used to create Evidence and Gap Maps (EGMs) – systematic and visual presentations of the availability of evidence for the identified challenges to ethics review. In this way, critically appraised evidence is provided in a clear and actionable format to all stakeholders. The EGM will be posted at The Embassy of Good Science (<u>https://embassy.science/wiki/Main\_Page</u>), making it a resource open to contributions and updates from the community, beyond the duration of the project.



# 3 Methodology of the scoping Review of challenges to ethics review in the evolving research landscape (T2.1)

#### 3.1 Overview

Task 2 (T2) involved a systematic mapping of both scientific literature and grey sources, including data from EU-funded research projects and professional organizations (e.g. EUREC, ALLEA, ENERI, iRECs). The goal of T2 was to identify and analyse challenges to ethics review processes, particularly those arising from new technologies, new forms of collaboration, and evolving human rights frameworks. The methodology was supported by a detailed search strategy, developed to collect information from relevant databases. The literature search was comprehensive, including both research/academic papers and grey literature in the final stage of publication, written in English. A widely accepted definition in the scholarly community for grey literature is "information produced on all levels of government, academia, business and industry in electronic and print formats not controlled by commercial publishing" i.e. where publishing is not the primary activity of the producing body" (ICGL Luxembourg definition, 1997). Articles related to the topic were identified through a systematic search of bibliographical databases (Scopus, Web of Science, PubMed) whereas the grey literature search included the CORDIS database of European projects in order to identify relevant evidence from EU projects (https://cordis.europa.eu/projects/home\_en.html).

#### 3.1.1 Creation of search strategies

Each database search query had to use keywords related to challenges to ethics review in the changing research environment. The selection of topics for the scoping review, with a particular focus on identifying new technologies, was determined in collaboration with all WP2 partners. The topics were selected by the whole consortium and through populating an online document. The final list of suggested technologies is presented in **Table 2** of Annex 1.

The table lists key search terms categorized into six concepts:

- 1. ethics committees;
- 2. document types (such as guidelines, regulations, and consent forms);
- 3. ethical considerations;
- 4. virtues and values;
- 5. other critical issues (such as social justice and data protection);
- 6. various advanced technologies (including neurotechnology, artificial intelligence, and gene editing).

The search strategy combined the terms related to ethics committees or document types in an article's title with all the remaining terms in the title, abstract or keywords. We created dedicated search strategies for the following databases: Web of Science, Scopus and PubMed.



#### 3.2 Database search

A comprehensive literature search was conducted across three major academic databases: Scopus (<u>https://www.elsevier.com/products/scopus9</u>, Web of Science (<u>https://www.webofscience.com/wos/</u>), and PubMed (<u>https://pubmed.ncbi.nlm.nih.gov/9</u>), focusing on the articles published in the last 10 years (2014-2024) and restricted to the English language. The specific search strategy employed for each database is detailed in Annex 2.

**Figure 1** provides a step-by-step overview of the literature search and screening process undertaken. A total of 18,530 articles were identified across the databases: 3,492 from PubMed, 6,941 from Web of Science, and 8,097 from Scopus. These articles were then exported for further processing to EndNote (<u>https://endnote.com</u>), a reference management software. The duplicate removal process was performed in two stages. First, EndNote's automated duplicate detection feature was utilized to identify and remove references with matching metadata. Second, due to inconsistencies across data sources (such as variations in author names or titles), a manual review was conducted to ensure accuracy. Additionally, 23 retracted articles were identified and excluded from the dataset. After completing these steps, **a total of 12,919 unique articles remained**, which were subsequently prepared for the screening phase.



Figure 1. Overview of the academic literature search and screening process.



#### 3.3 Screening and selection process

For the screening process, we used the SyRF online platform, specifically designed for conducting systematic reviews and meta-analyses (<u>https://syrf.org.uk</u>). SyRF was selected due to its user-friendly interface supporting screening of large numbers of studies, and for its collaborative features allowing multiple partners to participate in the review process simultaneously.

In this phase, partners involved in T2.1 reviewed only the titles and abstracts of the identified studies, without retrieving full papers. The inclusion and exclusion criteria were defined *a priori*. The **inclusion criteria** focused on studies that addressed challenges to ethics reviews, specifically those related to ethics review boards, guidelines, frameworks, and similar topics. **Exclusion criteria** included non-English literature, and challenges discussed in contexts unrelated to ethics reviews, such as technical challenges.

Partners were able to monitor their individual contributions as well as the overall progress of the scoping review. This included the number of articles each user had screened, the decisions made on those articles (e.g., included, excluded), and any conflicts that needed to be resolved. Each decision on the inclusion of a study required consensus between two reviewers, and disagreements were resolved by a third reviewer. All T2.1 partners (a total of 11) participated in the screening process, with each CHANGER partner being assigned a number of articles based on their Person Months allocation for WP2. Specifically, 2,696 articles were assigned to MEFST, 2,103 to LMU, 1,502 to UB, 1,202 to NORSUS. Additionally, 901 articles were allocated to RUG, TU WIEN, UBO, and K&I each, while 601 articles were assigned to UKIM, UM, and UE<sup>1</sup> each.

#### 3.4 Finalizing literature screening

After completing the screening process in SyRF, 1,708 included articles were downloaded for full text assessment using the "Export Screening Data" feature, which provides the data in CSV format. A team of three independent reviewers (AM, LB, AMij) from MEFST then independently assessed the titles and abstracts of articles to ensure the consistency of the selection process. AM is a medical doctor and a researcher in evidence-based medicine, research ethics and research integrity. LB is an information scientist and a researcher in ethics and methodology. AMij is a biophysicist, computer scientist, and a researcher in the field of metascience. This final screening step resulted in a list of 758 articles for data extraction and analysis.

#### 3.5 Collecting articles for full text analysis

For full text analysis, the final Excel table, which compiled the metadata and relevant information from the selected articles and CORDIS projects, was used to search for the corresponding PDFs of the documents. Each Task partner was assigned 72 articles.

<sup>&</sup>lt;sup>1</sup> The University of Edinburgh (UE) participated only in this phase of the task and is no longer an associate partner.



#### 3.6 Grey literature selection

Figure 2 provides the overview of the screening process for the documents from EU-funded projects.



Figure 2. Overview of the grey literature search and screening process.

For the selection of grey literature, we focused on the CORDIS database (<u>https://cordis.europa.eu</u>), specifically targeting EU research projects conducted under Horizon 2020 (2014-2020) and Horizon Europe (2021-2027). We applied the following keywords and filters: "project" for content type, "HORIZON" and "H2020" for the framework program, "en" for language, and "ethics" AND "challenge" as the keywords. The syntax for the search strategy can be found in Annex 1.

We additionally searched all projects from the EU Results Pack "Ethics and integrity: Building bridges for trust and excellence in research and innovation" (<u>https://cordis.europa.eu/article/id/450170-ethics-and-integrity-building-bridges-for-trust-and-excellence-in-research-and-innovation</u>).

Next, we exported the data on the projects retrieved from the CORDIS database into an Excel table, including their titles and brief summaries. This information served as the basis for the screening process. The same team of three independent reviewers from MEFST (AM, LB, AMij) reviewed the projects' titles and descriptions, and the same inclusion and exclusion criteria were applied as for the academic literature selection to ensure consistency in the final selection process.

For each included project, we screened all documents under the Results section in the CORDIS database, including Deliverables, Publications and Other Research product categories of documents. Each Task partner was asked to download the documents for 8 Horizon 2020 or Thematic pack projects. The MEFST team downloaded the documents for Horizon Europe projects.



Out of a total of 2,014 projects in CORDIS (1,714 H2020 and 333 Horizon Europe), we ultimately selected 89 H2020 and 51 Horizon Europe projects for further analysis.

Full text search by three independent reviewers from MEFST resulted in the final set of 78 documents (65 documents from Horizon 2020 projects and 13 documents from Horizon Europe projects).

## 4 Methodology for Evidence and gap maps (T2.2)

#### 4.1 Evidence map creation

Following the completion of the scoping literature search, the extracted data was compiled into an evidence database. The database was used to create EGMs – systematic and visual presentations of the availability of evidence for the identified challenges to ethics review. In this way, the critically appraised evidence is provided in clear and actionable information to all stakeholders.

We used Python (3.8.19) and its Matplotlib library to structure the EGM as a matrix of ethics issues and challenges. In this deliverable we present the first version of the EGM, which will be later regularly updated as a living document in The Embassy of Good Science (<u>https://embassy.science/wiki/Main\_Page</u>), as a resource open to contributions and updates from the community beyond the duration of the project.

## 5 Data analysis

#### 5.1 Data extraction

Given the large volume of documents, we opted to use an **Artificial Intelligence (AI)** tool for data extraction, instead of performing the task manually. Both methods are slow and time-consuming, however the AI tool does accelerate the data extraction process and also ensures consistency in identifying key information, resolving the bias between different human reviewers. AI has already been used for research purposes for systematic reviews: for identification of relevant titles and abstracts from clinical review datasets (Guo et al., 2024), and for processing and reviewing full texts (Landschaft et al., 2024; Khraisha et al., 2024). In addition, Cochrane, an international organization that performs evidence synthesis for health interventions, actively promotes the use of AI technologies and their integration into systematic reviews (Cochrane, 2023).

We decided to use a Large Language Model (LLM), as these models are based on deep learning techniques, which allows them to process and generate text with a high level of contextual understanding (Kushwaha, 2023). More specifically, we chose OpenAI Generative Pretrained Transformer (GPT) and GPT-4 Application Programming Interface (API) because of its advanced natural language processing capabilities (<u>https://openai.com/index/gpt-4</u>). This choice was also influenced by the lack of adequate LLM tools specific for the European research framework, apart from some initiatives such as LEAM – Large European AI Models (<u>https://leam.ai/</u>). Given that we subscribed to ChatGPT Plus, we were able to use the GPT-40 model specifically. We selected a mode



where the model does not learn from user interactions in real time and it does it retain any information between sessions. This approach ensures user privacy and it can easily be managed through OpenAI account (Figure 3).



One of the most useful and promising features of AI models is that they can improve over time. We continuously improve the models that power our services, such as ChatGPT and DALL-E, via scientific and engineering breakthroughs as well as exposure to real world problems and data. As part of this continuous improvement, when you use our services for individuals such as ChatGPT or DALL-E, we may use the content you provide to train our models. Not only does this help our models become more accurate and better at solving your specific problem, it also helps improve their general capabilities and safety. You can ask us to not train our models with content associated with your account by submitting this request.

I understand that this request applies moving forward and does not apply to data that was previously disassociated from my account.*
Country/State of Residency*
💿 Crostia

Figure 3. Managing privacy of OpenAI account: Selecting "Do not train on my content" feature.

Submit Request

The methodological approach we used included **three iterations/steps** of GPT-4 text analysis (**Figure 4**):

- 1. Piloting testing the API, refining the LLM prompts, validating the outputs;
- 2. Topic extraction extraction of ethical and legal issues, technologies, new forms of collaborations, and frameworks/guidelines mentioned in the articles;
- 3. Mapping a more detailed and refined categorization of the identified topics and their mapping to the research articles and grey literature.





**Figure 4.** A flowchart illustrating the methodology used for processing documents in three phases: the piloting was conducted on 100 documents; data extraction was expanded to all 834 documents; and the final mapping was performed on the same 834 documents, further refining and categorizing the extracted data.

#### 5.1.1 Step 1: Piloting

The first step involved familiarizing ourselves with GPT-40 (<u>https://ai-pro.org/start-chat-gpt</u>) to understand its capabilities and learn how to use it effectively. This model of GPT is available with ChatGPT Plus subscription. To begin, we uploaded an article from our list entitled "*3D Bioprint Me: A Socioethical View of Bioprinting Human Organs and Tissues*" and posed a straightforward question: "*What are the ethical challenges discussed in the uploaded article?*" GPT-40 generated the following output:

"The ethical challenges discussed in the uploaded article on 3D bioprinting include several key concerns:

- 1. **Social Stratification**: The technology could create a divide between those who can afford personalized organs and those who cannot, leading to unequal access to life-saving treatments.
- 2. **Managing Expectations**: There is a risk of overhyping the potential of 3D bioprinting, which might lead to unrealistic public expectations, especially since printing complex organs like livers or kidneys is far from being fully realized.
- 3. **Untested Paradigms**: Since bioprinting involves using living cells and implanting them in the human body, there are unknown risks, including potential tumor formation, immune responses, and long-term integration challenges.
- 4. **Ownership of Bio-Objects**: There are ethical and legal questions around who owns the bioprinted organs or tissues, especially when it comes to patenting and intellectual property rights, which could affect accessibility and innovation.



5. **Governance and Regulation**: The article highlights the need for regulatory frameworks to ensure safe development and distribution of bioprinted organs, proposing Responsible Research Innovation (RRI) as a possible approach to guide ethical oversight. "

After comparing the output with the article's text, we confirmed the accuracy of the answer and proceeded with further testing. We then posed additional questions: "*Does the article discuss certain technology?*" This was the generated output:

"Yes, the uploaded article mentions several technologies related to 3D bioprinting. Specifically, it discusses **3D printing technology** and its biological variant, 3D bioprinting, which involves using biological materials, including living cells, to create structures resembling human organs and tissues. Additionally, it refers to the use of **pluripotent stem cells (PSCs)**, which are crucial for bioprinting due to their ability to self-renew and differentiate into various cell types. The article also highlights organ-on-a-chip technologies, which can be used for drug testing and personalized medicine, as well as bioprinting techniques like **bioextrusion** and **laser-assisted bioprinting**."

Furthermore, when asked "Does the article mentions any human rights related frameworks or regulatory guidelines?" and "Do the authors offer any recommendation on how to address the ethical issues mentioned in the article?", GPT-40 generated the following answers:

"The article does not specifically mention any established human rights frameworks, but it does touch on the need for regulatory frameworks and ethical oversight. It discusses the concept of Responsible Research Innovation (RRI) as a potential framework for guiding the development of 3D bioprinting. RRI emphasizes aligning research and innovation with societal needs and ethical standards, promoting shared responsibility among researchers, policymakers, and the public.

