

## Chapter 11

# Experiments With Participants: Some Ethical Considerations



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### INTRODUCTION

Experiments involving human participants must abide by standards that have been built on the 10 points of the Nuremberg Code (1947) and laid down in the 1964 Declaration of Helsinki and further revisions. However, the way an experiment should be prepared and conducted may bring contradictions and raise ethical questions. This chapter focuses on key steps of an experiment and some related issues. [Section 2](#) focuses on who is involved in the experiment, i.e., the investigator or experimenter on the one hand, and the participants on the other hand. [Section 3](#) highlights some issues linked to the information that is given to the participants. Data issues are dealt with in [Section 4](#). Finally, [Section 5](#) focuses on publication and related ethical and scientific integrity concerns.

### WHO IS INVOLVED IN THE EXPERIMENT?

Two kinds of people are involved in an experiment: the investigator and the participants.

#### The Investigator

The principal investigator of an experiment must be a permanent researcher in the lab, which means that this person is accountable for the experiment even if it is actually conducted by a Ph.D. student, for example. The investigator's (or experimenter's) behavior, vocabulary, and nonverbal language during the experiment may not be neutral as far as the participants' behaviors and performance in the experiment are concerned.

#### The Participants

As participants are needed to conduct the experiment, who can be recruited and how they will be recruited have to be specified. Neither of these is ethically neutral.

- Who can be recruited: *inclusion* and *exclusion* criteria must be clearly stated, e.g., only right-handed participants with no hearing problems are invited to take part. This raised two issues: the criteria may be intrusive, so an aggregation of criteria may be relevant to avoid any emphasis on a particular ability or inability; and how the criteria are assessed—is it a mere statement of the participant, or an affidavit, or are the criteria checked by some means, e.g., a hearing test? In the latter case, who performs the test and the way the results of the test are processed may raise ethical or even legal issues (for instance, illegal practice of medicine).
- The way participants are recruited (online or newspaper advert, notice, flyer, email, etc.) and the targeted population for the advertisement (people in the street, office colleagues, students at the university, etc.) may not be neutral as far as experimental results are concerned because, for example, all the participants may share common features (age, education, knowledge of the research being conducted, etc.), which may introduce a bias in the results.

## INFORMATION GIVEN TO THE PARTICIPANTS

Before the experiment itself begins, each recruited participant must be given relevant information by the investigator about the purpose and procedure of the experiment and about the potential benefits and risks for themselves. Information should clarify several criteria,<sup>1</sup> the most important ones being:

- freedom: the participant enrolls willingly, i.e., with no constraint or pressure;
- justice (or equity): all participants are considered in the same way;
- benevolence (or no nuisance): participants are treated with respect and kindness;
- privacy and confidentiality.

Even when the experiment does not pertain to medical research, an *informed consent* is often signed by the participants (or their legal representatives).

### Can the Criteria Really Be Satisfied?

Several ethical issues about these criteria may be raised.

*Freedom* is likely to be impaired when there is an authority relationship between the experimenter and the participants, for example a professor with his/her own students, a doctor/patients, a manager/subordinates. As far as students are concerned, whether they enrol or not as participants in an experiment conducted by a professor at their university should not be linked in any way to grades, recommendations for application files, or more broadly to whatever they are involved in as students.

Real *equity* may be difficult to guarantee; indeed, experiments often require that participants are split up into different groups, e.g., a control group and several other groups with different experimental conditions. Consequently some participants may be involved in simple tasks with no physical or psychological constraints, whereas others may be involved in complex tasks undertaken in stressful, tiring, or questioning conditions.

Some neuroscience experiments rest on the fact that participants are put in some special states, such as stress, tiredness, boredom, physical or psychological discomfort, strong emotions, etc. For such experiments the *benevolence* criterion may be questioned.

Privacy and confidentiality are discussed in [Section 4](#).

### To What Extent Is the Participant Informed?

A first issue is whether clear and simple information is actually compatible with an explanation of all scientific challenges of the experiment.

