Research Ethics for Data Collection from Human Participants – Case Study and Recommendations

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Abstract. Human-Computer Interaction (HCI) is a discipline where scientists with different backgrounds meet. Especially with artificial intelligence (AI) in the equation, which is inherently data-intensive, researchers might be tasked with collecting data from human research participants. For technical disciplines, this task was traditionally not the focus of scientific work and training. Therefore, those researchers are faced with an undertaking they were not trained for and cannot be aware of its pitfalls, especially regarding ethical considerations concerning the well-being of human participants during data collection. This paper aims to raise awareness among researchers in the field of HCI and AI for the importance of collecting data from human participants according to ethical guidelines and to provide practical assistance. The paper is structured around the research use case of predicting vehicle maneuvers from the driver's gaze. First, the necessary procedures to ensure participant well-being during data collection for this use case are outlined. Second, we present a systematic literature review of 32 recent studies investigating this use case, and find that less than 30% report consideration of ethical matters in their articles. The paper concludes by broadening the view to encompass general guidelines for collecting data from human participants. A checklist is provided as practical tool to assist in ensuring ethical compliance. This paper is timely, since more and more publishers and research-funding agencies put emphasize on this topic across all scientific disciplines, and research cannot be funded or published without considering this issue any more.

Keywords: Research Ethics, Data Collection, Healthy Human Research Participants, Systematic Review.

1 Introduction

"Ethical guidelines and ethics committees do not concern my research since I do not conduct medical studies." – Statements like this are sometimes heard by researchers from technical disciplines, such as artificial intelligence (Al), or human computer interaction (HCI). It is often believed that only medical research or other life science needs to be conducted according to special ethical principles. Along this line, researchers from technical disciplines often seem to be unaware of the existence of non-medical

ethics committees. However, every researcher is subjected to their professional code of ethics as part of their professional community and as scientist. Furthermore, every researcher interacting with or collecting data from human research participants, regardless of the field, has an ethical obligation to ensure that research procedures do not infringe on participants well-being. Since some AI researchers and many HCI researchers do collect data from human research participants, these fields are used as examples for relevant technical disciplines.

Ethics in research can be broken down into three main categories:

1. **Good scientific practice** This category serves as ethical code for all academics and is the umbrella for the other two categories. It is built on four principles [1]: 1) reliability of one's own research; 2) honesty in developing und reporting research; 3) respect for people and environment; 4) accountability for research from training to management to societal impact. It comprises all aspects of academic work including research environment, researcher training and supervision, procedures, safeguards, data managements, collaborations, publication incl. authorship and review.
2. **Research impact** This category concerns the potential for application of research outcomes, i.e. the impact of the research on society, including issues of dual-use. For trustworthy AI, e.g., the European Union (EU) formulated seven key ethical requirements [2]: 1) human agency and oversight; 2) robustness and safety; 3) privacy and data governance; 4) transparency; 5) diversity, non-discrimination and fairness; 6) societal and environmental well-being; 7) accountability.
3. **Research participants** This category concerns the handling of research subjects, including healthy human participants, patients, and animals. For research involving human participants, medical research paved the way with the Declaration of Helsinki (DoH) [3]. These ethical principles laid the foundation for many other disciplines and are referenced throughout academia. In their core, they state that researchers who partake in research with human participants are obligated to ensure the well-being, integrity, privacy, dignity, autonomy, and confidentiality of personal information of the participants. This paper focuses on the sub-part of this category concerned with healthy human research participants.

Ethical principles concern the research community and adjunct institutions in several ways. In teaching and further training of researchers, awareness is raised and knowledge about the general principles as well as guidelines and regulations of the specific field are conveyed. The research community is built on a peer system in which guidance and review with respect to these principles should be offered. Institutions provide infrastructure such as specific guidelines and institutional ethics committees. Finally, government bodies, research institutes, funding agencies, and publishers enforce regulations based on these principles. This is not to restrain research, but to ensure its integrity and that research can be done freely by assuring it can be trusted.

Technical disciplines traditionally do not focus their education on handling human research subjects and therefore cannot have traditions and a peer culture concerned with that subject. Furthermore, guidelines and regulations in this area are only just develop-

ing and most likely not yet ubiquitous in the research communities. Based on the anecdotal findings outlined in the beginning of this paper, our work addresses two key questions:

1. Is this there a general problem with lack of awareness or knowledge regarding research ethics for data collection from human participants in technical research?
2. If there is a problem, how can it be solved?

In order to address the first question, we conduct a systematic review of articles on an exemplary research use case that we hope many AI and HCI researchers can relate to. The example comes from research on advanced driver assistance systems (ADAS) with the research question: How can driving maneuvers such as lane changes be predicted based on the driver's gaze? For data collection, participants drive in a car or driving simulator while their face or gaze and their driving behavior is recorded. This use case is chosen randomly but the principles outlined throughout this work also apply to many other use cases in which research is conducted with healthy human participants. To address the second question, this paper first provides background information on ethical principles for research with human participants. We then apply those principles to a tangible example, the use case outlined above, and close with practical guidance for a broader (technical) research community. By presenting this work at an international conference frequented by HCI and AI researchers, we bring it directly to the targeted audience and hope to raise awareness in thos community.

2 Background

Throughout this paper, we make a simplified distinction between two groups of researchers. The scientific fields having topics at their core that are not directly related to human state or behavior are termed *technical*. These comprise e.g. computer science and engineering, including AI and HCI. In these disciplines, researchers are traditionally not trained to handle human research participants. In contrast, fields that mainly concern themselves with human state or behavior and have a long-standing tradition to train their researchers and develop procedures for handling research participants are summarized under the umbrella term *life science*. Those disciplines include medicine, psychology and biological sciences such as neuroscience, as well as social sciences.

2.1 History of Research Ethics

Development of research ethics can be tracked back to events of ethical violations in history. While early isolated ethical regulations existed, like the Prussian regulation of 1900 [4], widespread ethical awareness was first catalyzed by the crimes uncovered by the Nuremberg Trials. Those revealed highly unethical experiments conducted on concentration camp prisoners in Germany during World War II. As response, the Nuremberg code was developed. It is the cornerstone of future frameworks such as the first draft of the DoH, which was developed by the World Medical Association (WMA) in 1964. Another critical event was the Tuskegee Syphilis Study conducted between 1932

and 1972 [5]. In this study, men with syphilis were observed but neither informed about their condition or the study nor were they provided therapy. This led to mistrust in research and a reform of research ethics, leading to the Belmont Report [6] in 1979.