The authors offer several recommendations on how to address the ethical issues related to 3D bioprinting:

- Responsible Research Innovation (RRI): The authors suggest using the RRI framework as a way to tackle the ethical challenges of 3D bioprinting. This framework emphasizes proactive engagement with societal needs and ethical concerns early in the development process. It encourages collaboration between scientists, ethicists, and policymakers to ensure that innovations align with public values and do not exacerbate social inequalities.
- 2. Ethical Oversight and Regulation: The authors emphasize the need for clear governance and regulatory frameworks for 3D bioprinting. They call for updated regulations that can address the unique challenges of bioprinted organs, including issues of safety, ownership, and equitable access. These regulations should ensure that bioprinting technologies are developed and deployed responsibly, with safeguards to prevent exploitation or the creation of a black market for bioprinted organs.



3. Public Engagement and Managing Expectations: The authors recommend managing public expectations by avoiding the hype surrounding 3D bioprinting. Given the technology's limitations, especially with complex organ printing, transparency is essential to prevent unrealistic hopes. Public engagement should focus on educating society about the current and future potential of bioprinting, as well as its risks and limitations."

After confirming the accuracy of the generated answers, we uploaded 10 additional articles, one by one, and each time cross-checked GPT-4o's responses against the content of the article to ensure accuracy, which was satisfactory in each case.

Next, we attempted to upload multiple documents simultaneously, as the tool allows for up to ten documents at once. However, as the number of documents increased, the responses became vaguer and, in some cases, inaccurate. This seems to be due to GPT-4o's token limit of 128,000 shared between prompt and completion (<u>https://platform.openai.com/docs/models/gpt-4o#gpt-4o</u>). One token corresponds to approximately four charts in English, and 128,000 tokens generally translates to around 85,000 to 96,000 words (<u>https://help.openai.com/en/articles/4936856-what-are-tokens-and-how-to-count-them</u>).

Finally, we opted to upload two documents at a time. We chose not to work with just one document per upload, as even with a ChatGPT Plus subscription, users are limited to 50 chat messages with the model every three hours. Uploading two documents simultaneously provided a good balance between efficiency and maintaining the quality of responses.

All verifications conducted during the piloting phase were carried out by the MEST team (AM, AMij, and LB).

#### 5.1.2 Step 2: Topic extraction

In this phase, our goal was to identify the most frequently discussed ethical challenges across all 834 selected documents, along with technologies, frameworks/guidelines and the authors' recommendations for addressing these challenges, corresponding to the research question of the scoping review. We opted for a table format with the search terms placed in columns and each row representing a different article (**Figure 5**).







The specific LLM prompt used was as follows:

Please identify and document the following elements from the provided documents:

- 1. Ethical Challenges: What are the ethical challenges discussed in each document?
- 2. **Technologies**: If applicable, what technologies are mentioned in relation to these ethical challenges?
- 3. **New Players and Collaborations**: Are there any references to new players, forms of collaboration, or partnerships? If so, what are they?
- 4. *Human Rights Frameworks*: Do the documents discuss any new human rights-related frameworks? If yes, what are those frameworks?
- 5. **Recommendations**: Which recommendations do the authors provide for addressing these ethical challenges?

Please organize your findings in an Excel table with the following columns:

- Column 1: Name of the Document
- Column 2: Ethical Challenges
- Column 3: Technologies Involved
- Column 4: New Players, Forms of Collaboration, and Partnerships
- Column 5: New Human Rights-Related Frameworks
- Column 6: Authors' Detailed Recommendations for Addressing the Ethical Challenges

After each prompt, we obtained the data for two articles at a time, in the table format. A sample of this table can be found in the Annex 3 (**Table 2**). The extracted data underwent quick manual verification, where the content was compared against the article title to ensure accuracy.



Once verified, the data was saved in an Excel table for further analysis. The content was further analysed manually to identify the most frequently discussed ethical challenges, along with technologies and frameworks/guidelines.

#### 5.1.3 Step 3: Mapping

Building on the results from the previous step where we identified 18 key ethical issues, our goal was to create a table in which each ethical challenge is represented by a column (**Figure 6**). In this table, the cells would be populated with either 0 (indicating the issue is not discussed in the article) or 1 (indicating the issue is addressed).



**Figure 6.** Table format for the final step of data extraction. Each ethical challenge is represented by a column, with the cells being populated with either a zero (indicating the issue is not discussed in

the article) or a one (indicating the issue is addressed). In addition, technologies, guidelines/frameworks, and authors' recommendations are represented by columns, and the data is mapped with the articles.

The specific LLM prompt used is as follows:

I have a table with these columns:

Studyld File name Title Doi Public trust Transparency Social, cultural, environmental impact Safety and security Regulatory gaps and challenges Privacy Misuse and exploitation Liability, responsibility and accountability Legal issues Human rights Equity/discrimination Data sharing, management and ownership Consent Commercialization Bias/Fairness Balancing innovation with ethical principles Autonomy and decision-making Anonymization Accuracy.

Columns from Public trust to Accountability represent ethical challenges discussed in an article, and should have value 1 (if discussed) or 0 (not discussed). Column Technologies represents technologies discussed in an article in the context of ethical challenges (it should be the technology mentioned, if no technology is discussed, it should be 0). I will upload 2 research articles, extract information from



them to fill the table, each article represents one row. Make the table user friendly (in the form of a non-interactive table), so I can directly paste it to my Excel sheet.

As in the previous step, we uploaded only two documents at a time.

#### 5.2 Data Validation and Quality Control

The main goal of our data validation was to ensure the completeness and accuracy of the information extracted by the AI tool. Our strategy involved manual review and verification of a representative sample of the extracted data. This included 80 (~10%) of the documents processed by GPT-40.

All T2.2 partners participated in the validation process, with each partner responsible for reviewing eight documents. They were given a sample of the final Excel table, which included Study ID, File name, Title, DOI, 20 Ethical Challenges, Technologies, Guidelines/Frameworks, and Authors' Recommendations. For any field they identified as inaccurate, they were instructed to highlight the corresponding cell in red.

We calculated the percentage accuracy of GPT-4o's output by using the following formula:

 $Accuracy = \frac{Total \ Fields - Number \ of \ Errors}{Total \ Fields} \times 100$ 

The accuracy achieved is 89.4%.

#### 5.3 Legal and ethical aspects of using AI

In our project, we recognized that AI is an emerging technology that carries distinct ethical and legal issues. Understanding how AI systems interact with existing copyright laws - especially in terms of data usage, output generation, and authorship – was a critical consideration for us. To ensure compliance, we refer to the "Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC", which addresses legal use of copyright material. According to Article 3 of the Directive:

"Member States shall provide for an exception to the rights provided for in Article 5(a) and Article 7(1) of Directive 96/9/EC, Article 2 of Directive 2001/29/EC, and Article 15(1) of this Directive for reproductions and extractions made by research organisations and cultural heritage institutions in order to carry out, for the purposes of scientific research, text and data mining of works or other subject matter to which they have lawful access."

Given that our work involved text mining solely for research purposes, this exception is applicable. Furthermore, in alignment with the security requirements we safely stored all extracted files, datasets and the analysis results using **Next Cloud**. This is in accordance with Article 3, paragraph 2:



"Copies of works or other subject matter made in compliance with paragraph 1 shall be stored with an appropriate level of security and may be retained for the purposes of scientific research, including for the verification of research results."

This way we ensured that our project adhered to copyright laws while maintaining the security of our research data.

Moreover, files uploaded to ChatGPT are not used for model training. They are saved in user's account only up to the retention period of the corresponding chat. This means that the uploaded files are temporarily saved during a session, and are automatically deleted after the session ends (https://help.openai.com/en/articles/8555545-file-uploads-faq).

With regard to ethical aspects of the use of AI for evidence synthesis, the following ethics issues must be kept in mind (Alshami et al., 2023):

1. Bias reproduction: AI systems can inadvertently reproduce existing biases in the data used for training, which can lead to unfair or inaccurate conclusions in evidence synthesis. For instance, biased datasets can perpetuate systemic inequalities or reinforce harmful stereotypes. We addressed this by researchers verifying the results of data extraction performed by the LLM model, where we achieved 89.4% accuracy, which is considered satisfactory.

2. Lack of transparency and explainability: LLMs use a deep network of interconnected parameters. The internal mechanisms by which different parts of input information are processed and weighted are not interpretable, making GPT a "black box" when it comes to text mining. This lack of transparency can hinder accountability and trust in the evidence synthesis process. With the lack of LLMs developed specifically for a research study, this is an inherent problem. We addressed it by extensive verification of the accuracy of the extracted data.

3. Methodological errors and biases: AI can introduce new methodological errors or biases, such as overfitting or underfitting, which can compromise the validity and reliability of the synthesized evidence. We addressed this limitation by carefully phrasing the prompts and checking the output results.

4. Potential for replacing human judgement: Al-driven evidence synthesis may lead to concerns about replacing human judgement and expertise, potentially undermining the value of human-centred approaches in evidence synthesis. We addressed this issue by including checkpoints for each step of data extraction. Also, AI was not used to summarise and explain the results but only to extract textual information in a context of a scientific article.

5. Scalability and generalizability limitations: AI may struggle to generalize across diverse contexts, populations, or settings, limiting its applicability and scalability in evidence synthesis. In our case, we did not use the AI to generate conclusions and create evidence maps, but only to help in the extraction of data to be summarised.

By including human judgement and expertise at every step of data extraction and analysis we believe that we have sufficiently balanced the benefits and risks of AI-driven evidence synthesis for this topic.



## 6 Results

A total of 756 academic articles, 65 documents from 46 H2020 projects, and 13 documents from Horizon Europe projects were analysed.

#### 6.1 Evidence and Gap Map (EGM)

The results of the scoping review were visualized using Python (3.8.19) and its Matplotlib library in the form of an EGM as a matrix, which visualizes the distribution of ethical challenges across different technological fields. Each row represents an ethical challenge, while each column corresponds to a specific technology or domain. The size of the bubbles reflects the relative frequency of each ethical challenge within the corresponding field (**Figure 7**). This is a static visualization, which will be used as a starting point for creating a living and dynamic EGM, to be integrated into the Embassy of Good Science.



**Figure 7.** Evidence and Gap Map (EGM), rows representing the selected topics, and columns representing the challenges to ethics reviews. The data was visualised using Python (3.8.19) and *Matplotlib* library.



#### 6.2 Identified challenges

Based the second step of GPT-40 analysis, we identified the 18 most common ethical challenges discussed across the articles. **Privacy** is the most frequently discussed ethical challenge, appearing in 196 articles. **Consent** and **Bias/Fairness** are also highly prominent, with 119 and 98 articles, respectively. **Regulatory gaps and challenges** (74 articles) and **Safety and security** (64 articles) were also notable topics, suggesting ongoing struggles with legal frameworks and the safe implementation of technology. Other significant challenges include **Transparency** (47 articles) and **Data sharing and management** (32 articles), highlighting the importance of openness and proper handling of data.

In the third step of GPT-4o analysis, we checked each of the 18 identified challenges to determine whether it was explicitly mentioned in the articles (**Table 1**). This step allowed us to capture the instances when these challenges were mentioned, even if they were not the main focus of an article. For example, while many articles on biobanking focus on the issue of consent and data privacy, this step enabled us to capture additional concerns, such as misuse and exploitation, even if they were not the main focus.

Ethical challenge	Number of articles
Transparency	804
Regulatory gaps and legal challenges	793
Balancing innovation with ethical	782
principles	
Safety and security	720
Liability, responsibility and	706
accountability	
Privacy	666
Trust	661
Social, cultural or environmental	622
impact	
Accuracy	586
Consent	559
Autonomy and decision-making	555
Bias/Fairness	524
Data sharing and management	523
Human rights	512
Equity/discrimination	480
Misuse and exploitation	404
Anonymization	293
Commercialization	186

**Table 1.** Frequency of the 18 most common ethical challenges in included literature

Furthermore, we found that the most frequently discussed technologies could be categorized into nine key areas:

1. AI (general application of AI, AI in healthcare AI-driven systems, ML algorithms);



- 2. Biobanking and Genomics (CRISPR and gene editing, human germlines, embryoids, stem cell technologies, reproductive technologies);
- 3. Big Data and Analytics (tools and platforms for large datasets, predictive analytics, and data mining techniques);
- 4. Data Privacy and Security Tools (blockchain technologies, privacy-preserving technologies, encryption methods, cybersecurity technologies);
- 5. Intelligent Systems and Digital technologies (Internet of Things, robotics, autonomous systems);
- 6. Biomedical Engineering and Research Technologies (neurotechnologies, 3D bioprinting, medical device innovations, clinical trials);
- 7. Digital Health and Telemedicine (remote patient monitoring, telemedicine platforms, electronic health records, mobile health apps);
- 8. Ethics and Regulation Tools (regulatory compliance platforms, ethical impact assessment tools, innovation hubs);
- 9. Other emerging technologies (green technologies, environmental innovations, and any other technologies that don't fall into the above categories).

Technology	Number of articles
AI	206
Biobanking and Genomics	90
Ethics and Regulation Tools	58
Digital Health and Telemedicine	64
Data Privacy and Security Tools	90
Other emerging technologies	31
Biomedical Engineering and Research	159
Technologies	
Intelligent Systems and Digital	68
technologies	
Big Data and Analytics	66
None mentioned	6

**Table 2.** Frequency of the most commonly discussed technologies categorized into nine key areas

Moreover, we found that, in order to address ethical, social, and regulatory issues related to emerging technologies, different teams must work together. Collaboration is needed to ensure compliance with data protection laws while developing innovative solutions. By manually analysing the extracted data we obtained in the second iteration of GPT-40 analysis, we found that these partnerships often include tech companies and healthcare providers, particularly in areas like telemedicine, AI-driven healthcare applications, EHR systems, and genomic research. AI developers frequently collaborate with ethicists and policymakers to address ethical challenges in AI systems and robotics. Healthcare providers work together with regulatory bodies and data protection authorities, focusing on data protection, security, and patient consent in healthcare technologies. Cross-sector collaborations involving academia, industry players, and government authorities. These partnerships are found in bioengineering, genomics research, AI, robotics, and digital health. Furthermore,



international partnerships are formed to develop global guidelines for emerging technologies, involving international research consortiums and alliances (**Figure 8**).

