ATTACHMENT 1: PROJECT DESCRIPTION

Problem statement and objectives

The use of research methodologies that **purposefully deceive research participants**, withhold information or in some cases only intend to obtain informed consent after an intervention, has ebbed and flowed over the last few decades. This methodology is often referred to as deception in research design. An example from retail service industries is the use of a mystery shopper (actor or pseudo customer) that utilise a service or purchase a product with a specific purpose, such as for the evaluation of the provision of information[1] or obedience to legal obligations.[2] In the field of social psychology, participants are often recruited to participate in a study in which they are intentionally misled about the real purpose of the study. To study cheating behaviour, for example, researchers may fool participants into thinking they are being evaluated on their math solving skills. Outside of the fields of social psychology and marketing research, little research has been done to explore the use, value, justification and societal impact of deception methodologies. While this methodology can increase a study's social and scientific value[3] or give access to data that cannot be obtained otherwise[4], the methodology remains controversial.

The **use of deception has various benefits.** Firstly, very often discrepancies are identified between real and reported behaviour, meaning that what individuals report or state does not always correspond to what they actually do.[5] Therefore, a methodology that studies real behaviours will provide more valid results than studies that report data based on surveys or interview-based studies. Secondly, certain findings might only appear in real life. Interviewees might not be consciously aware of certain things, and findings might only come to light through actually observing what is happening in practice. Thirdly, it is considered as one of the only methods that have the potential to "directly measure service performance across the full range of pre-set quality standards, including those behavioural aspects of performance."[6] It might help to provide specific feedback to service providers and service coordinators. Fourthly, it has been argued that the use of deception can help assess "the competitiveness of an organisation's service provision by benchmarking it against the offerings of others in an industry."[6]

Nevertheless, the **use of deception in research studies has also been heavily criticised for various reasons.** Firstly, this is because all international codes and guidelines, as well as relevant legislation, for biomedical research involving human subjects (e.g. CIOMS; WMA), emphasise that **participation in research should be voluntary and that individuals should provide informed consent** before participation in research, whereas such studies depart from the perspective of deceiving a participant. Secondly, the use of deception has attracted many negative responses from those who have been subject to this approach.[7,8] Some have argued that, compared to retail services, it is inappropriate to use deceit in a field such as medicine or health care where **trust and truthfulness** is a core value, and that "introducing this competitive market tactic reduces the practice of medicine to a business model and will imperil both the members of the profession and its patients."[9] Thirdly, the use of deception in a research study involves various **privacy considerations.** Lastly, an ethical challenge is connected to the appropriate evaluation of studies in which deception is used. Considering some particularly controversial cases in the history of research in which deceit has been used (such as the Milgram experiment), very often research **ethics committees have looked with suspicion at research proposals that include deception**.[10]

Since the 70s, when the use of deception methodologies in social psychology and the debate thereof has peaked, many things have changed. Doctor-patient relationships have shifted to value patient autonomy more; international laws like the GDPR have been put in place to ensure privacy rights and arguments have been made that deception should also be permitted in studies that pose an overall greater than minimal risk is.[3] But most significantly is the rise and normalisation of disinformation through social media and other internet-based communications. Societal trust in experts, research and science in a whole has decreased. In this context, we ask if intentional deception methodologies are still appropriate/justified and how should research ethics committees evaluate such research proposals.

It is, therefore, not surprising that deception research methodologies raise many challenges for research ethics committees. Not just for ethics committees from fields that have traditionally seen more use of deception research methodologies like humanities, but also biomedical sciences, behavioural economy, criminology. It is, however, surprising that **no data is available on the way research ethics committees currently approach research studies in which deception is being used**. Although various countries might have different ethical and legal requirements for research, the **specific methodology of deception research requires better frameworks to address the use of this controversial methodology** in a context where general disinformation is lowering societal trust in science and research.

The **general aims** of our research in this area are to (a) to provide a better understanding of the strengths and weaknesses of research in which deception is being used; (b) to articulate more clearly the conditions under which such research is justified, and (c) to develop ethical safeguards and conditions under which such a study could take place.

In order to achieve this aim in a comprehensive manner, various specific objectives have been defined for this CELSA proposal:

- Firstly, we aim to **identify and analyse research studies from a wide spectrum of research fields** (e.g. Social psychology, biomedical sciences, behavioural economy, criminology etc.) which deception has been used. This will help us understand the rationale for why deception was used in these studies and the extent of the use in various fields.