Catalyzing studies in psychology were the Milgram Obedience Experiment published in 1963 [7] and the Stanford Prison Experiment published in 1973 [8]. The obedience experiment was conducted to understand the obedience to authority and the willingness to inflict pain on others when instructed. In a similar spirit, the prison experiment simulated a prison in which participants were assigned the roles of prisoner or guard in order to understand the interaction between the two social groups. Both experiments stressed participants more than anticipated up to trauma responses. Furthermore, they revealed problems with voluntariness, consenting procedure, and oversight of the experiment. This led to the reform of informed consent procedures and the formalization of supervision from institutional review boards (IRB) for research with humans.

In social science, the Belfast Project [9] constitutes a turning point regarding ethics principles. Interviews about the conflict in Northern Ireland were conducted between 2000 and 2006 with the promise that the information would remain confidential. Legal authorities issued subpoenas to the institution leading to lawsuits against interviewed participants. This breach in confidentiality led to eroding trust in research and raised awareness about unrealistic promises and the need to critically assess the risks of harm to research participants. Consequences besides ethical reflections were a strengthening of data protection rules. Even though such events accrue, there is a division in some research communities regarding details of research ethics [10]. However, with the shared goal to improve the world, there is also a common understanding that basic ethical principles are necessary for research with human participants in order to foster trust in research the society and maintain freedom of research.

2.2 Guidelines and Regulations for Research Ethics

Several international organizations provide frameworks for ethical behavior of researchers, such as the WMA with the DoH, or the United Nations Educational, Scientific and Cultural Organization (UNESCO) with their Universal Declaration on Bioethics and Human Rights [11]. These frameworks are then incorporated into regional and national regulations such as the EU clinical trials regulation [12], the EU general data protection regulation (GDPR) [13], or the U.S. regulation 45 CFR 46, which includes the Common Rule [14]. In addition, many universities, research institutes, and professional organizations such as the Institute of Electrical and Electronics Engineers (IEEE) [15] and the Association for Computing Machinery (ACM) [16] provide their own regulations and guidelines that detail code of conduct for their researchers beyond legal necessity. These codes ensure the integrity of researchers and their work and foster trust in scientific processes and outcomes.

Funding agencies and publishers of scientific journals provide additional motivation to review thoroughly one's own research procedures with respect to ethical considerations. When applying for funding, for instance from the European Commission, an ethics self-assessment [17] might be necessary. For research with human participants, this assessment includes the production of an ethics approval and informed consent from

the participants. The same applies for submission of articles to scientific journals or conferences. While not all publishers might have adopted those procedures, examples from the five largest publishers that are part of the Committee on Publication Ethics (COPE) [18] demonstrate that this is widespread practice. These publishers include Elsevier [19], Sage Publishing [20], Springer Nature Ltd [21], Taylor & Francis Inc [22], and Wiley [23]. All five publishers require for publication of studies with human participants that the authors have obtained an ethics approval, participants have given informed consent, and that the research is conducted in accordance with the DoH. This shows that ethical processes are an integral part of research, regardless of the field, since it has consequences for the whole research community.

2.3 Ethics Committees

Ethics committees, ethics review boards, or institutional review boards (IRB) are part of the research infrastructure that universities, research institutes, and professional organizations provide. They are formal panels representing their organization on ethical matters that fall within their competence. One committee can have one or several areas of competence.

Common for many universities and research institutes is a committee or commission responsible for handling violations of good scientific practice. This type of commission usually acts retrospectively, i.e. when a complaint is filed against a researcher. Another type of committee is assessing the impact of research, and often acts in an advisory role before the start of a research project. The third type of committee is assessing the procedures of research conducted with human participants before the project starts. These committees also act in an advisory role and their positive vote is the ethics approval required for grant application or paper publication. The committees overseeing medical research often have a special role since their legal regulations are the tightest. Non-medical ethics committees assessing the research procedures for projects with human research participants are in the remainder of the paper simply referred to as IRB. Those IRBs can belong to a department such as psychology, social sciences, or computer science and only have the competence for research within this department. A researcher might therefore not have an IRB to turn to for advice or vote, even if the university has IRBs. IRBs can also be superordinate to departments and have the competence for all (non-medical) research of the university or research institute.

Some universities and research institutes include in their regulations that the assessment from an IRB is mandatory before the start of a research project as soon as human participants are involved but some only recommend it. A recent study on Chinese universities found that all of them have some kind of ethic committee but less than a third require consultation of an IRB for non-medical disciplines [24]. Additionally, they found that research ethics for non-medical disciplines lacks attention and training.

2.4 Ethical Inspection of the Use Case

Based on the use case of conducting a study on predicting vehicle maneuvers such as lane changes from the gaze of the driver, this chapter outlines the actions and issues

researchers need to consider before and during data collection. For a psychologist, this use case constitutes a standard behavioral experiment with healthy human participants. However, since the DoH forms the basis for ethical guidelines in most disciplines, we reference the respective paragraphs in round brackets. For convenience, we provide an excerpt of the paragraphs referred to in this chapter in the Supplementary Material 7.1.

Study Planning

Design of the study must produce reliable and valid knowledge (21), minimize risks and burden on the participant (17) and the environment (11). This includes balancing between cost and benefit of the research, optimizing the task to this maxim, and appropriate planning of the amount of data necessary for reliable and valid conclusions. While dataset size for statistical comparisons can be easily planned based on expected effect size [25], the methods to achieve this for machine learning studies are more controversial [26, 27]. The research needs to be planned and reviewed by an IRB before data collection starts (22, 23).

Recruitment

Participation has to be voluntary (25). Special care needs to be applied when participants are in a dependent relationship with the researcher (27), or cannot give legal consent (28). The former is often the case with students or employees. With students, it is recommended that a researcher, who is not responsible for grading, handles them. If the participation is part of course work, sufficient alternative studies should be provided to the students to choose freely ([28] ch. 8.04 b). Inclusion of employees might additionally be protected by institution/company guidelines or legal requirements to involve staff or work council. The latter might arise for this use case, for example, when student drivers participate who are not yet of legal age. Here, legal guardians need to be included in recruitment, information, and consenting procedures (28).