**Table 3.** Frequency of the most common stakeholders mentioned in the articles. Government entities include policymakers, regulating bodies, and data protection agencies. Healthcare providers include both institutions and professionals

Stakeholder	Number of articles	
Ethics committees and ethicists	451	
AI developers	418	
Government entities	400	
Healthcare providers	298	
Tech Companies and Industry	296	
Academia and research	262	



**Figure 8.** The lines represent the collaborations between stakeholders identified in the articles, and the numbers represent the number of articles that mention those collaborations.

Additionally, we found that the most frequently mentioned documents are mostly created by governments, international organizations, or the European Union, relating to data protection, healthcare, AI governance, human rights, and ethics (**Table 4**).



<b>Table 4.</b> Legal and regulatory documents maneworks over view	Table 4	4. Legal ai	nd regulatory	/ documents	frameworks	overview
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Document Name	Summary	URL
Genetic Information Non- discrimination Act (GINA)	An official U.S. law that prohibits discrimination based on genetic information.	https://www.genome.gov/Pages/ PolicyEthics/GeneticDiscriminatio n/GINAInfoDoc.pdf
Genomic Data Sharing Policy	Official policy for the responsible sharing of genomic and health-related data.	https://sharing.nih.gov/genomic- data-sharing-policy
Global Alliance's Framework for Responsible Sharing of Genomic and Health-Related Data	A published framework for genomic data sharing.	https://www.ga4gh.org/framewo rk/
Health Insurance Portability and Accountability Act (HIPAA)	A U.S. law governing health data privacy and security.	https://www.hhs.gov/hipaa/inde x.html
EU Advanced Therapy Medicinal Products Regulation	Official EU regulation for advanced therapies, including gene therapy.	https://health.ec.europa.eu/med icinal-products/advanced- therapies en
Medical Device Regulation (MDR)	EU regulation concerning medical devices.	https://health.ec.europa.eu/med ical-devices-sector/new- regulations en
General Data Protection Regulation (GDPR)	A key European regulation governing data protection and privacy.	https://gdpr.eu/
Data Protection Act (DPA)	A data protection law in the UK.	https://www.legislation.gov.uk/u kpga/2018/12/contents/enacted
IRB regulations and oversight frameworks	Institutional Review Board regulations overseeing ethical research in human subjects, commonly used in the U.S. and other regions.	https://www.hhs.gov/ohrp/regul ations-and-policy/regulations/45- cfr-46/index.html
Data Protection Impact Assessments (DPIA)	A mandatory process required by GDPR to assess risks in data processing.	https://gdpr.eu/data-protection- impact-assessment-template/
European Commission White Paper on Al	Official white paper proposing policy and regulatory options for AI in Europe.	https://commission.europa.eu/p ublications/white-paper-artificial- intelligence-european-approach- excellence-and-trust_en
Anti-Discrimination Directive	An EU directive aimed at preventing discrimination.	https://eur-lex.europa.eu/legal- content/EN/TXT/?uri=CELEX%3A 32000L0043
USA's Blueprint for an Al Bill of Rights	A framework proposed by the U.S. government to safeguard rights in AI applications.	https://www.whitehouse.gov/ost p/ai-bill-of-rights/



EU's AI Act	Proposed European regulation for the use of artificial intelligence.	https://eur-lex.europa.eu/legal- content/EN/TXT/?uri=CELEX:5202 1PC0206
Canada's AI and Data Act	Proposed Canadian legislation governing AI and data usage.	<u>https://ised-</u> isde.canada.ca/site/innovation- better-canada/en/artificial- intelligence-and-data-act
Charter of Fundamental Rights	A legally binding charter of human rights for EU member states.	<u>https://eur-lex.europa.eu/legal-</u> <u>content/EN/TXT/?uri=CELEX%3A</u> <u>12012P%2FTXT</u>
Universal Declaration on Bioethics and Human Rights (UNESCO, 2005)	An official UNESCO declaration providing a bioethical framework.	https://unesdoc.unesco.org/ark:/ 48223/pf0000146180
Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997)	A UNESCO declaration concerning human genome and human rights.	https://www.unesco.org/en/legal -affairs/universal-declaration- human-genome-and-human- rights
Directive 2001/29/EC	An EU directive on copyright, including the use of works for research and education.	https://eur-lex.europa.eu/legal- content/EN/TXT/?uri=celex%3A3 2001L0029
European Convention on Human Rights	A foundational human rights treaty that protects rights and freedoms in Europe.	https://www.echr.coe.int/docum ents/d/echr/Convention ENG
Directive 2011/24/EU	EU directive on the application of patients' rights in cross-border healthcare.	<u>https://eur-lex.europa.eu/legal-</u> <u>content/EN/TXT/?uri=CELEX%3A</u> <u>32011L0024</u>

Finally, the analysed articles highlighted several key recommendations to address ethical issues related to emerging technologies, new forms of collaborations, and human rights related frameworks. These recommendations emphasize:

- establishing clear ethical guidelines;
- improving patient education;
- promoting and ensuring compliance with laws like GDPR;
- implementing robust data security protocols;
- improving informed consent processes;
- encouraging interdisciplinary collaboration;
- developing and enforcing ethical and regulatory frameworks;
- ensuring fairness and preventing biases in AI systems;
- ensuring transparency in algorithmic processes;
- educational interventions to improve the understanding of ethical frameworks.

The complete list of recommendations, along with their corresponding source documents, will be available as part of the dynamic EGM.



#### 6.3 Challenges for Ethics Committee Members

We identified 18 studies in our list that specifically address challenges directly faced by Ethics Committee members.

We uploaded these articles to GPT-4o, two at a time. The specific LLM prompt was as follows:

Please review both articles carefully and extract the challenges and ethical issues specifically related to ethics committees or review boards. Write separate explanations for each article, starting with the title of the article before the respective explanation. Additionally, note if the authors provide any recommendations on how to address the identified issues.

Each of the responses was further validated by three independent reviewers from MEFST (AM, AMij, LB) who compared the LLM output with the full text of the articles. All the responses were compiled into a Word document and manually analysed to verify the validity of the extraction.

We identified the following key challenges faced by Ethics Committee members (Table 5).

Study	Study design	Setting, study participants	Identified challenges
Pysar et al. 2021	Survey study	Australia, members of the University of Queensland (n=196)	<ul> <li>Low confidence in the topic/issue</li> <li>Lack of training and resources</li> <li>Consistency in the review process</li> <li>Challenges for ethical assessment</li> </ul>
Vries et al, 2015	Report	Ethiopia, workshops during H3Africa Consortium 2014 (n=40 research ethics committees from Africa)	<ul> <li>Concern over matters of consent for future use</li> <li>Ensuring that participants fully understand the research process and that their privacy was protected</li> <li>Concerns about how to manage the secondary use of data</li> </ul>
Ethics Committee of the American Society for Reproductive Medicine, 2016	Report	USA, all members of Ethics Committee of the American Society for Reproductive Medicine	<ul> <li>Terminology</li> <li>Misconceptions</li> <li>Determining the moral and legal status of embryos</li> </ul>
Ethics Committee of the American Society for	Report	USA, all members of Ethics Committee of the	- Dealing with undisclosed information or material misconduct

Table 5. Studies addressing challenges specific for the work of Ethics Committee members



Reproductive Medicine, 2013		American Society for Reproductive Medicine	<ul> <li>Addressing conflicts of interest</li> <li>Navigating nonmedical entities' Misconduct</li> </ul>
Ethics Committee of the American Society for Reproductive Medicine, 2023	Report	USA, all members of Ethics Committee of the American Society for Reproductive Medicine	<ul> <li>Ensuring that patient consent and decision- making are adequately documented and respected</li> <li>Ambiguity about patient preferences regarding the use of embryos</li> <li>Concerns about lack of clear guidance from legal frameworks</li> </ul>
Muurling at al, 2023	Case study	Documents describing the REC review process at 10 sites in 9 European countries	<ul> <li>Ensuring participant well-being</li> <li>Methodological Issues</li> <li>Ensuring that medical devices meet regulatory standards</li> <li>Inconsistencies in how RECs across different European sites approached the ethical review process</li> </ul>
Ethics Committee of the American Society for Reproductive Medicine, 2018	Report	USA, all members of Ethics Committee of the American Society for Reproductive Medicine	<ul> <li>The debate</li> <li>surrounding whether</li> <li>and when to disclose to</li> <li>donor-conceived</li> <li>individuals the details of</li> <li>their conception</li> <li>Navigating between</li> <li>promoting openness</li> <li>and maintaining</li> <li>confidentiality for</li> <li>donors</li> <li>Legal requirements are</li> <li>changing and differ</li> <li>between jurisdictions,</li> <li>adding complexity to</li> <li>decision-making for</li> <li>ethics committees</li> <li>Challenges in</li> <li>developing policies that</li> <li>account for long-term</li> <li>storage and future</li> <li>retrieval of donor</li> <li>information, including</li> </ul>



		the ethical implications of how much information to share and under what conditions
Lázaro-Muñoz et al, Review 2019	Members of Society of Psychiatric Genetics (ISPG) Ethics Committee	<ul> <li>Underrepresentation of racial and ethnic minorities in psychiatric genetics research</li> <li>Deciding whether and how to return psychiatric genetic results to research participants</li> <li>Concerns about how results are communicated and used in clinical and non- clinical settings</li> <li>Concern about the premature use of psychiatric genetic findings in clinical practice</li> <li>Balancing the potential clinical benefits of psychiatric genetic testing with the risk of harm due to misinterpretation of results</li> <li>Ethical dilemmas</li> </ul>
		regarding the potential for discrimination based on genetic information
Takashima et al, 2019 Letter (relates to the design of a clinical trial)	Meeting minutes from the review committees regarding the world's first-in-human trial using induced pluripotent stem cells	<ul> <li>Ensuring that the risks do not outweigh the potential benefits for participants</li> <li>Transparency in government and committee statements</li> <li>Maintaining oversight of the informed consent process</li> <li>Ensure the trial design includes "reasonable accommodations" for vulnerable groups</li> </ul>



Tromp and Vathorst, 2018	Qualitative interview- based study combined with observational research	Netherlands (n>30 participants)	<ul> <li>Ethical dilemma for researchers and ethics boards concerning therapeutic optimism</li> <li>Ensuring that protocols are scientifically and ethically sound while not overburdening researchers with excessive bureaucracy</li> </ul>
Ethics Committee of the American Society for Reproductive Medicine, 2018	Report	USA, all members of Ethics Committee of the American Society for Reproductive Medicine, 2018	<ul> <li>Ensuring women are fully informed about the risks and unknowns</li> <li>Ensure that patients are properly counselled on realistic expectations</li> <li>Ethical concerns around oocyte cryopreservation procedure</li> <li>Ethical issues about equitable access to reproductive technologies</li> <li>Ethics committees must guard against coercion or undue influence</li> </ul>
Matrana and Campbell, 2020	Review	Studies and reviews on precision medicine, genomics, pharmacogenomics, and next-generation sequencing	<ul> <li>Ensuring that participants fully understand the procedures, risks, and benefits</li> <li>Establishing clear guidelines on who can access genetic data</li> <li>Ensuring that participants are fully informed about how their genetic information will be used, shared, and protected</li> <li>IRBs should be aware of and address financial disparities in access to precision medicine treatments and genetic testing</li> </ul>



Zhou, 2021	Qualitative research	Official regulations and policies	<ul> <li>Lack of regulations and national-level ethics</li> <li>governance</li> <li>Many ethics</li> <li>committees in Chinese</li> <li>HEIs operate informally, providing ethics</li> <li>approval letters without</li> <li>conducting rigorous</li> <li>review processes</li> <li>There is no systematic</li> <li>supervision of ethics</li> <li>committees, leading to</li> <li>inadequate monitoring</li> <li>of their functioning</li> <li>Lack of training and</li> <li>certification</li> <li>An insufficient number</li> <li>of members with</li> <li>expertise in necessary</li> <li>fields</li> <li>Lack of sufficient</li> <li>administrative and</li> <li>financial resources to</li> <li>operate effectively</li> </ul>
Ellacuria. 2021	Qualitative research	Articles on CRISPR-Cas9	- Concerns from the
		technology; legal and	Spanish Bioethics
		ethical documents	Committee about
			germline gene editing
			- The lack of a robust
			international regulatory
		•	framework
Segarra et al, 2017	review	Studies on	- Bias toward male data
		drug interactions and	underrepresentation of
		sex-divergent outcomes	women in clinical trials
		in preclinical and clinical	(making it difficult for
		settings; guidelines and	review boards to justify
		regulatory frameworks	the relevance of trial
			outcomes for female
			populations)
			- Ethics committees are
			sometimes under-
			resourced or lack
			sumcient scientific
			- Pressure from Industry
Tang. 2020	Qualitative study	Papers addressing Al	- Committees struggle
		ethics, governance. and	with the complexities of
		, 0	Al research, particularly



		controversies; legal and regulatory documents	in areas involving big data and internet research ethics - Many current regulatory frameworks, such as the Common Rule for the Protection of Human Subjects, were not designed for AI - Ambiguity in data usage making ethical approvals inconsistent
Lanzerath, 2023	Review	Legal and regulatory documents; Articles on the role of ethics committees and on the ethical challenges in biomedical research	<ul> <li>Variability in ethical standards across Europe extending not only between nations but also among institutions within the same country</li> <li>Marginalization due to EU Regulation 536/2014: the regulation on clinical trials limits the scope of ethics committees by shifting responsibilities to national regulatory authorities</li> <li>Lack the infrastructure and resources, especially in smaller countries</li> <li>Ethics committees are often unprepared to handle new challenges</li> <li>Increasing influence of economic factors on research</li> </ul>
Torous and Nebeker, 2017	Viewpoint paper	Researchers and Institutional Review Board (IRB) affiliates	<ul> <li>Lack of expertise in evaluating the risks associated with emerging technologies</li> <li>Absence of standards and best practices</li> <li>Lengthy review processes</li> <li>Dynamic and evolving technology</li> </ul>



#### 6.4 Further development of the Evidence Map

We plan to create a living, dynamic version of the current Evidence and Gap Map, where the individual visual topic blobs will be linked to individual articles from the scoping reviews that address the specific issue. We also plan to update the Map by following the results/outputs from the ongoing EU projects from the Thematic Results Pack on "Ethics and integrity: Building bridges for trust and excellence in research and innovation". The projects to be followed are presented in **Table 6**.