Furthermore, some experiments may rest on the fact that the participant is deceived about the real purpose of the study, e.g., the well-known Milgram experiment, as telling the truth would impair the scientific issue. In such cases the participant gets information which does not disclose all aspects of the experiment (omission) or which states purposes that are not the actual ones (deception). Even if it is recommended that participants are informed about the real purpose of the experiment immediately after they have taken part, the debriefing may be counterproductive in so far as the participants may feel worried about what they have done (Milgram-type experiment), angry about having been deceived, etc.

### Potential Benefits and Risks

Information must include the potential benefits of the experiment to the participant and the foreseeable risks.

As far as benefits are concerned, the consent should at least mention that participants will be informed of the global results of the experiment if they wish. The participant may learn new skills while taking part, which has to be mentioned. Compensation in cash or in kind may be contemplated provided that it is derisory and the same for all participants whatever their role in the experiment, e.g., even if they decide to leave the experiment before it is finished, according to the equity criterion. Indeed, the motivation of the participant should not be linked to compensation, as this would contradict the very notion of voluntary participation.

Foreseeable risks should be minor, e.g., light tiredness, allergy to adhesive strips used to put sensors on the skin, etc. Any induced risks of the experiment should be considered, e.g., a complex task with added stress or fatigue is likely to bring about a feeling of failure and lowered self-confidence, especially when the participant is a professional and the experiment is linked to their skills, e.g., a pilot facing a difficult landing task in a flight simulator. A key ethical question is to balance the benefit/risk ratio: to what extent is it worth provoking the participant's inconvenience for the sake of science?

## Incidental Findings

Neuroergonomics experiments may involve fNIRS (functional near-infrared spectroscopy), MRI (magnetic resonance imaging), or other means that are likely to show pathologies of which the participant is unaware; but the experimenter is not competent to interpret images or data outside their own field. Consequently information given to the participant should mention that they should not expect any diagnosis from the experiment. Nevertheless a crucial issue is whether the participant's data should undergo a clinical check.<sup>2</sup>

## DATA

The first goal of an experiment with participants is to collect data from the participants. Several issues are raised by data collection, data processing, and data storage. Indeed, a good starting point is to apply the who, what, why, and when test to the collection and storage of personal information.<sup>3</sup>

### Which Data Is Really Necessary?

This is the why, i.e., why is the data required?<sup>3</sup>

If data is not necessary for the study, it should not be collected. Indeed, data minimization is especially important when personal data is at stake. For example, if the participant's picture is not necessary or can be replaced by an avatar, it should not be collected; and if only the participant's age is required, there is no need to collect their date of birth.

### Personal Data

Personal data has been defined, for example by the European Union and the IEEE Meaning of I-E-E-EIIEEE, pronounced "Eye-triple-E," stands for the Institute of Electrical and Electronics Engineers. The association is chartered under this name and it is the full legal name. However, as the world's largest technical professional association, IEEE's membership has long been composed of engineers, scientists, and allied professionals. These include computer scientists, software developers, information technology professionals, physicists, medical doctors, and many others in addition to IEEE's electrical and electronics engineering core. For this reason the organization no longer goes by the full name, except on legal business documents, and **is referred to simply as IEEE**.

"Personal data shall mean any information relating to an identified or identifiable natural person; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity."<sup>4</sup>

"Personally identifiable information (PII) is defined as any data that can be reasonably linked to an individual based on their unique physical, digital, or virtual identity."<sup>3</sup>

Consequently the participant's pictures, voice, and to a certain extent physiological data are personal data. Indeed, recent findings are that neural signals should be treated as a user's PII.<sup>5</sup>

### Anonymization and Pseudonymization

Anonymization breaks the link between data and a given participant so that the participant cannot be identified, directly or indirectly (e.g., through cross-referencing), from their data. Anonymized data is not PII any more. Pseudonymization aims at making data less identifiable but allows data to be tracked back to the participant, e.g., through a correspondence table between pseudonyms and identity data, or a random number replacing identity data. Pseudonymized data is still PII.