Information and Consent

Free and informed consent must be given by each research participant (25), and if necessary by their legal guardian (28). This procedure necessitates providing sufficient information about the study in a way the consenting person understands (26). It includes the assurance that the participation is voluntary and can be stopped at any time without negative consequences for the participant (25). Furthermore, potential risks and burdens must be fully disclosed. If it is necessary to leave out information, to e.g. record fully natural behavior, this omission needs to be disclosed to the participant after the study ([28] ch. 8.07). In this use case, it might be advised not to tell a participant that the focus is on gaze behavior in order to not bias them towards more explicit gaze behavior. Information and consenting procedures need to be formally documented (26).

Conducting the Study

During data collection, the researcher must be prepared to discontinue the experiment at any time, either prompted by the participant or when risk for the participant is foreseeable (17, 26). The task of this use case is driving either a car or a driving simulator with extensive behavioral data recording. In case of the driving simulator, the participant may experience simulator sickness [29, 30]. For the case of open-street driving, the normal risks of participating in car traffic are present. Possible insurance issues need

to be addressed in advance and communicated to the participant. Furthermore, being a research participant is a special situation for many people and might be perceived as a test, in which exam anxiety might be triggered, or another kind of stressful situation, e.g. the experience of social pressure. While this personal experience is hard to foresee or prevent, researchers need to be aware of this possibility and if necessary adjust their interaction with a participant in order to minimize stress for them. This might also be a reason for discontinuation of data collection.

Data (Protection)

Privacy of the research participant and the confidentiality of their personal information must be protected (24) and storage of this data needs to be consented to (32). This use case usually includes massive data collection such as camera recording of the participant, potentially additional eye tracking or recording of physiological measures, driving behavior, e.g. movement of the steering wheel. Each data modality has their own challenges. When gaze is tracked via normal cameras, the face of the participant is recorded, which makes them clearly identifiable. Any other data linked to this camera data cannot be anonymized. Physiological data such as electrocardiogram (ECG), heart rate, or movement pattern including gaze are potentially suited to identify a participant as well [31] and have the potential to serve as biomarker for disease identification [32-36]; I.e. they should be handled with equal care as medical data. Depending on the nature of the data, they need to be stored with sufficient security measures and handled according to local legislation, e.g. the GDPR in the EU. Extra precaution needs to be taken regarding individual (e.g. exemplary) participant data published in articles, and data that is made publicly available. For the latter case, the respective declaration from the WMA for health databases and biobanks can serve as orientation: the Declaration of Taipei [37].

3 Systematic Review

3.1 Methods

IEEE *Xplore* [38] and the ACM Guide to Computing Literature [39] were searched on January 5th 2025. These two bibliographic databases were chosen because they index the largest article collections for engineering, technology, and computing. Both databases were searched with the string (*"driver assistance" AND "eye tracking" AND "lane change" AND prediction*). The search was filtered by date including only articles from 2019 to 2025 in order to keep the results recent. Exclusion criteria were 1) no full paper; 2) review or survey; 3) no data from human participants was used, e.g. report of technical tests or simulations. To expand the corpus of literature, we also included publicly available data sets that were referenced in the articles from the original search.

The two key metrics regarding ethical considerations in a study are whether they report 1) the involvement of an IRB and 2) obtaining informed consent from the participants. If the corresponding information was not provided in the methods, the remainder of the article was searched. For the public data sets, we additionally looked for consent for publication of the data. Assessment of potential influencing factors include

year of publication, outlet of publication, the country of data collection, whether the research facility where the data was collected has an IRB, and training of authors. Country of data collection was gathered from the methods or inferred from the institutes of the authors. Information about an IRB at the research facility was gathered from the institute's official website, if not provided in the methods. Sources for the training of the authors (from Bachelor to Doctorate) included their official institute website, ORCID, IEEE or ACM profile, Research Gate, Google Scholar, and their personal website if it was linked by any of the previous.

Both authors assessed the information independently and resolved conflicts by discussion. Significance of the potential influence factors was assessed with X^2 tests for the categorical data or Spearman rank correlation for year, both assuming a significance level of α=.05.

3.2 Results

The database searches provided eleven results in IEEE and 44 results in ACM. The ACM search included 21 abstract collections and proceedings, which were excluded. The remaining 34 results overall did not contain duplicates and were therefore pooled. Title and abstract screening revealed six review or survey papers, one simulation study, and two studies that conducted technical tests only. These were excluded as well as the five studies that used only public datasets [40-44]. This resulted in 20 studies that collected their own data [45-64]. Eight of those articles do not match the use case completely but are still close enough in terms of behavioral experiment and data collection to be included in the review. Twelve articles introducing public datasets that were used in one of the original papers extended the corpus of articles for review [65-76]. Note that half of these papers were published before the time that we originally included in this review.

Nine of the 32 overall studies report the involvement of an IRB. Eight of the overall 32 studies report that informed consent was obtained from the participants. Three of the 14 studies that publish their data explicitly state about data protection. For four institutes, we could not find information about whether they have an IRB but we cannot exclude that we missed the information due to language barriers on the website. For two institutes, we assume that they do not have an IRB since ethical guidelines for research with human subjects are explicitly stated but no reference to an IRB is included. The remaining institutes all have an IRB. However, it is not always clear whether this board is available for all non-medical departments or only specific ones.

None of the factors depicted in **Fig. 1** has a sign. effect on whether the involvement of an IRB was reported or obtaining informed consent from the participants was reported (all p>.05). The nineteen journal papers were published by Elsevier (n=9), Springer (n=4), IEEE (n=4), ACM (n=1), or National Academies Publishing (n=1). The twelve conference papers were published by IEEE (n=6), ACM (n=3), Elsevier (n=2), or Springer (n=1). The one preprint is not included in **Fig. 1**. The data from the 13 European locations was collected in France, Germany, Greece, Italy, Norway, Spain, or the UK, data from the ten Asian locations was collected in China, India, or South Korea, and data from the nine American locations was collected in Brazil or the US.

The groups that include life science trained researchers have training in biomedical science, neuroscience, or psychology.