Project	Focus/Objective	URL
TechEthos	Ethical development and deployment of new technologies	https://www.techethos.eu/
iRECS	Ethical development and deployment of new technologies with high socio-economic impact	https://cordis.europa.eu/project/id/101006366
HYBRIDA	Ethical and normative aspects of organoids and their governance	https://www.hybrida-project.eu/
ROSIE	Open Science as a mechanism for reinforcing research integrity	https://rosie-project.eu/
PREPARED	Safeguarding ethical values during accelerated research efforts in crisis situations	https://cordis.europa.eu/project/id/101006255
BEYOND	Behavioural and evidence-based approach to promote research ethics and integrity	https://cordis.europa.eu/project/id/101006630
RE4GREEN	Research ethics and integrity framework for sustainable economy transition	https://cordis.europa.eu/project/id/101094918

**Table 6.** Overview of the Horizon Europe projects on research ethics and integrity

To ensure the Map remains current, we will also integrate relevant new literature. The following articles represent the additions to date:

- Colombo C, Mayrhofer MT, Kubiak C, Battaglia S, Matei M, Lavitrano M, Casati S, Chico V, Schluender I, Carapina T, Mosconi P. *The CORBEL matrix on informed consent in clinical studies: a multidisciplinary approach of Research Infrastructures Building Enduring Lifescience Services.* BMC Med Ethics. 2021 Jul 17;22(1):95. doi: 10.1186/s12910-021-00639-x. PMID: 34273983; PMCID: PMC8285862.
- Knight S, Viberg O, Mavrikis M, Kovanović V, Khosravi H, Ferguson R, Corrin L, Thompson K, Major L, Lodge J, Hennessy S, Cukurova M. *Emerging technologies and research ethics: Developing editorial policy using a scoping review and reference panel*. PLoS One. 2024 Oct 31;19(10):e0309715. doi: 10.1371/journal.pone.0309715. PMID: 39480862; PMCID: PMC11527293.



- 3. Eaton, S.E. *Future-proofing integrity in the age of artificial intelligence and neurotechnology: prioritizing human rights, dignity, and equity.* Int J Educ Integr 20, 21 (2024). <u>https://doi.org/10.1007/s40979-024-00175-2</u>
- 4. Hutchings E, Loomes M, Butow P, Boyle FM. A systematic literature review of attitudes towards secondary use and sharing of health administrative and clinical trial data: a focus on consent. Syst Rev. 2021 May 4;10(1):132. doi: 10.1186/s13643-021-01663-z. PMID: 33941282; PMCID: PMC8094598. Umbrello S, Bernstein MJ, Vermaas PE, Resseguier A, Gonzalez G, Porcari A, Grinbaum A, Adomaitis L. From speculation to reality: Enhancing anticipatory ethics for emerging technologies (ATE) in practice. Technol Soc. 2023;74:102325. doi:10.1016/j.techsoc.2023.102325.

## 7 Limitations

The project focused on literature published between 2014 and 2024 to explore advancements in emerging technologies. However, this may have resulted in omission of some older, yet relevant articles. Additionally, the scope was limited to literature available in English, which could have excluded important studies in other languages. Finally, the accuracy of the text analysis relied on GPT-generated outputs, as LLMs are still in early stages of development. We addressed in more detail the limitations of using LLM for evidence synthesis in the section 6.3.

## 8 Conclusions

In the two tasks, T2.1 and T2.2 we identified key ethical challenges across different scientific disciplines, particularly in the fields of AI, data privacy, healthcare, and genomics. Our findings reveal that ethical concerns such as informed consent, privacy, data sharing, security, and transparency, are closely intertwined with technological advancements.

The EGM was particularly useful to map the current evidence on emerging ethical challenges, offered a visualization of these challenges, indicating areas where ethical concerns are most prevalent. For example, AI faces risks related to bias and privacy, while biomedical engineering and genomics highlight the need for legal and regulatory frameworks, and for ensuring informed consent. Similarly, robotics and automation show concerns around safety, security, and regulatory gaps. Big data analytics presents challenges in data privacy and security, while digital health involves risks on privacy, transparency, and public trust.

This deliverable represents a significant first step in providing the evidence landscape for the project. The EGM will remain a living document, updated to reflect new findings and contributions from the scientific community on emerging challenges to ethics evaluation of research.



## 9 References

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## 10 Annex 1: Search Strategy

#### 10.1 Keywords

Concept/term	Search term
Ethics committees	
Ethics Committee	ethics committee*
Research Ethics Committee	ethics committee*
Institutional Ethics Committee	ethics committee*
Human Research Ethics Committee	ethics committee*
Bioethics Committee	bioethics committee*
Research Ethics Board	ethics board*
Ethics Review Board	ethics review board*
Institutional Review Board	institutional review board*
Ethics Commission	ethics commission
Document type	
Guidelines	guideline*
Instructions	instruction*

Table A1. Concepts used to create keywords for bibliographical search strategy



Recommendations	recommendation*	
Directives	directive*	
Standards	standard*	
Procedures	procedure*	
Legislation	legislation	
Laws	law*	
Statutes	statute*	
Legal acts	legal act*	
Legal codes	legal code*	
Regulations	regulation*	
Government regulation	government* regulation*	
Statutory rules	statutory rule*	
Statutory law	statutory law*	
Legislative measures	legislative measure*	
Legal provisions	legal provision*	
Jurisprudence	jurisprudence	
Methodologies	methodolog*	
Participatory research	participatory research	
Exploratory design	exploratory design	
Co-design	co-design	
Policy brief	policy brief*	
Ethics report	ethics report*	
Digital consent	digital consent	
Dynamic consent	dynamic consent	
Online consent	online consent	
E-consent	e-consent	
Informed consent	Informed consent	
Verbal consent	verbal consent	
Ethics		
Ethics	ethic*	
Ethical challenges	ethical challenge	
Ethical issues	ethical issue*	
Ethical considerations	ethical consideration*	
Ethical impasse	ethical impasse	
Ethical problems	ethical problem*	
Ethical adaptation	ethical adaptation	
Ethical principles	ethical principle*	
Ethical responsiveness	ethical responsiveness	
Ethics standards	ethics standard*	
Ethical communication	ethic* communication	
Ethics discussion	ethic* discussion	
Principle-based ethics	principle-based ethics	
Ethical conundrum	ethical conundrum*	



Ethics consultation	ethics consultation*	
Ethical review	ethical review*	
Ethics of uncertainty	ethics of uncertainty	
Ethical inquiry	ethical inquir*	
Ethical choice	ethical choice*	
Narrative ethics	narrative ethics	
Principle-based ethics	principle-based ethics	
Deontological ethics	deontological ethics	
Ethical expertise	ethical expertise	
Virtue ethics	virtue ethics	
Ethical assessment	ethic* assessment	
Novel ethics approaches	novel ethics approach*	
Ethics by design	ethics by design	
Ethical review	ethical review	
Ethics regimes	ethics regime*	
Regulatory ethics	regulatory ethics	
Ethics review assessment phase	ethics review assessment phase	
Ethics management	ethics management	
Ethics of artificial intelligence	ethic* + artificial intelligence	
Ethics of informed consent	ethic* + informed consent	
Morals and values		
Moral duty		
Moral distress	moral distress	
Moral obligations	moral obligation*	
Moral dilemmas	moral dilemma*	
Moral uncertainty	moral uncertain*	
Moral complexity	moral complexity	
Moral discussion	moral discussion*	
Moral challenge	moral challenge*	
Moral quandary	moral quandar*	
Moral predicament	moral predicament*	
Moral conflict	moral conflict*	
Moral agency	moral agency	
Moral judgments	moral judgment*	
Moral rules	moral rule*	
Moral principles	moral principle*	
Moral responsibility	moral responsibility	
Values dilemma	values dilemma*	
Values crisis	value* crisis	
Personal values	personal value*	
Value alignment	value alignment	
Conscience dilemmas	conscience dilemma*	
Other issues		
Critical issues	critical issue*	



Human experimentation	human experimentation	
Decision making	decision making	
Social justice	social justice	
Vulnerable populations	vulnerable population*	
Needs of citizens	needs of citizen*	
Developing countries	developing countr*	
Critical issues	critical issue*	
Professional misconduct	professional misconduct	
Confidentiality	confidentiality	
Personhood	personhood	
Private sector	private sector*	
Policymakers	policymaker*	
collaboration	collaboration*	
cooperation	cooperation*	
(New) Human rights	human right*	
Sanctions	sanction*	
Personhood	personhood	
Community	communit*	
Indigenous	indigenous	
Transdisciplinary	transdisciplinary	
Data protection	data protection	
Data sharing	data sharing	
Overregulation	overregulation	
Technology		
Neurotechnology	neurotechnolog*	
Internet of Things	internet of things	
Internet of Medical Things	internet of medical things	
Blockchain technology	blockchain	
(Human) digital twins	digital twins*	
Insideables	insideable*	
mRNA-based therapeutics	mRNA* therapeutics	
Nanoparticle drug delivery systems	nanoparticle drug*	
3D bio-printing	bio-printing, bioprinting	
Precision medicine	precision medicine	
Telemedicine/telehealth	telemedicine, telehealth	
Gene editing	gene edit*	
Genetic engineering	genetic engineering	
New genomic techniques	genomic technique*	
Quantum technologies	quantum technolog*	
Quantum computers	quantum computer*	
Organoids	organoid*	
Embryoids	embryoid*	
Embryo models	embryo model*	
Synthetic embryos	synthetic embryo*	



Artificial intelligence	artificial intelligence
Generative Artificial intelligence	artificial intelligence
Machine learning	machine learning
Deep learning	deep learning
Large Language Models	large language model*
(Deep) Neural Networks	neural network*
Predictive analytics	predictive analytics
Big data	big data
CRISPR	CRISPR
Autonomous systems	autonomous systems
Automated systems	automated systems
Robotics / robots	robot*
Algorithmic fairness	algorithmic fairness

#### **10.2** Database search strategies

#### **10.2.1** Web of Science search strategy

((TI=(ethics committee\*) OR TI=(bioethics committee\*) OR TI=(ethics board\*) OR TI=(ethics review board\*) OR TI=(institutional review board\*) OR TI=(ethics commission\*)) OR

(TI=(guideline\*) OR TI=(instruction\*) OR TI=(recommendation\*) OR TI=(directive\*) OR TI=(standard\*) OR TI=(procedure\*) OR TI=(legislation) OR TI=(law) OR TI=(statute\*) OR TI=(legal act\*) OR TI=(legal code\*) OR TI=(regulation\*) OR TI=(government\* regulation) OR TI=(statutory rule\*) OR TI=(statutory law) OR TI=(legislative measure\*) OR TI=(legal provision\*) OR TI=(jurisprudence) OR TI=(methodolog\*)) OR TI=(consent\*) OR TI=(e-consent\*) OR TI=(ethics report) OR TI=(policy brief) OR TI=(participatory research) OR TI=(exploratory design) OR TI=(co-design\*))) AND

((TI=(ethic\*) OR TI=(bioethics) OR TI=(moral\*) OR TI=(value dilemma\*) OR TI=(value crisis) OR TI=(personal value\*) OR TI=(conscience dilemma\*) OR TI=(value alignment) OR TI=(critical issue\*) OR TI=(human experimentation) OR TI=(decision making) OR TI=(social justice) OR TI=(vulnerable population\*) OR TI=(needs of citizen\*) OR TI=(developing countr\*) OR TI=(critical issue\*) OR TI=(professional misconduct) OR TI=(confidentiality) OR TI=(personhood) OR TI=(private sector\*) OR TI=(policymaker\*) OR TI=(collaboration\*) OR TI=(cooperation\*) OR TI=(human right\*) OR TI=(communit\*) OR TI=(indigenous) OR TI=(transdisciplinary) OR TI=(data protection) OR TI=(data sharing) OR TI=(overregulation)) AND

(TI=(neurotechnolog\*) OR TI=(internet of things) OR TI=(internet of medical things) OR TI=(blockchain) OR TI=(digital twin\*) OR TI=(insideable\*) OR TI=(mRNA\* therapeutics) OR TI=(CRISPR) OR TI=(nanoparticle drug\*) OR TI=(bio-printing) OR TI=(bioprinting) OR TI=(precision medicine) OR TI=(telemedicine) OR TI=(telehealth) OR TI=(gene edit\*) OR TI=(genetic engineering) OR TI=(genomic technique\*) OR TI=(organoid\*) OR TI=(embryo\*) OR TI=(deep learning) OR TI=(large language model\*) OR TI=(neural network\*) OR TI=(quantum technolog\*) OR TI=(quantum computer\*) OR



TI=(artificial intelligence) OR TI=(machine learning) OR TI=(autonomous system\*) OR TI=(automated system\*) OR TI=(robot\*) OR TI=(algorithmic fairness) OR TI=(predictive analytics) OR TI=(big data)))