- Secondly, we aim to **investigate the experiences of researchers who have used a methodology in which deception was used.** This will help to understand the motivations for using this methodology, their feelings and attitudes about the use of deception in their methodology, the strengths and weaknesses they identified with the methodology, their experiences with ethics approval (if any), their ethical concerns and the ethical safeguards implemented when using the methodology.
- Thirdly, we aim to **analyse research ethics guidelines and recommendations** in order to identify to what extent, the use of deception has been discussed in such documents, and to what extent conflicting or harmonised recommendations already exist towards the methodological, ethical and legal challenges related to research utilising deception.

These various objectives will allow us to develop further research in this area.

Envisaged progress beyond the state of the art

Innovative topic. While the **use of deception and the use of actors** in research could potentially provide valuable information, it raises important ethical issues. There is an important **lack of understanding** about the conditions under which deception in a research design might be justified and a lack of concrete guidance on specific issues such as the need for ethics approval, the need for informed consent, privacy considerations, or feedback mechanisms. Specific guidance on this topic is lacking and empirical studies that analyse experiences, views and considerations on the use of deceptions are non-existent.

Interdisciplinary character. By focusing on the use of deception and actors in research, we will be confronted with researchers from various disciplines and working in various contexts. We will study them in an integrated way by **bridging** these **different disciplines**.

Impact on academic research: The development of policy recommendations will guide future research projects that want to integrate deception within the design of the study, and will provide useful instruments for research ethics committees to assess such research protocols.

Methodology

WP 1: Mapping the current studies in which deception has been used, studying their various features and exploring associated ethical, legal and methodological considerations.

In order to inform further activities in the project, it is essential to develop an appropriate state of the art. The only systematic review on deception research methodology founded, performed a review limited to the field of social psychology in the period of 1921 to 1994.[11] Therefore, we plan to systematically map studies in which deception was used. This review will provide us with an appropriate overview of the approaches that use deception as part of their research methodology and will allow us to report on the approaches used at the level of ethics approval, informed consent, confidentiality and privacy, data withdrawal, potential to harm, participant debriefment or feedback and use of the findings. Moreover, additional areas of concerns might be identified.

A systematic review will be used for this purpose. A systematic review is "a review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review."[12] The approach used will follow the PRISMA guidelines on performing and reporting systematic reviews.[12] To achieve this, a systematic search will be conducted in databases such as PubMed, ISI Web of Science, Embase, CINAHL, PsycINFO, CSA Sociological Abstracts, ASSIA (Applied Social Sciences Index and Abstracts) using keywords that allow retrieval of research studies that used deception as a main part of their research design.

The articles resulting from the search strategies will be assessed on the basis of the titles and abstracts first, and subsequently on the full text, by two independent researchers. In the case of disputes about potential inclusion, a third reviewer will be consulted. Publications will be included if they match the inclusion criteria (using deception, peer-reviewed publication, in a language mastered by the research team). From each study, various characteristics will be extracted independently by two researchers: study participants, research field, data collection method, study context, motivation to use deception, ethics approval, informed consent, confidentiality and privacy measures, data withdrawal, potential to harm, participant debriefment or feedback, impact of the findings and any other relevant area of concern. Subsequently, the quotes addressing our research questions will be retrieved from selected articles and coded. Codes will then be clustered under overarching themes and discussed by the research team. This methodology follows the approach of data analysis used in qualitative studies, which is described below in WP2. We have previously used the approach of systematic review successfully in various fields, including organ donation[13], participation in scientific research[14] and data sharing.[15]

WP 2. Understanding experiences, perspectives, and motivations of researchers that used deception in their research design

In order to investigate the experiences, perspectives and motivations of researchers that have used a methodology that used deception in its research design, we plan to interview the researchers of the studies that were identified in Activity WP1. Using semi-structured interviews, we will explore why the researchers decided to use this methodology, the methodological strengths, weakness and challenges they identified, the experiences they had with the ethics committee approval (if applicable), their ethical and legal concerns, and any ethical and legal safeguards that they implemented when performing the study.

Participants will be recruited internationally and will be identified through Activity WP1. We anticipate interview approximately 40 researchers. Corresponding authors will be contacted, and individual interactions will make clear who is the best-placed person to interview for each study. Ethics approval will be sought for this study. We will use an inductive, content-driven thematic approach for data analysis, in which common patterns or themes across the data are identified and analysed through a coding process. This coding process will involve the identification of text fragments that are relevant to answer our research questions and the attribution of codes that express the meaning and content of these fragments. These codes will be grounded in the data, rather than pre-determined prior to data analysis. In order to facilitate this process of data analysis, we will use the 6-phase thematic analysis method of Braun and Clarke: (1) Familiarisation with data set and common themes and patterns across these data by using repeated reading; (2) Organization of the data into meaningful segments and attribution of codes that conceptualise "aspects in the data items that may form the basis of repeated patterns across the data"[16]; (3) Classification of codes into themes and subthemes by interpretative analysis of meaningful relationships between and across data; (4) Reviewing and refining identified themes (5) Defining and naming themes in order to set up a codebook, providing an overview of the identified themes, their definition and their relationship with other themes and subthemes. (6) Producing a final written report, describing the themes and their relationships in a narrative way. Although thematic analysis distinctively involves a hermeneutic process on the part of the researcher, who "is trying to make sense of the participant trying to make sense of their personal and social world"[16], several measures will be taken to increase the accuracy and credibility of our data interpretations, such as carefully documenting all steps of data collection and by using triangulation methods.