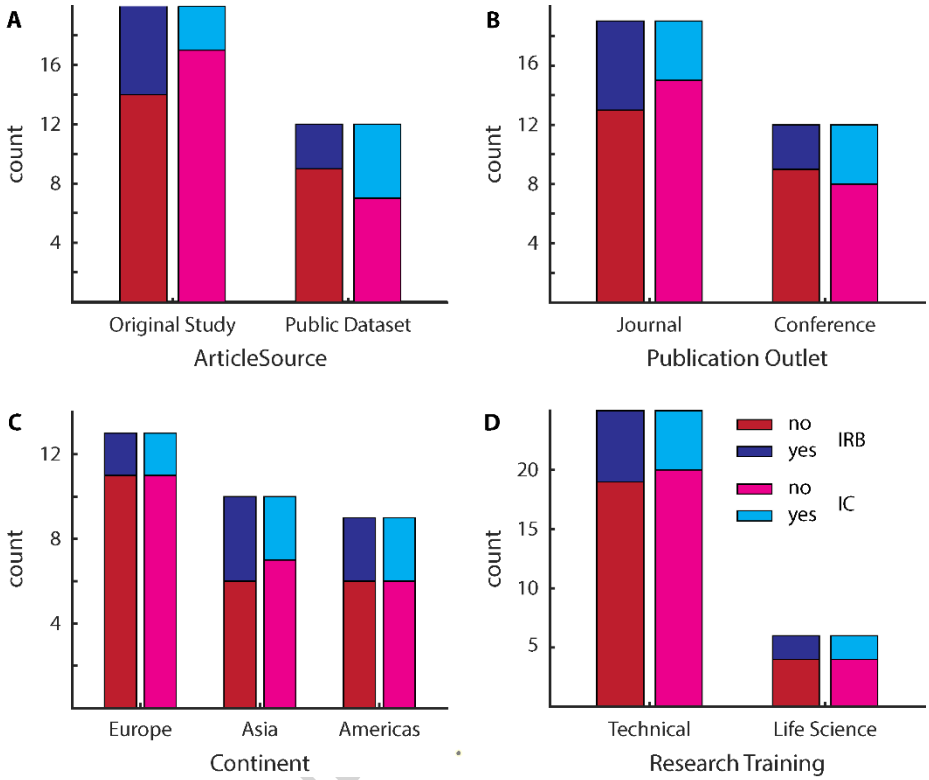

Fig. 1. Number of studies not reporting (red-ish) and reporting (blue-ish), respectively, the involvement of an Institutional Review Board (IRB) and obtaining Informed Consent (IC), respectively, split by A) article source, B) publication outlet (excluding the one preprint in the graphic), C) continent of data collection, and D) training of researchers involved, i.e. authors.

Both metrics have a tendency to increase over time (**Fig. 2**), but only reporting the IRB increases sign. (ρ=1; p=.042), but not obtaining informed consent (ρ =.4; p=.375).

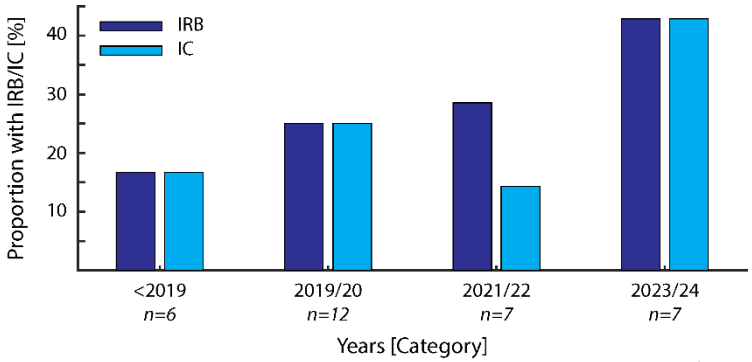

Fig. 2. Proportion of studies reporting the involvement of an Institutional Review Board (IRB) and obtaining Informed Consent (IC), respectively, over the years including the number of overall articles per time span.

4 Checklist for Study Planning

This chapter provides a compilation of issues to check or questions to address when planning a study with healthy human participants. These are compiled based on the DoH and the experience of the senior author with various IRBs (across Europe).

- Check the resources of your IRB, including the possibility of a consultation. Be aware of their deadlines with respect to the planned start of data collection.
- Check the legal requirements for your research (e.g. data protection).
- Is the amount of data planned to collect sufficient – but not too much – to obtain reliable and valid knowledge? – If not sure: Consult a statistician.
- Is the procedure and the task for the participant optimized to minimize risks and burden on the participant? Testing the data collection process on oneself and conducting pilot studies can help to optimize the task.
- Is the procedure or task a burden to the participant that extends beyond everyday life, e.g. inducing stress (including e.g. posing intimate or potentially stigmatizing questions), fear, exhaustion, pain, or other negative effects? – If yes: Evaluate whether the scientific gain justifies these burdens. Participants need to be truthfully informed about this, and precautions need to be implemented to monitor the well-being of the participants during task execution, and to stop the task immediately as soon as either the participant wants to stop or the burden is not ethically acceptable any more. Provide aftercare by a trained professional if necessary.
- Is the procedure or task posing a risk to the participant that extends beyond everyday life, e.g. invasive or other potentially harmful procedures? – If yes: Evaluate whether the scientific gain justifies these risks. Participants need to be truthfully informed about this, and precautions need to be implemented to monitor the well-being of the participants the whole time, and to stop immediately as soon as either the participant wants to stop or the risk is not ethically acceptable any more. Provide aftercare by a trained professional if necessary. Double-check the law.