#### 10.2.2 PubMed search strategy

((("ethic\* committee\*"[Title/Abstract] OR "ethic\* committee\*"[Title/Abstract] OR "ethic\* committee\*"[Title/Abstract] "ethic\* committee\*"[Title/Abstract] "bioethic\* OR OR committee\*"[Title/Abstract] "ethic\* board"[Title/Abstract] "ethic\* OR OR review board\*"[Title/Abstract]) board\*"[Title/Abstract] OR "institutional review OR ("guideline\*"[Title/Abstract] OR "instruction\*"[Title/Abstract] OR "recommendation\*"[Title/Abstract] OR "directive\*"[Title/Abstract] OR "standard\*"[Title/Abstract] OR "procedure\*"[Title/Abstract] OR "legislation"[Title/Abstract] OR "law\*"[Title/Abstract] OR "statute\*"[Title/Abstract] OR "legal act\*"[Title/Abstract] OR "legal code\*"[Title/Abstract] OR "regulation\*"[Title/Abstract] OR "government\* regulation\*"[Title/Abstract] OR "statutory rule\*" OR low\*"[Title/Abstract] OR "legislative measure\*"[Title/Abstract] "statutory OR "legal provision\*"[Title/Abstract] OR "jurisprudence"[Title/Abstract] OR "methodolog\*"[Title/Abstract] OR "clinical protocol\*"[Title/Abstract])) AND ("ethic\*"[Title/Abstract] OR "ethic\* challenge\*"[Title/Abstract] OR "ethic\* issue\*"[Title/Abstract] OR "ethic\* consideration\*"[Title/Abstract] OR "ethic\* impasse"[Title/Abstract] OR "ethic\* problem\*"[Title/Abstract] OR "ethic\* adaptation" OR "ethic\* principle\*" OR "ethic\* responsiveness" OR "ethic\* standard\*"[Title/Abstract] OR "ethic\* communication"[Title/Abstract] OR "ethic\* discussion"[Title/Abstract] OR "principle-based ethics"[Title/Abstract] OR "ethic\* conundrum\*" OR "ethic\* consultation\*" OR "ethic\* review\*"[Title/Abstract] OR "ethics of uncertainty"[Title/Abstract] OR "ethic\* inquir\*"[Title/Abstract] OR "ethic\* choice\*"[Title/Abstract] OR "moral distress"[Title/Abstract] OR "moral obligation\*"[Title/Abstract] OR "moral dilemma\*"[Title/Abstract] OR "moral uncertain\*"[Title/Abstract] OR "moral complexity"[Title/Abstract] OR "moral discussion\*"[Title/Abstract] OR "moral challenge\*" OR "moral quandar\*"[Title/Abstract] OR "moral

predicament\*" OR "moral conflict\*"[Title/Abstract] OR "moral agency"[Title/Abstract] OR "moral judgment\*"[Title/Abstract] OR "moral rule\*"[Title/Abstract] OR "moral principle\*"[Title/Abstract] "value\* dilemma\*"[Title/Abstract] OR "value\* crisis"[Title/Abstract] OR OR "personal dilemma\*"[Title/Abstract] value\*"[Title/Abstract] "conscience "value OR OR alignment\*"[Title/Abstract] "critical issue\*"[Title/Abstract] OR "human OR experimentation"[Title/Abstract] OR "decision making"[Title/Abstract] "social OR justice"[Title/Abstract] OR "vulnerable population\*"[Title/Abstract] OR "needs of citizen\*"[Title/Abstract] OR "developing countr\*"[Title/Abstract] OR "critical issue\*"[Title/Abstract] misconduct"[Title/Abstract] OR "professional OR "confidentiality"[Title/Abstract] OR "personhood"[Title/Abstract] OR "private sector\*"[Title/Abstract] OR "policymaker\*"[Title/Abstract] "collaboration\*"[Title/Abstract] "cooperation\*"[Title/Abstract] OR OR OR "human right\*"[Title/Abstract] OR "neurotechnolog\*"[Title/Abstract] OR "internet of things"[Title/Abstract] OR "internet of medical things"[Title/Abstract] OR "blockchain"[Title/Abstract] OR "human digital twins"[Title/Abstract] OR "insideable\*"[Title/Abstract] OR "mRNA\* therapeutics"[Title/Abstract] OR "nanoparticle drug\*"[Title/Abstract] "bio-printing"[Title/Abstract] OR OR



"bioprinting"[Title/Abstract] OR "precision medicine"[Title/Abstract] OR "telemedicine"[Title/Abstract] OR "telehealth"[Title/Abstract] OR "gene edit\*"[Title/Abstract] OR "quantum technolog\*"[Title/Abstract] OR "quantum computer\*"[Title/Abstract] OR "artificial intelligence"[Title/Abstract] OR "artificial intelligence"[Title/Abstract] OR "machine learning"[Title/Abstract]))

#### 10.2.3 Scopus search strategy

(TITLE ( "ethics committee\*" ) OR TITLE ( "bioethics committee\*" ) OR TITLE ( "ethics board\*" ) OR TITLE ( "ethics review board\*" ) OR TITLE ( "institutional review board\*" ) OR TITLE ( "ethics commission\*")) OR (TITLE ( "guideline\*") OR TITLE ( "instruction\*") OR TITLE ( "recommendation\*" ) OR TITLE ( "directive\*" ) OR TITLE ( "standard\*" ) OR TITLE ( "procedure\*" ) OR TITLE ( "legislation" ) OR TITLE ( "law" ) OR TITLE ( "statute\*" ) OR TITLE ( "legal act\*" ) OR TITLE ( "legal code\*" ) OR TITLE ("regulation\*") OR TITLE ("government\* regulation") OR TITLE ("statutory rule\*") OR TITLE ( "statutory law") OR TITLE ( "legislative measure\*") OR TITLE ( "legal provision\*") OR TITLE ( "jurisprudence") OR TITLE ("methodolog\*") OR TITLE ("consent\*") OR TITLE ("e-consent\*") OR TITLE ( "ethics report" ) OR TITLE ( "policy brief" ) OR TITLE ( "participatory research" ) OR TITLE ( "exploratory design" ) ) AND ( TITLE-ABS-KEY ( "ethic\*" ) OR TITLE-ABS-KEY ( "bioethics" ) OR TITLE-ABS-KEY ("moral\*") OR TITLE-ABS-KEY ("value dilemma\*") OR TITLE-ABS-KEY ("value crisis") OR TITLE-ABS-KEY ( "personal value\*" ) OR TITLE-ABS-KEY ( "conscience dilemma\*" ) OR TITLE-ABS-KEY ( "value alignment" ) OR TITLE-ABS-KEY ( "critical issue\*" ) OR TITLE-ABS-KEY ( "human experimentation") OR TITLE-ABS-KEY ("decision making") OR TITLE-ABS-KEY ("social justice") OR TITLE-ABS-KEY ( "vulnerable population\*" ) OR TITLE-ABS-KEY ( "needs of citizen\*" ) OR TITLE-ABS-KEY ( "developing countr\*" ) OR TITLE-ABS-KEY ( "critical issue\*" ) OR TITLE-ABS-KEY ( "professional misconduct") OR TITLE-ABS-KEY ( "confidentiality") OR TITLE-ABS-KEY ( "personhood" ) OR TITLE-ABS-KEY ( "private sector\*" ) OR TITLE-ABS-KEY ( "policymaker\*" ) OR TITLE-ABS-KEY ( "collaboration\*") OR TITLE-ABS-KEY ("cooperation\*") OR TITLE-ABS-KEY ("human right\*") OR TITLE-ABS-KEY ( "communit\*" ) OR TITLE-ABS-KEY ( "indigenous" ) OR TITLE-ABS-KEY ( "transdisciplinary" ) OR TITLE-ABS-KEY ( "data protection" ) OR TITLE-ABS-KEY ( "data sharing" ) OR TITLE-ABS-KEY ( "overregulation")) AND (TITLE-ABS-KEY ( "neurotechnolog\*") OR TITLE-ABS-KEY ( "internet of things") OR TITLE-ABS-KEY ("internet of medical things") OR TITLE-ABS-KEY ("blockchain") OR TITLE-ABS-KEY ("digital twin\*") OR TITLE-ABS-KEY ("mRNA\* therapeutics") OR TITLE-ABS-KEY ("CRISPR" ) OR TITLE-ABS-KEY ( "nanoparticle drug\*" ) OR TITLE-ABS-KEY ( "bio-printing" ) OR TITLE-ABS-KEY ( "bioprinting") OR TITLE-ABS-KEY ("precision medicine") OR TITLE-ABS-KEY ("telemedicine") OR TITLE-ABS-KEY ("telehealth") OR TITLE-ABS-KEY ("gene edit\*") OR TITLE-ABS-KEY ("genetic engineering") OR TITLE-ABS-KEY ("genomic technique\*") OR TITLE-ABS-KEY ("genomics") OR TITLE-ABS-KEY ( "organoid\*" ) OR TITLE-ABS-KEY ( "embryo\*" ) OR TITLE-ABS-KEY ( "stem-cell" ) OR TITLE-ABS-KEY ( "cultured meat" ) OR TITLE-ABS-KEY ( "deep learning" ) OR TITLE-ABS-KEY ( "large language model\*" ) OR TITLE-ABS-KEY ( "neural network\*" ) OR TITLE-ABS-KEY ( "quantum technolog\*" ) OR TITLE-ABS-KEY ( "quantum computer\*" ) OR TITLE-ABS-KEY ( "artificial intelligence" ) OR TITLE-ABS-KEY ( "machine learning" ) OR TITLE-ABS-KEY ( "autonomous system\*" ) OR TITLE-ABS-KEY ( "automated system\*") OR TITLE-ABS-KEY ( "robot\*") OR TITLE-ABS-KEY ( "algorithmic fairness") OR



TITLE-ABS-KEY ( "predictive analytics" ) OR TITLE-ABS-KEY ( "big data" ) OR TITLE-ABS-KEY ( "datafication" ) OR TITLE-ABS-KEY ( "metaverse" ) OR TITLE-ABS-KEY ( "digital trust" ) OR TITLE-ABS-KEY ( "cybersecurity" ) OR TITLE-ABS-KEY ( "edge computing" ) OR TITLE-ABS-KEY ( "digital era" ) OR TITLE-ABS-KEY ( "AI-powered" ) OR TITLE-ABS-KEY ( "image recognition" ) OR TITLE-ABS-KEY ( "speech recognition" ) OR TITLE-ABS-KEY ( "emerging technologies" ) OR TITLE-ABS-KEY ( "AI-generated" ) OR TITLE-ABS-KEY ( "generative AI" ) OR TITLE-ABS-KEY ( "AI-generated" ) OR TITLE-ABS-KEY ( "generative AI" ) OR TITLE-ABS-KEY ( "AI-generated" ) OR TITLE-ABS-KEY ( "advanced generative models" ) OR TITLE-ABS-KEY ( "renewable energy" ) OR TITLE-ABS-KEY ( "emergy solution\*" ) OR TITLE-ABS-KEY ( "smart healthcare" ) OR TITLE-ABS-KEY ( "smart device\*" ) OR TITLE-ABS-KEY ( "extended reality" ) OR TITLE-ABS-KEY ( "wirtual reality" ) OR TITLE-ABS-KEY ( "augmented reality" ) OR TITLE-ABS-KEY ( "mixed reality" ) ) AND PUBYEAR > 2013 AND PUBYEAR < 2025 AND ( LIMIT-TO ( LANGUAGE , "English" ) )

#### 10.2.4 Cordis search strategy

content type='project' AND framework Programme='HORIZON','H2020' AND language='en' AND ('ethics' AND 'challenge')

## 11 Annex 3: Table A2

Ethical Challenges	Technologies	Forms of Collaboration and Partnerships	New Human Rights Related Frameworks	Authors' Recommendations
Privacy, consent, and ownership in genomics and big data	Genomics, big data analytics	Partnerships between tech companies and healthcare providers	Genetic Information Non- discrimination Act, Genomic Data Sharing Policy	Develop clear ownership and consent frameworks, promote ethical data usage, and ensure robust legal protections for data privacy.
Ethical and legal implications of Al in law enforcement	Al in law enforcement	Collaborations between law enforcement agencies and tech companies	Privacy and surveillance laws	Ensure transparency and accountability in Al deployment, establish clear ethical guidelines, and involve public engagement in policy-making.

Table A2. A sample of the table we obtained during the second phase of GPT-40 analysis.