WP3: Mapping the current scope of methodological guidance researchers and research ethics committees have on the use of deception methods

Over the years, the international research community has developed various sets of guidelines and position papers on research ethics. Well-known is the Declaration of Helsinki and the International Ethics Guidelines for Biomedical Research Involving Human Subjects, but many other relevant documents have been released such as the Canadian Tri-Council Policy Statement on the ethical conduct for research involving humans, published by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada.

Using the methodology explained in WP1 we will systematically review research ethics guidelines and recommendations to analyse how recommendations deal with the use of deception in research. By doing so, we will identify whether the use of deception is considered acceptable and under which conditions. This will allow us to identify conflicting statements and positions within guidelines and identify areas of agreement. In contrast to WP1 where the systematic search was limited to established databases, research ethics guidelines will also be searched for in the grey literature using interfaces such as Google Scholar and Google. We will also systematically search the websites of national medical associations, and national bioethics committees. We have used this approach previously when searching for positions papers and guidelines on genetic testing in children.[17,18] Each guideline identified will be analysed for sections connected to the use of deception in research, and the quotes addressing our research questions will be retrieved from selected articles and codes.

The codes will then be clustered under overarching themes and discussed by the research team. The methodology used follows the approach of data analysis used in qualitative studies, which is described above in WP3. In addition, we will critically review the academic literature that discusses the use of deception in scientific research, with a special focus on its appropriateness and the conditions under which it is considered acceptable. This will be done using a "systematic review of reasons".[19]

As mentioned by Strech and Sofaer "a systematic review of reasons is likely to reveal a greater range of such information than the informal reviews of reasons that are usual in bioethics and philosophy, which sample literature using unsystematic, undocumented search methods to the unspecified point at which it seems to the author (often the only author) that no relevant new reasons emerge."[19] The point of this process's systematic nature is to collect all the relevant literature and to minimise bias in characterising it, as well as to describe which reasons and arguments have been given when discussing the use of deception in research. The search strategy used will closely follow the method described in WP1 but will focus on research ethics guidelines, position papers and academic literature. The analysis of the data will follow the approach of data analysis used in qualitative studies, which is described above in WP2.

Anticipated results

The various research activities will all lead to academic publications, at least one for each research activity. We also aim to present these research activities at national and international meetings. We anticipate that the research activities in this project and beyond will lead to the development of policy recommendations that will guide future research projects that want to integrate deception within the design of the study, and will provide useful instruments for research ethics committees to assess such research protocols.

Managerial aspects and timing

The project will be led and supervised by Prof. Pascal Borry from the Centre for Biomedical Ethics and Law in KU Leuven, in close collaboration with Prof. Dieter Baeyens from the Faculty of Psychology and Educational Sciences (KU Leuven) and Prof. Jan Piasecki from the Jagiellonian University Medical College. All three have extensive experience in ethics review and the functioning of ethics

committees. Three meetings (kickoff meeting (month 1), mid-term meeting, (month 12), and final meeting, (month 18)) are planned to discuss the progress of the project.

The research project has been structured into four different steps. Each step is coordinated by the Principal Investigator Pascal Borry (KU Leuven), who has ample expertise in the management of similarly structured projects. One PhD researcher will be hired on this project. This research project will be spread over a period of two years and will be based on a strategy of triangulation in which various types of information will be collected, and various types of analysis will be performed. This will include an analysis of current studies in which deception has been used (WP1), an interview study with researchers that used deception in their research designs (WP 2), and an analysis of normative guidelines regarding the use of deception in research (WP 3). These different activities will drive the development of a new research project (see attachment 4).

Task	Description Months	1-4	5-8	9-12	13-16	17-20	21-24
WP1	**Mapping the current studies in which deception has been used, studying their various features and exploring associated ethical, legal and methodological considerations.**						
WP2	**Interview study with researchers that used deception in their research design**						
WP3	**Mapping normative guidelines regarding the use of deception in research**						
WP 4	**Development of leverage in preparation of EU proposal**						

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