- Do you administer drugs or other substances, e.g. caffeine, or alcohol? – If yes: Evaluate whether the scientific gain justifies possible risks. Participants need to be truthfully informed about this, and precautions need to be implemented to monitor the well-being of the participants the whole time, and to stop immediately as soon as either the participant wants to stop or the risk is not ethically acceptable any more. If the substance diminishes the ability to act sanely, monitor the participant until the effect washes out. Note that in most countries only a physician may give medication.
- Do you have (written) information for the participants about the task, possible risks and burdens? Is it made explicitly clear to the participant that their participation is voluntary, and that they can withdraw from the study at any time without having to fear negative consequences? Do you have (written) instructions for the participants? Is this information legible and digestible for the participant group? Testing the information and instructions on the target group can help to improve those documents.
- Prepare informed consent forms with signature fields for participant, their legal representative if necessary, and the researcher handling the participant. The consent needs to be given for conducting the study, collecting the data, the right to store the data, and publish it (aggregated / anonymized / not anonymized – whichever holds true for the study). The signature also needs to confirm that the information about the study (see above) was provided and understood.
- Are participants planned that are not legally competent, e.g. minors? – If yes: A legal representative needs to consent in addition to the participant.
- Are participants planned that belong to a vulnerable group, e.g. people with subpar intelligence, people in the correctional system? – If yes: Consider how you can ensure that these people are not exploited by the research.
- Are participants planned that are in a dependent relationship to one of the researchers, e.g. student or employee? – If yes: Consider how you can ensure that the voluntariness of participation is not affected by the dependent status of the participant.
- Is it necessary to withhold information about the study or provide wrong information in order not to bias the behavior? – If yes: Evaluate whether the scientific gain justifies the deception. Have the information about the deception and its justification ready after completion of the data collection in order to fully de-brief the participant.
- Is it possible to infer medical conditions from the data, e.g. when collecting physiological data? – If yes: Have a procedure in place how to deal with incidental findings. Include in the informed consent form the question whether the participant wants to be informed about incidental findings. If they do not want it, do not tell them. If they want to know, keep in mind that only physicians may communicate diagnoses. Never communicate the suspicion of a medical condition to a research participant; For many participants a researcher is a figure of authority and trustworthy, even if they are not physicians. For such cases, establish a procedure with a hospital or physician.
- Ensure that all personal data can be stored securely and that only authorized personnel can access the data.
- Ensure that participants know about data security and their rights regarding the data (depending on local law), see information and informed consent.

– Inform the participants about their insurance status with respect to the study procedures: Are they covered on the way to the experiment? Are they covered during study participation?

5 Discussion

We reviewed 32 studies that collected behavioral data from human participants for the use case of maneuver prediction from driver's gaze and related research questions. Only 28% of studies explicitly report the involvement of an IRB for data collection, and a quarter of the studies report that informed consent was obtained from the participants prior to conducting the experiments. This leads to the conclusion that the answer to our first question is: Yes, there is a general problem with lack of awareness or knowledge regarding research ethics for data collection from human participants in technical research communities. However, we find a trend for an increase of IRB and IC reporting over the past years. Still, the IRB/IC reporting quota in the papers published in the last two years is less than 50%. Interestingly, we found no influence of the other factors that we investigated. We expected that collection of data that is made publicly available would be subjected to stricter processes but could not confirm this. Neither are articles published in journals scrutinized more than conference articles. Most surprising is the finding that it makes no difference whether researchers trained in life science are amongst the authors. Admittedly, only a small portion of the research teams included such members and we cannot know the circumstances in the institutes and the involvement of those researchers.

Neither reporting IRB involvement nor obtaining informed consent does not indicate that the research was conducted without ethical standards. We presume best intentions in every researcher, collecting data at least with compliance to implicit ethical principles, or even with explicit guidelines. They might even have applied explicit guidelines and get the research reviewed by an IRB but neglected to report it in the article. However, those procedures are part of the research methods and as such good scientific practice commands to report this in the article. Furthermore, publisher policy often requires such explicit statements as outlined in the background chapter. For illustration, we cite the corresponding paragraph 8.1.1 E from the IEEE Publication Services and Products Board Operations Manual [77] as a publisher who specializes in technical disciplines:

"*Authors of articles reporting research involving human subjects or animals, including but extending beyond medical research, shall include a statement in the article that research was performed under the oversight of an institutional review board or equivalent local/regional body, including the official name of the IRB/ethics committee, or include an explanation as to why such a review was not conducted. For research involving human subjects, authors shall also report that consent from the human subjects in the research was obtained or explain why consent was not obtained.*"

Our review includes only one use case and can therefore merely serve as an example. However, it was conducted systematically and should therefore provide an unbiased picture of the research processes involved in this particular field. We take this as a clear

indication that there is a need to catch up on research ethics for data collection involving healthy human participants in at least some (technical) fields.

In addition to the systematic review, this paper provides background information on research ethics, the breakdown of ethical requirements based on a specific use case relevant to the target audience, and a general checklist for studies collecting data from human research participants. We hope that this compete package provides practical guidance in reviewing and potentially improving the processes surrounding research with human participants, including that kind of research in technical fields.

The focus of this paper was on the ethical considerations surrounding data collection from healthy human research participants. When patients are included, ethical and legal demands increase. In such cases, medical researchers trained for this kind of research should be included in the team. Similarly with animal research, including the necessary considerations here would push the limits of this article. Furthermore, the issue of data protection was only touched upon briefly. We included this issue mainly from the ethical perspective but the extensive legal requirements in many countries on this subject need to be taken into account as well.

6 Conclusions

We conclude with recommendations for researchers and institutes. We hope that we could raise awareness amongst the readers for the necessity of ethical processes and regulation when including human research participants. Researchers should regularly review their own research procedures according to the recommendations outlined in this article, or similar guidelines. Furthermore, knowledge about these principles and their application should be included in education and professional training. Finally yet importantly, these principles should be kept in mind when advising peers or reviewing manuscripts for publication. Universities and research institutes should include teaching of these principles and tangible application in their curricula if not yet done. Furthermore, they might review their research ethics guidelines and provide IRBs for all researchers regardless of discipline.

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References

1. All European Academies, n. *The European Code of Conduct for Research Integrity - Revised Edition 2023*. 2023 [cited 2025 Jan 26]; Available from: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf.
2. Madiega, T. *EU guidelines on ethics in artificial intelligence: Context and implementation*. 2019 [cited 2025 Jan 26]; Available from:

https://www.europarl.europa.eu/RegData/etudes/BRIE/2019/640163/EPRS_BRI(2019)640163_EN.pdf.