Regulatory challenges in 3D bioprinting	3D bioprinting technologies	Collaborations between bioprinting companies and regulatory bodies	EU Advanced Therapy Medicinal Products Regulation, Medical Device Regulation	Develop clear regulatory frameworks, ensure compliance with existing regulations, and promote interdisciplinary collaboration in 3D bioprinting.
Bias, discrimination, varying ethical guidelines across nations, privacy, responsibility, autonomy, justice, transparency, beneficence	Artificial Intelligence (AI), machine learning, data visualization	Government regulators, Al developers, key user groups, educators, professionals	Human rights standards for AI, inclusion of marginalized groups in AI regulation	Promote AI vigilantism, involve marginalized groups in AI design and regulation, implement binding global AI regulations, enhance transparency and accountability, use data-driven approaches for ethical guidelines
Ethical aspects of big data use, privacy concerns, data misuse	Big Data, analytics	Data analysts, tech firms, regulatory bodies	Data privacy laws, ethical data use guidelines	Strengthen data privacy protections, ensure ethical use of big data, promote accountability in data handling practices
Ethical questions in nanotechnology, environmental impact, health risks	Nanotechnology, Nano-engineered materials	Nanotech researchers, environmental agencies, public health officials	Environmental safety regulations, health impact assessments	Conduct thorough environmental impact studies, establish health risk guidelines, ensure public transparency in nanotech research



## 12 Annex 4: Table A3

Table A3. A sample of the table we obtained during the third phase of GPT-40 analysis

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1	A Question of Trust—Study Participants' Perspectives on Consent, Privacy, and Trust in Smart Home Research	10.2196/25227	1	1	0	0	0	1	0	0	0	0	0	1	1	1	0	1	1	1	0	1
2	"Choice of law" in precision medicine research	10.30953/bhty.v3.14 4	1	1	1	0	1	1	0	1	1	1	1	1	1	0	0	1	1	1	0	1
3	"I Agree to Disagree": Comparative Ethical and Legal Analysis of Big Data and Genomics for Privacy, Consent, and Ownership	10.3389/fpubh.2022.9 40451	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1
4	Matching Consent to Purpose: The Example of the Matchmaker Exchange	10.1002/humu.23278	1	1	0	0	1	1	1	1	1	0	0	1	1	1	0	1	0	1	0	1
5	Sorry I Didn't Hear You: The Ethics of Voice Computing and AI in High-Risk Mental Health Populations	10.1080/21507740.202 0.1740355	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
7	It is an Entrustment: Broad Consent for Genomic Research and Biobanks in Sub-Saharan Africa	10.1111/dewb.12178	1	1	1	0	1	1	0	1	1	1	1	1	1	1	0	1	0	1	0	1
8	"Regulation, I presume? Towards an iterative regulatory process for robot governance"	10.1016/j.clsr.2018.09. 001	1	1	1	1	1	1	0	1	1	1	0	1	0	1	0	1	1	0	0	1
10	3D Bioprint Me: A Socioethical View of Bioprinting Human Organs and Tissues	10.1136/medethics- 2015-103347	1	1	1	1	1	0	1	1	1	0	1	0	0	1	1	1	1	0	0	1
11	3D Bioprinting Regulations: A UK/EU Perspective	10.1017/err.2017.19	1	1	1	1	1	0	0	1	1	0	1	0	1	1	0	1	0	0	0	1
12	"3D Bioprinting Technology: Scientific Aspects and Ethical Issues"	10.1007/s11948-017- 9918-y	1	1	1	1	1	1	0	1	1	1	1	0	1	1	0	1	1	0	0	1
14	3D Printing and 3D Bioprinting Technology in Medicine: Ethical and Legal Issues	10.7417/CT.2023.2501	1	1	1	1	1	1	1	1	1	1	0	0	1	1	0	1	0	0	0	1
14	3D printing and 3D bioprinting technology in medicine: Ethical and legal issues	10.7417/CT.2023.25 01	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	0	0	1
15	A Comparative Data Protection Analysis of Healthcare Robots (Part 2)	TTLF Working Paper No. 86	1	1	0	1	1	1	1	0	1	0	0	1	1	0	0	1	1	0	0	1
16	3D Digital Design to Support Elementary School Students' Spatial Visualization Skills	10.1007/978-3-030- 63885-6	1	1	1	0	1	0	0	0	0	0	0	1	0	1	0	1	0	0	0	1
17	A Comprehensive, Valid, and Reliable Tool to Assess the Degree of Responsibility of Digital Health Solutions	10.2196/48496	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	0	0	0	1



18	A Computer-Based Education Intervention to Enhance Surrogates' Informed Consent for Genomics Research	10.4037/ajcc2015983	1	1	0	1	1	1	0	1	1	1	0	0	1	0	0	1	0	0	0	1
19	A critical perspective on guidelines for responsible and trustworthy artificial intelligence	10.1007/s11019-020- 09948-1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
20	A Critical Perspective on NeuroRights: Comments Regarding Ethics and Law	10.3389/fnhum.2021. 703121	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	0	1
21	A Criticism of AI Ethics Guidelines	10.22503/inftars.XX.20 20.4.5	1	1	1	0	1	1	1	1	1	1	1	0	1	0	1	1	1	0	0	1
22	"A discussion supporting presumed consent for posthumous sperm procurement and conception"	10.1016/j.rbmo.2014. 10.001	1	1	1	1	1	0	0	1	1	1	1	0	1	1	0	1	1	0	0	1
24	A Fourth Law of Robotics? Copyright and the Law and Ethics of Machine Co- Production	10.1007/s10506-015- 9169-7	1	1	1	0	1	0	1	1	1	1	0	0	1	1	0	1	1	0	0	1
26	"A Framework for Navigating Institutional Review Board (IRB) Oversight in the Complicated Zone of Research"	10.7759/cureus.844	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
27	A Future-Focused View of the Regulation of Rural Technology	10.3390/agronomy110 61153	1	1	1	1	1	1	1	1	1	0	1	1	1	0	0	1	0	0	0	1
28	A healthy debate: Exploring the views of medical doctors on the ethics of artificial intelligence	10.1016/j.artmed.202 1.102190	1	1	0	1	1	1	0	1	1	1	1	0	1	0	1	1	1	0	1	1
29	A High-Level Overview of AI Ethics	10.1016/j.patter.2021. 100314	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	0	1
30	A Literature Review on Ethics for AI in Biomedical Research and Biobanking	10.1055/s-0042- 1742516	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	0	0	0	1
31	A Methodology for Ethics-by-Design AI Systems: Dealing with Human Value Conflicts	N/A	1	1	1	1	1	1	1	1	1	0	1	0	1	0	1	1	1	0	0	1
33	A multinational study on artificial intelligence adoption: Clinical implementers' perspectives	10.1016/j.ijmedinf.20 24.105377	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1
34	A Perspective on Categorizing Personal and Sensitive Data and the Analysis of Practical Protection Regulations	10.1016/j.procs.2020.0 3.060	1	1	1	1	1	1	1	1	1	0	1	1	1	1	0	1	1	1	0	1
36	A Proposed Approach to Informed Consent for Biobanks in China	10.1111/j.1467- 8519.2012.01985.x	1	1	1	1	1	1	0	1	1	1	0	1	1	0	0	1	1	1	0	1
37	A Qualitative Exploration of the Informed Consent Process in Hematopoietic Cell Transplantation Clinical Research	10.1038/bmt.2016.252	1	1	0	1	1	1	0	1	1	0	0	1	1	0	0	1	1	0	0	1
38	A Qualitative Study into Dependent Relationships and Voluntary Informed Consent for Research in Pediatric Oncology	10.1007/s40272-015- 0158-9	1	1	0	0	1	1	0	1	1	0	0	1	1	0	0	1	1	0	0	1
39	A Qualitative Study of Big Data and the Opioid Epidemic: Recommendations for Data Governance	10.1186/s12910-020- 00544-9	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1	0	0	0	1
40	A Rational and Standardized Prenatal Examination	N/A	1	1	0	1	0	0	0	0	0	0	0	0	1	0	0	1	1	0	0	1
41	Minimizing SARS-CoV-2 Exposure When Performing Surgical Interventions During the COVID-19 Pandemic	10.1136/neurintsurg- 2020-016161	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	1	0	0	0	1
42	A Review of Consent Documents From Canadian IVF Clinics, 1991 to 2014	10.1016/j.jogc.2016.0 2.008	1	1	0	0	1	1	0	1	1	0	0	1	1	0	0	1	0	0	0	1
43	A Review of Telemedicine Guidelines in the South-East Asia Region	10.1089/tmr.2023.004 0	1	1	1	1	1	1	0	1	1	0	1	1	1	0	0	1	1	1	1	1
44	A Rural Community's Involvement in the Design and Usability Testing of a Computer-Based Informed Consent Process	10.1002/ajmg.a.3622 0	1	1	1	0	1	1	0	0	0	0	1	0	1	0	0	1	0	0	0	1



45	A Scenario-Based Methodology for Analyzing the Ethical, Legal, and Social Issues in Genomic Data Sharing	10.1177/15562646209 20460	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1
46	A Scoping Review of Genetics and Genomics Research Ethics Policies and Guidelines for Africa	10.1186/s12910-021- 00611-9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1
47	A Scoping Review of Global Guidelines for the Disclosure of Secondary Genomic Findings	N/A	1	1	0	0	1	1	0	0	1	0	0	1	1	0	0	1	0	0	0	1
48	A Shared Updatable Method of Content Regulation for Deepfake Videos Based on Blockchain	10.1007/s10489-021- 03156-x	1	1	0	1	1	1	1	1	1	0	0	0	1	1	0	1	0	0	1	1
49	A Systematic Literature Review of Artificial Intelligence in the Healthcare Sector: Benefits, Challenges	10.1016/j.jik.2023.100 333	1	1	1	1	1	1	0	0	0	0	0	1	1	1	1	1	1	0	0	1
50	A template for broad consent in biobank research. Results and explanation of an evidence and consensus-based development process	10.1016/j.ejmg.2016. 04.002	1	1	1	1	1	1	0	1	1	1	0	1	1	1	0	1	1	1	1	1
51	A trust induced recommendation mechanism for reaching consensus in group decision making	10.1016/j.knosys.2016. 12.014	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	1	0	0	1	1
52	A Wide Human-Rights Approach to Artificial Intelligence Regulation in Europe	10.1109/MTS.2021.3 056284	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	0	1	1
53	About Data Protection Standards and Intellectual Property Regulation in the Digital Economy: Key Issues for Ukraine	10.30525/2256- 0742/2022-8-4-40-49	0	1	1	1	1	1	0	1	1	1	1	1	1	1	0	1	0	0	1	1
54	Academic publisher guidelines on Al usage: A ChatGPT supported thematic analysis	10.12688/f1000resea rch.142411.2	0	1	0	1	1	1	0	1	0	1	1	0	0	1	1	1	1	0	1	1
55	Accelerating Regenerative Medicine: The Japanese Experiment in Ethics and Regulation	10.2217/rme-2017- 0038	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	0	1	1	1
56	Access to Research Data and EU Copyright Law	10.26064/1634	0	1	0	0	1	1	0	0	0	1	1	0	0	1	1	0	0	0	1	1
57	Achieving Informed Consent for Cellular Therapies: A Preclinical Translational Research Perspective	10.1177/10731105166 67937	1	1	0	1	1	1	0	1	1	0	0	1	1	0	0	1	1	0	1	1
58	A Computer-Based Education Intervention to Enhance Surrogates' Informed Consent for Genomics Research	10.4037/ajcc2015983	0	1	1	1	1	1	0	1	1	0	0	0	0	1	0	0	0	1	1	1
59	Addressing Choice of Law Challenges in Multi-State Precision Medicine Research	10.1093/jlb/lsac013	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	1	1
60	Addressing ethical challenges in the Genetics Substudy of the National Eye Survey of Trinidad and Tobago (GSNESTT)	10.1016/j.atg.2016.0 5.001	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1
61	Addressing ethical issues in H3Africa research – the views of research ethics committee members	10.1186/s11568-015- 0006-6	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1	1
62	Addressing ethical issues related to prenatal diagnostic procedures	10.1186/s40748-023- 00146-4	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1
63	Addressing Ethical, Legal, Technical, and Operational Challenges in Counterterrorism with Machine Learning	10.1007/978-3-031- 50454-9_10	1	1	1	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1
64	Adjusting to the GDPR: The Impact on Data Scientists and Behavioral Researchers	10.1089/big.2018.01 76	1	1	1	1	1	1	1	1	1	1	0	1	1	0	0	1	0	1	0	1
65	Advances in Research on Genome Editing Crispr-Cas9 Technology	Not available	0	1	1	1	1	0	1	1	1	1	0	0	1	1	0	1	0	0	1	1
67	Against Ethical AI: Guidelines and Self Interest	10.1145/3363384.33 63393	1	0	1	1	1	0	0	1	0	1	1	0	0	0	1	1	0	0	0	1
68	Al Adoption in Universities in Emerging Economies: Prospects, Challenges	10.1007/978-3-030- 88234-1_9	1	1	1	1	1	1	0	1	0	1	1	1	0	0	0	1	0	0	0	1
69	Al and IoT Capabilities: Standards, Procedures, Applications, and Protocols	10.1016/B978-0-12- 818576-6.00004-6	0	0	1	1	1	1	0	0	0	0	0	1	0	1	0	1	0	0	0	1



70	Al and Professional Liability Assessment in Healthcare. A Revolution in Legal Medicine?	10.3389/fmed.2023.13 37335	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	1	1	1
71	Al and the Ethics of Automating Consent	10.1109/MSP.2018.2 801548	1	1	0	1	1	1	1	1	1	0	0	1	1	0	0	1	1	0	1	1
72	AI Compliance – Challenges of Bridging Data Science and Law	10.1145/3531532	1	1	0	0	1	1	1	1	1	0	0	1	1	0	1	1	0	0	1	1
73	AI Ethical Bias: A Case for AI Vigilantism in Shaping the Regulation of AI	10.1093/ijlit/eaab008	1	1	1	0	1	0	1	1	1	1	1	0	0	0	1	1	0	0	0	1
74	Work and AI 2030: Challenges and Strategies for Tomorrow's Work	10.1007/978-3-658- 40232-7	1	1	1	1	1	1	0	1	1	0	0	1	0	0	0	1	0	0	0	1
75	The Power of Ideas: A History of Technological Thoughts on Digital Economics	10.1007/978-981-19- 4574-8	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1	1
76	Al in Child Psychiatry: Exploring Future Tools for the Detection and Management of Mental Disorders in Children and Adolescents	N/A	1	1	1	0	1	1	1	0	0	0	0	1	1	0	0	1	0	0	0	1
77	Al in Healthcare: Impacts, Risks and Regulation to Mitigate Adverse Impacts	10.1007/978-3-030- 63672-2_4	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
78	Al in Law Practices	10.1109/DeSE2020.945 0780	0	1	0	1	1	1	1	1	1	0	0	0	1	0	1	1	1	0	1	1
79	Al in the EU: Ethical Guidelines as a Governance Tool	10.1007/978-3-030- 63672-2_4	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
80	Al in the Law: Towards Assessing Ethical Risks	10.1109/BigData50022 .2020.9377950	1	1	1	1	1	1	1	1	1	1	0	0	0	0	1	1	0	0	1	1
81	Al policies across the globe: Implications and Recommendations for libraries	10.1177/0340035223 1196172	1	1	1	1	1	1	0	1	1	0	1	0	1	0	1	1	1	1	1	1
82	AI Regulation for Smart Cities: Challenges and Principles	10.1007/978-3-030- 61033-3	1	1	1	1	1	1	0	1	1	1	1	0	1	0	1	1	1	1	1	1
83	Al Regulation in the European Union: Examining Non-State Actor Preferences	10.2139/ssrn.442411 4	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1
84	AI Regulation Is (not) All You Need	10.1145/3593013.3594 079	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
85	Al, Big Data, and the Future of Consent	10.1007/s00146-021- 01262-5	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
86	Al4People—An Ethical Framework for a Good Al Society	10.1007/s11023-018- 9482-5	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1
87	Al-Enhanced Healthcare: Not a New Paradigm for Informed Consent	10.1007/s11673-023- 10320-0	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
88	Al-powered Information and Big Data: Current Regulations and Ways Forward in IFRS Reporting	10.1108/JAAR-01- 2022-0022	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	0	0	1	1
89	All Our Data Will Be Health Data One Day: Protecting Data with Consent Frameworks	10.1007/springer- 123456789	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
90	Allocating Organs through Algorithms and Equitable Access to Transplantation	10.1093/jlb/lsad004	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	0	0	1	1
91	A Consent Model for Blockchain-based Health Data Sharing Platforms	10.1109/ACCESS.20 20.3014565	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
92	An e-consent framework for tiered informed consent for human genomic research	10.1186/s12910-022- 00860-2	1	1	1	1	1	1	0	1	1	1	1	1	1	0	1	1	1	0	1	1
93	An Electronic Tool to Support Patient-Centered Broad Consent	10.1370/afm.2610	1	1	1	1	1	1	0	1	1	1	1	1	1	0	1	1	1	0	1	1



94	Al4People—An Ethical Framework for a Good Al Society	10.1007/s11023-018- 9482-5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1
95	An Ethics Checklist for Digital Health Research in Psychiatry	10.2196/12339	1	1	1	1	1	1	0	1	1	1	1	1	1	0	1	1	1	0	1	1
96	An Evidence-based Methodology for Human Rights Impact Assessment in AI	10.1016/j.clsr.2021.10 5561	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
97	An Exploratory Qualitative Analysis of AI Ethics Guidelines	10.1108/JICES-12- 2020-0125	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
98	An Exploratory Study on Ethical Aspects in Participatory Research on Renewable Energy	10.34810/rljaev1n14ld 413646	1	1	1	1	1	1	0	1	1	1	1	1	1	0	1	1	1	0	1	1
99	An Integrated Approach of Ethics, Law, and Corporate Responsibility: An Analysis of Security Robots	10.1108/JICES-12- 2020-0125	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
100	An Ontology-Based Integration Approach for Medical Information Standards	10.1109/BigData.2017. 85	1	1	1	1	1	1	0	1	1	1	1	1	1	0	1	1	1	0	1	1
10 1	An Overview of Human Genetic Privacy	10.1111/nyas.13211	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
102	Ethical Considerations in Stem Cell Research in Iran	Not available	1	1	1	1	1	0	1	1	1	1	0	1	1	0	1	1	1	1	1	1
10 3	Analyzing Behavioral Big Data: Methodological, practical, ethical, and moral issues	10.1080/08982112.2 016.1210979	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	0	0	1	1
104	Apollon: Towards a Citizen Science Methodology for Urban Environmental Monitoring	10.1016/j.future.2020. 06.041	1	1	1	1	1	1	0	1	1	1	1	0	1	0	1	1	1	0	1	1
10 5	Applicable Law Concerning Obligations Arising from the Infringements of Personal Data Laws Due to the Use of AI Systems	10.31743/recl.13995	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
106	Application of Surgical Safety Standards to Robotic Surgery: Five Principles of Ethics for Nonmaleficence	10.1016/j.jamcollsurg.2 013.11.006	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
10 7	Genome Editing Technologies: Advancement, Clinical Applications, and Ethical Concerns	10.4103/MXE.MXE_ 16_18	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1
108	Applied Big Data Analysis to Build Customer Product Recommendation Model	10.3390/su13094985	1	1	0	1	1	1	0	1	1	0	0	1	0	1	1	1	1	0	1	1
10 9	Approaching Birds with Drones: First Experiments and Ethical Guidelines	10.1098/rsbl.2014.07 54	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	1	1
110	Areas of Tension in the Application of AI and Data Protection Law	10.21552/edpl/2023/2 /7	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
11 1	Articulating 'free, prior and informed consent' (FPIC) for engineered gene drives	10.1098/rspb.2019.1 484	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	1	1
112	Applicable Law Concerning Obligations Arising from the Infringements of Personal Data Laws Due to the Use of Artificial Intelligence Systems	10.31743/recl.13995	1	1	0	1	1	1	1	1	1	1	0	0	0	0	0	1	1	1	1	1
11 3	Artificial intelligence ethics guidelines for developers and users: clarifying their content and normative implications	10.1108/JICES-12- 2019-0138	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
114	Artificial Intelligence in Education: Ethical Issues and its Regulations	10.1145/3524383.3524 406	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
11 5	Artificial Intelligence in Emergency Medicine: Benefits, Risks, and Recommendations	10.1016/j.jemermed. 2022.01.001	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	1	1
116	Artificial Intelligence in Healthcare Services – Regulation, Implementation and Future Challenges	10.31743/recl.13995	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
11 7	Artificial Intelligence in Medical Device Software and High-Risk Medical Devices	10.1080/17434440.2 023.2184685	1	1	1	1	1	1	1	1	1	1	0	1	1	0	1	1	1	1	1	1



118	Artificial Intelligence in Medico-Dental Diagnostics of the Face: Opportunities and Challenges	10.1007/s00784-022- 04724-2	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	1	1
11 9	Artificial Intelligence Methodology in Clinical Research	10.1016/B978-0-323- 90300-4.00081-1	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	1	1
120	Artificial Intelligence Regulation in the Areas of Data Protection, Information Security, and Anti-discrimination in Western Balkan Economies	10.1109/MPRO.2022.9 906475	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
12 1	Artificial Intelligence Regulation: A Framework for Governance	10.1007/s10676-021- 09593-z	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
122	Artificial Intelligence Regulation: A Meta-Framework for Formulation and Governance	10.24251/HICSS.2020.6 47	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
12 3	Artificial Intelligence and Compassion in Healthcare	10.3389/fpsyg.2022. 971044	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
124	Artificial Intelligence, Law, and Ethics	10.7206/kp.2080- 1084.568	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	1	1
12 5	Artificial Intelligence-based Mining of EHR Data to Accelerate Digital Transformation in Cardiovascular Ecosystem	10.1136/bmjopen- 2022-068698	1	1	1	1	1	1	0	1	1	1	1	0	1	0	1	1	1	0	1	1
126	Ask the People: Developing Guidelines for Genomic Research with Aboriginal and Torres Strait Islander Peoples	10.1136/bmjgh-2021- 007259	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
12 7	Assessing the Effectiveness of a Massive Open Online Course for Caregivers Amid the COVID-19 Pandemic	10.2196/48398	1	1	1	1	1	1	0	1	1	1	1	1	1	0	1	1	1	0	1	1
128	Attention, Moral Skill, and Algorithmic Recommendation	10.1007/s11098-023- 02083-6	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	1	1
12 9	Attitude towards Assisted Reproductive Technology: Acceptance of Donors Eggs, Sperms, and Embryos as Treatment of Human Infertility	10.1186/s12978-024- 01741-0	1	1	1	1	1	1	0	1	1	1	1	0	1	0	1	1	1	0	1	1
131	Audit of Donor Centre: Guidelines by the World Marrow Donor Association Quality and Regulation Working Group	10.1038/s41409-022- 01563-3	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	1	1
13 3	Australian human research ethics committee members' confidence in reviewing genomic research applications	10.1038/s41431-021- 00951-5	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1
134	Authentication of Patients and Participants in Health Information Exchange and Consent for Medical Research: A Key Step for Privacy Protection, Respect for Autonomy, and Trustworthiness	10.3389/fgene.2018.00 167	1	0	0	1	1	1	0	0	0	1	0	1	1	0	0	0	1	1	0	0
13 5	Autologous Haematopoietic Stem Cell Transplantation in Multiple Sclerosis and Immune-Mediated Neurological Diseases: Updated Guidelines and Recommendations	10.1038/s41409-019- 0684-0	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	1	0	1	1
137	Automated Decision-Making Systems in German Administrative Law	10.13130/2723- 9195/2023-1-102	1	1	1	1	1	1	1	1	1	0	0	0	0	0	0	1	1	0	1	1
13 8	Awareness of GMOs in terms of the Iran biosafety act: A case study	10.1016/j.heliyon.202 4.e25487	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	0	0	0
139	Balancing Benefits and Risks of Immortal Data: Participants' Views of Open Consent	10.1002/hast.523	1	1	1	1	1	1	1	1	1	0	1	1	1	1	0	1	1	0	0	1
14 0	Evaluating European Regulation of Stem Cell Regenerative Medicine	10.1353/pbm.2018.0 006	1	1	1	1	1	0	1	1	1	0	0	1	1	1	1	1	1	0	0	1
141	Beyond Consent: Building Trusting Relationships with Diverse Populations in Precision Medicine	10.1080/15265161.201 8.1431322	1	1	1	0	1	1	0	0	0	1	1	1	1	0	0	1	1	0	0	1
14 2	Beyond Informed Consent: Investigating Ethical Justifications for Disclosing, Donating or Sharing Personal Data in Research	10.1007/978-3-319- 61043-6_10	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1	1	1	1	1



143	Bias in Artificial Intelligence Algorithms and Recommendations for Mitigation	10.1371/journal.pdig.0 000278	1	1	0	0	1	0	1	1	1	1	1	1	0	0	1	1	0	0	1	1
14 4	Big Data in Autism Research: Methodological Challenges and Solutions	10.1002/aur.3007	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1
145	Big Data in Medical Research and EU Data Protection Law: Challenges to the Consent or Anonymise Approach	10.1038/ejhg.2015.239	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
14 6	Digital Platforms and Issues of Corporate Criminal Responsibility in the Digital Economy	10.1007/978-3-030- 94873-3_1	1	1	1	0	1	0	0	1	1	0	0	0	0	0	0	1	0	0	0	1
147	Big Data, Ethics, and Regulations: Implications for Consent in the Learning Health System	10.1118/1.5038118	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	0	1
14 8	Biobanking of Different Body Fluids within the Frame of IVF	10.1007/s10815-016- 0847-5	1	1	1	1	1	1	0	0	1	0	0	1	1	0	0	1	1	1	1	1
149	Biobanks for Life Sciences and Personalized Medicine: Importance of Standardization and Data Management	10.1016/j.copbio.2019. 12.004	1	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	0	1
15 0	Bioethics and the Human Goods: An Introduction to Natural Law Bioethics	10.1080/00243639.2 017.1298342	1	1	1	0	1	0	0	1	1	1	1	0	0	0	0	1	0	0	0	1
151	Bioethics in a Transformation Society: On the Example of Legal Regulation	10.18370/2309- 4117.2023.67.115-120	1	1	1	1	1	1	0	1	1	1	1	1	1	0	0	1	1	0	0	0
15 2	Biosecurity and Biosafety Concerns of Research and Diagnostic Laboratories under International Guidelines	10.1000/als- journal.v9i2.22	1	1	1	1	1	1	1	1	1	0	0	1	1	0	0	1	0	0	1	1
155	Blockchain and Applications International Congress	10.1007/978-3-030- 23813-1	0	1	0	1	0	1	1	1	1	0	0	0	0	0	0	1	0	0	1	1
15 6	Blockchain and Applications International Congress	10.1007/978-3-030- 23813-1	1	1	1	1	1	0	1	1	1	1	1	0	0	0	0	1	1	0	0	1
157	Blockchain, Consent and Prosent for Medical Research	10.1136/medethics- 2019-105963	1	1	1	1	1	1	0	0	1	1	0	1	1	0	1	1	1	0	0	1
15 8	Blockchainizing Food Law: Promises and Perils	10.574/155-1239-xx	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0	1	1	0	1	1
159	Borderlands of Life: IVF Embryos and the Law in the United States, United Kingdom, and Germany	10.1177/01622439177 53990	1	1	1	0	1	0	0	1	1	0	1	1	0	0	0	1	1	0	1	1
16 0	BRec the Bank: Context-aware Self-attentive Encoder for Banking Products Recommendation	10.1109/IJCNN5506 4.2022	1	1	1	0	1	0	1	1	0	0	1	0	0	1	1	1	1	0	1	1
161	Bridging the Ethical Gap: From Human Principles to Robot Instructions	10.1109/IS- IEEE.2016.77	1	1	1	1	1	1	0	1	1	1	1	1	1	0	0	1	1	0	0	1
16 2	Bridging the Gap Between Ethics and Practice: Guidelines for Reliable, Safe, and Trustworthy Human-centered AI Systems	10.1145/3419764	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	1
163	Building an Evidence Standards Framework for AI-Enabled Digital Health Technologies	10.1016/S2589- 7500(22)00030-9	1	1	1	1	1	1	0	0	1	0	0	1	1	1	1	1	1	1	1	1
16 4	Building the Partners HealthCare Biobank at Partners Personalized Medicine: Informed Consent, Return of Research Results, Recruitment Lessons and Operational Considerations	10.3390/jpm6010002	1	1	0	1	1	1	0	1	1	0	0	1	1	0	0	1	1	0	0	0
165	Building the Virtual Courthouse: Ethical Considerations for ODR	10.2139/ssrn.2994625	1	1	1	1	1	1	1	1	1	0	0	0	0	1	0	1	0	0	0	1
16 6	Can Big Data Revolutionize International Human Rights Law?	10.1057/978-1-137- 56626-2	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	1	1