3. World Medical Association, n., *World Medical Association Declaration of Helsinki: ethical principles for medical research involving human participants.* JAMA, 2024.
4. Vollmann, J. and R. Winau, *The Prussian regulation of 1900: Early ethical standards for human experimentation in Germany.* IRB: Ethics & Human Research, 1996. **18**(4): p. 9-11.
5. Vonderlehr, R.A., et al., *Untreated syphilis in the male Negro: a comparative study of treated and untreated cases.* Journal of the American Medical Association, 1936. **107**(11): p. 856-860.
6. Department of Health, E., and Welfare, none. *The Belmont Report.* 1979 [cited 2025 Jan 27]; Available from: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.
7. Milgram, S., *Behavioral study of obedience.* The Journal of abnormal and social psychology, 1963. **67**(4): p. 371.
8. Haney, C., et al., *A study of prisoners and guards in a simulated prison*. 1973.
9. Democratic Progress Institute, n. *The Belfast Project: An Overview*. 2014 [cited 2025 Jan 28]; Available from: https://www.democraticprogress.org/wp-content/uploads/2014/11/Belfast_Project-ENG-version.pdf.
10. Israel, M., *Research Ethics and Integrity for Social Scientists: Beyond Regulatory Compliance*. 2014: SAGE.
11. United Nations Educational Scientific and Cultural Organization, n. *Universal Declaration on Bioethics and Human Rights*. 2005 [cited 2025 Jan 26]; Available from: https://www.unesco.org/en/legal-affairs/universal-declaration-bioethics-and-human-rights?hub=387.
12. Directorate-General for Health and Food Safety, n. *Clinical trials - Regulation EU No 536/2014*. 2022 [cited 2025 Jan 26]; Available from: https://health.ec.europa.eu/medicinal-products/clinical-trials/clinical-trials-regulation-eu-no-5362014_en.
13. Directorate-General for Communication, n. *Legal framework of EU data protection*. 2018 [cited 2025 Jan 26]; Available from: https://commission.europa.eu/law/law-topic/data-protection/legal-framework-eu-data-protection_en.
14. Office for Human Research Protections, n. *45 CFR 46*. 2018 [cited 2025 Jan 26]; Available from: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.
15. IEEE. *Organizational Ethics*. N/A [cited 2025 Jan 26]; Available from: https://www.ieee.org/about/compliance.html.
16. Association for Computing Machinery, n. *ACM Code of Ethics and Professional Conduct*. 2018 [cited 2025 Jan 26]; Available from: https://www.acm.org/code-of-ethics.
17. European Commission, n. *EU Grants: How to complete your ethics self-assessment* 2021 [cited 2025 Jan 26]; Available from: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf.

18. Committee on Publication Ethics, n. *Committee on Publication Ethics*. N/A [cited 2025 Jan 26]; Available from: https://publicationethics.org/.
19. Elsevier, n. *Publishing ethics*. N/A [cited 2025 Jan 26]; Available from: https://www.elsevier.com/about/policies-and-standards/publishing-ethics#4-duties-of-authors.
20. Sage Publications, n. *Publication ethics and research integrity: policy guidelines for authors*. N/A [cited 2025 Jan 26]; Available from: https://uk.sagepub.com/en-gb/eur/publication-ethics-and-research-integrity-policy-guidelines-for-authors#Studies%20involving%20humans.
21. Springer Nature Ltd, n. *Research Ethics*. N/A [cited 2025 Jan 26]; Available from: https://www.nature.com/nature/editorial-policies/ethics-and-biosecurity#Research-with-human-participants-their-data-or-biological-material.
22. Taylor & Francis Inc, n. *Taylor & Francis Editorial Policies*. N/A [cited 2025 Jan 26]; Available from: https://authorservices.taylorandfrancis.com/editorial-policies/.
23. Wiley, n. *Best Practice Guidelines on Research Integrity and Publishing Ethics*. N/A [cited 2025 Jan 26]; Available from: https://authorservices.wiley.com/ethics-guidelines/index.html#Human_studies_and_subjects.
24. Li, D., *Ethical governance in Chinese universities: an overview of research ethics committees.* Ethics & Behavior, 2025. **35**(1): p. 1-12.
25. Field, A., *An Adventure in Statistics: The Reality Enigma*. 2022: SAGE.
26. Balki, I., et al., *Sample-size determination methodologies for machine learning in medical imaging research: a systematic review.* Canadian Association of Radiologists Journal, 2019. **70**(4): p. 344-353.
27. Goldenholz, D.M., et al., *Sample size analysis for machine learning clinical validation studies.* Biomedicines, 2023. **11**(3): p. 685.
28. American Psychological Association, n. *Ethical Principles of Psychologists and Code of Conduct*. 2017 [cited 2025 Jan 27]; Available from: https://www.apa.org/ethics/code.
29. Brooks, J.O., et al., *Simulator sickness during driving simulation studies.* Accident analysis & prevention, 2010. **42**(3): p. 788-796.
30. Classen, S., M. Bewernitz, and O. Shechtman, *Driving simulator sickness: an evidence-based review of the literature.* The American Journal of Occupational Therapy, 2011. **65**(2): p. 179-188.
31. Abdulrahman, S.A. and B. Alhayani, *A comprehensive survey on the biometric systems based on physiological and behavioural characteristics.* Materials Today: Proceedings, 2023. **80**: p. 2642-2646.
32. Schiweck, C., et al., *Heart rate and high frequency heart rate variability during stress as biomarker for clinical depression. A systematic review.* Psychological medicine, 2019. **49**(2): p. 200-211.
33. Kourtis, L.C., et al., *Digital biomarkers for Alzheimer's disease: the mobile/wearable devices opportunity.* NPJ digital medicine, 2019. **2**(1): p. 9.
34. Horak, F.B. and M. Mancini, *Objective biomarkers of balance and gait for Parkinson's disease using body-worn sensors.* Movement Disorders, 2013. **28**(11): p. 1544-1551.

35. Graham, L., et al., *Digital Eye-Movement Outcomes (DEMOs) as Biomarkers for Neurological Conditions: A Narrative Review.* Big Data and Cognitive Computing, 2024. **8**(12): p. 198.
36. Chetran, A., et al., *ECG and biomarker profile in patients with acute heart failure: a pilot study.* Diagnostics, 2022. **12**(12): p. 3037.
37. World Medical Association, n. *WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks*. 2016 [cited 2025 Jan 27]; Available from: https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/.
38. IEEE Publications, n. *IEEE Xplore*. N/A [cited 2025 Jan 27]; Available from: https://ieeexplore.ieee.org/Xplore/home.jsp.
39. Association for Computing Machinery, n. *The ACM Guide to Computing Literature*. N/A [cited 2025 Jan 27]; Available from: https://libraries.acm.org/digital-library/acm-guide-to-computing-literature.
40. Gite, S., et al., *ADMT: Advanced Driver's Movement Tracking System Using Spatio-Temporal Interest Points and Maneuver Anticipation Using Deep Neural Networks.* IEEE Access, 2021. **9**: p. 99312-99326.
41. Bhagat, H., et al. *Driver Gaze Fixation and Pattern Analysis in Safety Critical Events*. in *2023 IEEE Intelligent Vehicles Symposium (IV)*. 2023.
42. Lv, K., et al., *Improving Driver Gaze Prediction With Reinforced Attention.* IEEE Transactions on Multimedia, 2021. **23**: p. 4198-4207.
43. Fu, R., et al., *A multimodal deep neural network for prediction of the driver's focus of attention based on anthropomorphic attention mechanism and prior knowledge.* Expert Syst. Appl., 2023. **214**(C): p. 12.
44. Kotseruba, I. and J.K. Tsotsos. *Understanding and Modeling the Effects of Task and Context on Drivers' Gaze Allocation*. in *2024 IEEE Intelligent Vehicles Symposium (IV)*. 2024.
45. Hsieh, S.-J., et al., *Adaptive Driving Assistant Model (ADAM) for Advising Drivers of Autonomous Vehicles.* ACM Trans. Interact. Intell. Syst., 2022. **12**(3): p. Article 21.
46. Nambi, A.U., et al., *ALT: towards automating driver license testing using smartphones*, in *Proceedings of the 17th Conference on Embedded Networked Sensor Systems*. 2019, Association for Computing Machinery: New York, New York. p. 29–42.
47. Gao, J., J. Yi, and Y.L. Murphey, *Attention-based global context network for driving maneuvers prediction.* Mach. Vision Appl., 2022. **33**(4): p. 11.
48. Jain, N. and S. Mittal, *Bayesian Nash Equilibrium based Gaming Model for Eco-safe Driving.* J. King Saud Univ. Comput. Inf. Sci., 2022. **34**(9): p. 7482–7493.
49. Cheng, K., et al., *Deep learning approach for unified recognition of driver speed and lateral intentions using naturalistic driving data.* Neural Netw., 2024. **179**(C): p. 13.
50. Wasi, A., et al., *Early Anticipation of Driving Maneuvers*, in *Computer Vision – ECCV 2024: 18th European Conference, Milan, Italy, September 29–October 4, 2024, Proceedings, Part LXX*. 2024, Springer-Verlag: Milan, Italy. p. 152–169.
51. Gao, J., J. Yi, and Y.L. Murphey, *An efficient driving behavior prediction approach using physiological auxiliary and adaptive LSTM.* Mach. Vision Appl., 2024. **35**(5): p. 12.

52. Causse, M., et al., *Encoding decisions and expertise in the operator's eyes: Using eye-tracking as input for system adaptation.* Int. J. Hum.-Comput. Stud., 2019. **125**(C): p. 55–65.
53. Fan, X., et al., *GazMon: Eye Gazing Enabled Driving Behavior Monitoring and Prediction.* IEEE Transactions on Mobile Computing, 2021. **20**(4): p. 1420-1433.
54. Amadori, P.V., T. Fischer, and Y. Demiris, *HammerDrive: A Task-Aware Driving Visual Attention Model.* IEEE Transactions on Intelligent Transportation Systems, 2022. **23**(6): p. 5573-5585.
55. Tang, J., et al., *A hierarchical prediction model for lane-changes based on combination of fuzzy C-means and adaptive neural network.* Expert Syst. Appl., 2019. **130**(C): p. 265–275.
56. Li, J., et al., *Lane changing maneuver prediction by using driver's spatio-temporal gaze attention inputs for naturalistic driving.* Adv. Eng. Inform., 2024. **61**(C): p. 15.
57. Gao, J., J. Yi, and Y.L. Murphey, *Multi-scale space-time transformer for driving behavior detection.* Multimedia Tools Appl., 2023. **82**(16): p. 24289–24308.
58. Deng, Q., et al. *Online intention recognition applied to real simulated driving maneuvers*. in *2020 IEEE Conference on Cognitive and Computational Aspects of Situation Management (CogSIMA)*. 2020.
59. Deng, Q., et al., *Prediction Performance of Lane Changing Behaviors: A Study of Combining Environmental and Eye-Tracking Data in a Driving Simulator.* IEEE Transactions on Intelligent Transportation Systems, 2020. **21**(8): p. 3561-3570.
60. Tonutti, M., et al., *Robust and subject-independent driving manoeuvre anticipation through Domain-Adversarial Recurrent Neural Networks.* Robot. Auton. Syst., 2019. **115**(C): p. 162–173.
61. Papakostopoulos, V., D. Nathanael, and L. Psarakis, *Semantic content of motorcycle riders' eye fixations during lane-splitting.* Cogn. Technol. Work, 2020. **22**(2): p. 343–355.
62. Yeo, D., G. Kim, and S. Kim, *Toward Immersive Self-Driving Simulations: Reports from a User Study across Six Platforms*, in *Proceedings of the 2020 CHI Conference on Human Factors in Computing Systems*. 2020, Association for Computing Machinery: Honolulu, HI, USA. p. 1–12.
63. Rehm, J., I. Reshodko, and O.E. Gundersen, *A virtual driving instructor that assesses driving performance on par with human experts.* Expert Syst. Appl., 2024. **248**(C): p. 19.
64. Wiehr, F., et al., *Why Do I Have to Take Over Control? Evaluating Safe Handovers with Advance Notice and Explanations in HAD*, in *Proceedings of the 2021 International Conference on Multimodal Interaction*. 2021, Association for Computing Machinery: Montréal, QC, Canada. p. 308–317.
65. Yang, D., et al. *Aide: A vision-driven multi-view, multi-modal, multi-tasking dataset for assistive driving perception*. in *Proceedings of the IEEE/CVF International Conference on Computer Vision*. 2023.
66. Jain, A., et al., *Brain4cars: Car that knows before you do via sensory-fusion deep learning architecture.* arXiv preprint arXiv:1601.00740, 2016.