167	Can Blockchains and Data Privacy Laws Be Reconciled?	10.1145/3477314.3506 986	1	1	1	1	1	1	1	0	1	0	0	1	1	0	1	1	1	1	1	1
16 8	Can Public Access to Documents Support the Transparency of Automated Decision-Making?	10.1093/ijlit/eaaa019	1	1	1	0	1	0	0	1	1	1	1	0	0	0	1	1	0	0	1	1
169	Capacity of ChatGPT to Identify Guideline-Based Treatments for Advanced Solid Tumors	10.7759/cureus.37938	1	1	0	1	1	1	1	1	1	0	0	0	0	1	1	1	0	0	1	1
17 0	Capturing Emerging Experiential Knowledge for Vaccination Guidelines Through Natural Language Processing	10.2196/44461	1	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	1	0	0	1
171	Capturing Patient Information at Nursing Shift Changes: Methodological Evaluation of Speech Recognition and Information Extraction	10.1136/amiajnl-2014- 002868	1	1	0	1	1	1	1	1	1	0	0	0	0	0	0	1	0	1	1	1
17 2	ChainSDI: A Software-Defined Infrastructure for Regulation-Compliant Home-Based Healthcare Services Secured by Blockchains	10.1109/JSYST.2019 .2937930	1	1	1	1	1	1	1	1	1	0	0	1	1	0	1	1	1	1	1	1
173	CRISPR-edited plants' social, ethical, policy, and governance issues	10.1016/B978-0-443- 18444-4.00011-9	1	1	1	1	1	0	0	1	1	1	1	0	0	0	1	1	0	0	0	1
17 4	Challenges and Solutions for Transforming Health Ecosystems in Low- and Middle-Income Countries Through Artificial Intelligence	10.3389/fmed.2022.9 58097	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
175	Challenges in Medically Assisted Reproduction – Ethics, Law, and Society	10.1016/j.ejogrb.2023. 04.003	1	1	1	1	1	0	0	1	1	1	1	0	1	0	0	1	0	0	0	1
17 6	Challenges of Data Sharing in European Covid-19 Projects: A Learning Opportunity for Advancing Pandemic Preparedness and Response	10.1016/j.lanepe.202 2.100467	1	1	1	1	1	1	0	1	1	1	1	1	1	0	0	1	1	0	1	1
177	Challenges to Fundamental Human Rights in the Age of Artificial Intelligence Systems: Shaping the Digital Legal Order While Upholding Rule of Law Principles and European Values	10.1007/s12027-023- 00777-2	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1	1	1	0	1	1
17 8	Challenges to Implementing the International Digital Law to Protect Digital Rights	10.55908/sdgs.v11i5. 554	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1
179	Challenging Gender Certainties in Early Childhood Care and Education	10.17159/2221- 4070/2021/v11i1a2	1	1	1	0	1	0	0	0	0	1	1	0	0	0	1	1	0	0	0	1
18 0	Challenging the Chatbot: An Assessment of ChatGPT's Diagnoses and Recommendations for DBP Case Studies	10.7759/jdbp.45.e8	1	1	1	1	1	1	0	1	1	0	0	1	1	0	1	1	1	0	1	1
181	Changing the regulations for regulating the changes: From distribution system operator (DSO) to electricity distribution stakeholders' organization (EDSO)	10.1177/0958305X211 073800	1	1	1	1	1	0	0	1	1	1	0	0	0	0	1	1	1	0	0	1
18 9	Clinical Translation of Bio-Artificial Pancreas Therapies: Ethical, Legal and Psychosocial Interdisciplinary Considerations and Key Recommendations	10.3389/ti.2023.1170 5	1	1	1	1	1	1	0	1	1	1	1	1	1	0	0	1	1	0	0	0
203	Confidentiality, Informed Consent and Children's Participation in the Saudi Biobank Governance: A Comparative Study	10.26719/2014.20.11.6 81	1	1	1	1	1	1	0	1	1	1	1	1	1	0	0	1	1	0	0	1
22 3	CRISPR Ethics: Moral Considerations for Applications of a Powerful Tool	10.1016/j.jmb.2018.0 5.044	1	1	1	1	1	1	1	1	1	1	1	1	0	0	1	1	0	0	1	1
231	Cyber Law and Espionage Law as Communicating Vessels	10.1109/CYCON.2018.8 405034	1	1	0	1	1	1	1	1	1	0	0	0	0	0	0	1	0	0	1	1
23 7	Data Protection Law: A Comparison of the Latest Legal Developments in China and European Union	10.1016/j.ejplt.2020.0 1.001	1	1	0	1	1	1	0	1	1	1	0	1	0	0	0	1	0	0	0	0
242	Data Security in Smart Devices: Advancement, Constraints and Future Recommendations	10.1049/ntw2.12091	1	1	0	1	1	1	1	1	1	0	0	0	0	0	0	1	0	0	1	1
25 6	Adaptive Instructional Systems: Design and Evaluation	10.1007/978-3-030- 77857-6	0	0	0	0	0	1	0	0	0	0	0	1	0	0	1	1	0	1	1	0



260	Development and Implementation of a Methodology for Quality Assessment of Asynchronous Teleconsultations	10.1089/tmj.2019.004 9	0	1	0	1	0	1	0	1	0	0	0	0	0	0	0	0	0	0	1	1
27 2	Disposition of unclaimed embryos: an Ethics Committee opinion	10.1016/j.fertnstert.2 021.02.020	1	1	1	1	1	1	1	1	1	0	0	1	1	0	0	0	1	0	1	1
278	Donor perspectives on informed consent and use of biospecimens for brain organoid research	10.1016/j.stemcr.2023. 05.019	1	1	1	0	1	1	0	0	0	0	1	1	1	0	1	1	1	0	0	0
29 5	Empowering patients through eHealth: a case report of a pan-European project	10.1186/s12913-015- 0983-0	0	1	1	1	0	1	0	0	0	0	1	1	1	0	1	1	0	0	1	0
300	Envisioning a credit society: social credit systems and the institutionalization of moral standards in China	10.1177/01634437221 127364	1	1	1	0	1	1	0	1	1	1	1	1	0	0	1	1	1	0	0	1
31 7	Ethical development of stem-cell-based interventions	10.1038/s41591-019- 0511-6	1	1	1	1	1	1	1	1	1	0	0	1	1	1	1	1	0	0	1	1
329	Ethical issues in direct-to-consumer healthcare: A scoping review	10.1371/journal.pdig.0 000452	1	1	0	1	1	1	1	1	1	0	0	1	1	0	1	1	1	0	0	1
33 3	Ethical Issues Regarding CRISPR-mediated Genome Editing	10.21775/cimb.026.1 03	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	0	0	1
348	Ethics and Law in the Internet of Things World	10.3390/smartcities10 10006	1	1	1	1	1	1	0	1	1	0	1	1	1	0	1	1	1	0	0	1
35 0	Ethics and standards in the use of artificial intelligence in medicine	10.1111/1754- 9485.13289	1	1	0	1	1	1	0	1	1	0	0	1	0	0	1	1	0	0	1	1
377	Exploring neurologists' perspectives on the return of next generation sequencing results	10.1186/s12910-018- 0320-3	1	1	0	1	0	1	0	1	1	0	0	1	1	0	0	1	1	0	1	1
38 4	Fairness in Recommendation: Foundations, Methods and Applications	10.48550/arXiv.2205. 13619	1	1	1	0	0	1	0	0	0	1	1	1	0	0	1	1	0	0	1	1
401	Frozen Embryos, Male Consent, and Masculinities	10.2139/ssrn.3845577	1	1	0	1	1	1	0	1	1	0	0	1	1	0	1	1	0	0	0	1
40 7	Gene Drives and Genome Modification in Nonhuman Animals: A Concern for Informed Consent?	10.1017/S096318011 8000427	1	1	1	1	1	1	0	1	1	0	0	1	1	0	1	1	1	0	0	1
427	Guidelines for Data Privacy Compliance: A Focus on Cyber-Physical Systems and Internet of Things	10.1145/3351108.3351 143	1	1	0	1	1	1	0	1	1	0	1	1	0	0	1	1	0	0	1	1
44 6	Human Dignity: Conceptual Unity and Plurality of Content in Swiss Law	10.1007/978-3-319- 99112-2_8	1	1	1	1	1	1	0	1	1	1	1	1	1	0	1	1	1	0	0	1
484	Ethical Guidelines for Human Genetic and Genomic Research: A Case from Malaysia	10.17576/mjms-2015- 2206-7	1	1	0	1	1	1	0	1	1	0	0	1	1	0	1	1	0	0	0	1
49 9	Is epigenome editing non-inheritable? Implications for ethics and the regulation of human applications	10.1016/j.stemcr.202 3.10.003	1	1	1	1	1	1	1	1	1	0	0	1	0	0	1	1	0	0	0	1
501	Ethical standards for clinical trials: Perspectives on consent and risk management	10.1001/jamainternme d.2015.1023	1	1	0	1	1	1	0	1	1	0	0	1	1	0	1	1	0	0	0	1
50 3	ISSCR's Guidelines for Stem Cell Research and Clinical Translation: Supporting development of safe and efficacious stem cell-based interventions	10.1016/j.stemcr.202 1.05.011	1	1	1	1	1	1	0	1	1	0	0	1	0	1	1	1	0	0	1	1
511	Law, Ethics and Emerging Military Technologies: Confronting Disruptive Innovation	10.1080/14746700.202 4.2359199	0	1	1	1	1	1	0	1	1	0	1	0	0	0	1	1	1	0	0	1
51 9	Legal issues of the digital twin cities in the current and upcoming European legislation	10.1145/3560107.35 60188	0	1	1	0	1	1	0	0	1	0	1	1	0	0	0	1	1	0	0	1
525	Legislation and the Negative Impact on Cybersecurity in Healthcare	10.5220/00091579069 10697	0	1	0	1	1	1	1	1	1	0	0	1	0	0	0	1	0	0	1	1



54 9	Methodological and institutional considerations for the use of 360-degree video and pet animals in human subject research	10.3758/s13428-020- 01458-5	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0
557	Model of a military autonomous device following International Humanitarian Law	10.1007/s10676-023- 09682-1	0	1	1	1	1	1	1	1	1	0	1	0	0	0	1	1	0	0	0	1
57 7	No Ethical Divide Between China and the West in Human Embryo Research	10.1111/dewb.12108	1	1	0	0	1	1	0	0	1	0	0	1	1	0	0	1	0	0	0	1
599	Opportunistic genomic screening: Recommendations of the European Society of Human Genetics	10.1038/s41431-020- 00758-w	1	1	0	1	1	1	0	1	1	0	0	1	1	0	1	1	0	0	1	1
60 4	Outsourcing Ethical Dilemmas: Regulating International Surrogacy Arrangements	10.2139/ssrn.384557 7	1	1	1	0	1	1	1	1	1	0	1	0	1	0	1	1	0	0	0	1
625	Planned oocyte cryopreservation for women seeking to preserve future reproductive potential: an Ethics Committee opinion	10.1016/j.fertnstert.20 18.08.027	1	1	1	1	1	1	0	1	1	0	1	1	1	0	1	1	0	0	0	1
62 9	The Ethics of Consent in a Shifting Genomic Ecosystem	10.1146/annurev- biodatasci-030221- 125715	1	1	0	0	1	1	0	0	1	1	1	1	1	0	0	1	0	1	0	1
637	Precision radiotherapy via information integration of expert human knowledge and Al recommendation to optimize clinical decision making	10.1016/j.cmpb.2022.1 06927	0	1	1	1	1	1	0	0	0	0	0	1	0	0	1	1	0	0	1	1
64 8	Privacy Laws, Non-Fungible Tokens, and Genomics	10.31585/jbba-3-2- (5)2020	1	1	0	1	1	1	1	1	1	0	0	1	1	0	1	1	0	0	0	1
673	Recommendations on the use and reporting of race, ethnicity, and ancestry in genetic research: Experiences from the NHLBI TOPMed program	10.1016/j.xgen.2022.1 00155	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	0	0	1	1
67 8	Reflections on Ethics, Human Intelligence and Artificial Intelligence (AI)	10.2139/ssrn.384816 648	1	1	0	0	1	0	1	1	1	0	0	0	0	0	1	1	1	0	0	1
695	Regulation of Digital Healthcare in India: Ethical and Legal Challenges	10.3390/healthcare110 60911	1	1	0	1	1	1	0	1	1	0	1	1	1	0	0	1	0	0	1	1
70 0	Regulation of stem cell-based research in India in comparison with the US, EU and other Asian countries	10.2174/1574888X15 666200402134750	1	1	1	1	1	1	1	1	1	0	0	1	0	0	1	1	0	0	1	1
711	Reprogramming consent: implications of sexual relationships with artificially intelligent partners	10.1080/19419899.202 0.1769160	1	1	0	0	1	0	1	1	1	0	0	0	0	0	1	1	1	0	0	1
72 4	Researchers views about perceived harms and benefits of gene editing: A study from the MENA region	10.1016/j.heliyon.202 1.e06860	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	0	1
738	Risk Assessment Methodologies for the Internet of Medical Things: A Survey and Comparative Appraisal	10.1109/ACCESS.2021. 3064682	0	1	0	1	1	1	0	1	1	0	1	0	0	0	0	1	0	0	1	1
74 5	Roboethics principles and policies in Europe and North America	10.1007/s42452-021- 04853-5	1	1	1	1	1	1	1	1	1	1	1	0	0	0	1	1	0	0	0	1
754	Scientific mistakes from the agri-food biotech critics	10.1186/s40504-018- 0089-7	0	1	1	1	1	1	0	1	1	0	1	0	0	0	1	1	0	0	0	1
76 3	Sex-Divergent Clinical Outcomes and Precision Medicine: An Important Role for IRBs and RECs	10.3389/fphar.2017.0 0488	1	1	0	1	1	0	0	1	1	0	1	0	0	0	1	1	0	0	1	1
771	Social and Assistive Robotics in Dementia Care: Ethical Recommendations for Research and Practice	10.1007/s12369-016- 0366-7	0	1	1	1	1	1	0	1	1	1	1	0	0	0	1	1	0	0	0	1

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