67. Ortega, J.D., et al. *Dmd: A large-scale multi-modal driver monitoring dataset for attention and alertness analysis*. in *Computer Vision–ECCV 2020 Workshops: Glasgow, UK, August 23–28, 2020, Proceedings, Part IV 16*. 2020. Springer.
68. Alletto, S., et al. *Dr (eye) ve: a dataset for attention-based tasks with applications to autonomous and assisted driving*. in *Proceedings of the ieee conference on computer vision and pattern recognition workshops*. 2016.
69. Schwarz, A., et al. *Driveahead-a large-scale driver head pose dataset*. in *Proceedings of the IEEE Conference on Computer Vision and Pattern Recognition Workshops*. 2017.
70. Rangesh, A., B. Zhang, and M.M. Trivedi. *Driver gaze estimation in the real world: Overcoming the eyeglass challenge*. in *2020 IEEE Intelligent vehicles symposium (IV)*. 2020. IEEE.
71. Ribeiro, R.F. and P.D. Costa. *Driver gaze zone dataset with depth data*. in *2019 14th IEEE International Conference on Automatic Face & Gesture Recognition (FG 2019)*. 2019. IEEE.
72. Deng, T., et al., *How do drivers allocate their potential attention? Driving fixation prediction via convolutional neural networks.* IEEE Transactions on Intelligent Transportation Systems, 2019. **21**(5): p. 2146-2154.
73. Kasahara, I., S. Stent, and H.S. Park. *Look both ways: Self-supervising driver gaze estimation and road scene saliency*. in *European Conference on Computer Vision*. 2022. Springer.
74. Diaz-Chito, K., A. Hernández-Sabaté, and A.M. López, *A reduced feature set for driver head pose estimation.* Applied Soft Computing, 2016. **45**: p. 98-107.
75. Nuevo, J., L.M. Bergasa, and P. Jiménez, *RSMAT: Robust simultaneous modeling and tracking.* Pattern Recognition Letters, 2010. **31**(16): p. 2455-2463.
76. Campbell, K.L., *The SHRP 2 naturalistic driving study: Addressing driver performance and behavior in traffic safety.* Tr News, 2012(282).
77. IEEE Publications, n. *IEEE Publication and Products Board Operation Manual*. 2024 [cited 2025 Jan 27]; Available from: https://pspb.ieee.org/images/files/PSPB/opsmanual.pdf.

7 Supplementary Material

7.1 Excerpt from the Declaration of Helsinki

This supplemental provides direct quotes from the DoH that are generally relevant to research conducted with (healthy) human participants. Medical-specific terms are greyed out and substitutes added in blue.

Preamble

Article 2: […] these principles should be upheld by all individuals, teams and organizations involved in medical research, as these principles are fundamental to respect for and **protection of all research participants, including both patients and healthy volunteers.**

General Principles

Article 6: Medical research involving human participants is subject to ethical standards that promote and **ensure respect for all participants and protect their health and rights.**

Article 7: The primary purpose of medical research involving human participants is to **generate knowledge** […] These purposes **can never take precedence over the rights and interests of individual** research participants.

Article 9: It is the duty of physicians researchers who are involved in medical research **to protect the life, health, dignity, integrity, autonomy, privacy and confidentiality of personal information of research participants**. The responsibility for **the protection of research participants must always rest with physicians or other researchers** and never with the research participants, even though they have given consent.

Article 10: Physicians and other researchers must consider the **ethical, legal, and regulatory norms and standards** for research involving human participants in the **country** or countries in which the research originated and where it is to be performed, as well as applicable **international norms and standards**.

Article 11: Medical research **should be designed and conducted in a manner that avoids or minimizes harm to the environment** […]

Article 12: Medical research involving human participants must be **conducted only by individuals with the appropriate ethics and scientific education, training and qualifications**. […]

Article 15: Appropriate **compensation** and treatment for participants who are harmed as a result of participating in research must be ensured.

Risks, Burdens, and Benefits

Article 16: Medical research involving human participants may only be conducted if **the importance of the objective outweighs the risks and burdens** to the research participants

Article 17: […] Measures **to minimize the risks and burdens** must be implemented.

Article 18: Physicians and other researchers **may not engage in research involving human participants unless they a confident that the risks and burdens have been adequately assessed** and can be satisfactorily managed. […]

Scientific requirements and Research Protocols

Article 21: Medical research involving human participants must have **a scientifically sound and rigorous design** and execution that are likely to **produce reliable, valid and valuable knowledge**. The research must conform to **generally accepted scientific principles** [...]

Article 22: The design and performance of all medical research involving human participants must be **clearly described and justified** in a research protocol. The protocol should **contain a statement of the ethical considerations** involved […]

Research Ethics Committees

Article 23: The **protocol must be submitted** for consideration, comment, guidance, and approval **to the concerned research ethics committee** […]. When collaborative research is performed internationally**, the research protocol must be approved by research ethics committees in both the sponsoring and host countries**

Privacy and Confidentiality

Article 24: Every precaution must be **taken to protect the privacy of research participants and the confidentiality of their personal information**.

Free and Informed Consent

Article 25: […] Participation by individuals capable of giving informed consent in medical **research must be voluntary**

Article 26: […] each potential participant must be **adequately informed** in plain language of the aims, methods, anticipated benefits and potential risks and burdens […] The potential participant must be informed of the **right to refuse to participate** in the research or to **withdraw consent to participate at any time** without reprisal. […] formally **documented** on paper or electronically. […]

Article 27: When seeking informed consent for participation in research, the physician or other researcher must be particularly cautious **if the potential participant is in a dependent relationship with them or may consent under duress.** […]

Article 28: In medical research involving human **participants incapable of giving free and informed consent**, the physician or other qualified individual must seek informed consent from the legally authorized representative, **considering preferences and values expressed by the potential participant**. […]

Article 30: […] **Free and informed consent** to remain in the research **must be obtained as soon as possible** from a legally authorized representative […]

Article 32: Physicians or other qualified individuals must obtain free and informed consent from research participants **for the collection, processing, storage, and foreseeable secondary** use of biological material and **identifiable or re identifiable data**. […]

Research Registration, Publication, and Dissemination of Results

Article 36: Researchers, authors, sponsors, editors, and publishers all have ethical **obligations with regard to the publication and dissemination of the results of research**. […]