As a matter of fact, real anonymization methods hardly exist, although there are some attempts.<sup>6</sup>

Several issues are raised by so-called anonymization.

- Information given to the participants often mentions data anonymization, while most data processes that are used are actually pseudonymization.
- Participants are informed that they may leave the study at any time, which suggests that they may ask that their data be destroyed at any time. This is impossible if data is really anonymized, since a given participant's data could no longer be found to be removed and destroyed. Only pseudonymization allows participants to leave *at any time*.

- Video blurring does not seem to bring sufficient anonymization any more.<sup>7</sup> Consequently all identifying features (face, tattoos, etc.) have to be hidden. If they cannot be hidden and the videos are likely to be watched by people other than the researchers involved in the experiment, a specific permission must be obtained from the participants.
- Online questionnaires which are said to be “anonymous” most of the time are not. Indeed, a unique identifier associated with, e.g., the participant’s IP address must be implemented so as to avoid multiple participation and ballot-box stuffing. Yet IP addresses are personal data in some cases.<sup>8</sup> Moreover, cross-referencing a given participant’s answers is likely to identify this participant.

## Data Storage and Access

Anonymized or pseudonymized collected raw data should be stored separately from the participants’ consents and the correspondence table between pseudonyms and identity data. The storage conditions must be secure and placed under the responsibility of the principal investigator. In particular, storing data on a cloud on the internet, even if it is said to be “secure,” or on a shared space on the lab intranet must be questioned.

As far as access to data is concerned, the following questions have to be raised.<sup>3</sup>

- Who requires access and for what duration?
- What is the purpose of the access? Data collected for a study the participant has consented to should not be reused for another study, unless each participant is asked to sign a new consent. Nevertheless, extending or generalizing the scope of data usage can be considered when giving initial information to the participant provided that what the participant consents to is clear enough.

How long data will be kept and when, how, and by whom it will be destroyed should be specified. The fact that data should be kept for only a limited duration may conflict with the necessity of providing data supporting the content of a publication or with experiment replication.

## TOWARD EXPERIMENT RESULTS PUBLICATION

### Approval by an Ethics Committee

Experiment projects involving human participants should be reviewed by an ethics committee prior to the beginning of the experiment: appropriate approval, licensing, or registration should be obtained before the research begins and details should be provided in the report (e.g., institutional review board, research ethics committee approval, national licensing authorities for the use of animals, etc.).<sup>9</sup> This is compulsory for collaborative projects, such as European projects,<sup>10</sup> and above all to enable the publication of results. For example, the publishers Elsevier and Springer mention that when reporting studies which involve human participants, authors should include a statement that the studies have been approved by the appropriate institutional and/or national research ethics committee and have been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Two issues are worth mentioning as far as ethics committee reviews are concerned. First, the significance of ethics committee reviews might be questioned in so far as they depend on who actually reviews, who attends the committee meetings, etc. Second, ethics committees can hardly check that an experiment will actually be conducted as presented for review. The obligation to submit the actual experiment protocol and the informed consent to journals could be relevant.

### Conflicts of Interest

Researchers involved in an experiment are supposed to declare any conflict of interest when they design the protocol. Whether this requirement is sufficient or even relevant is illustrated below by three issues. The analysis is based on a general recognized definition.<sup>11</sup>

One issue concerns honesty: even the most upright researcher might be unwilling to declare a conflict of interest if this is likely to cancel a project that matters to them.

Another issue is the involvement of companies with a high degree of bias. For example, a recent study<sup>12</sup> highlighted dramatic statistics in the field of genetically modified organisms (GMOs). During the last two decades, 40% of 672 published

articles presented a conflict of interest. It is worth noting that the results of experiments in cases of conflict of interest are more frequently favorable to the interests of the GMO industry, but the link between conflicts of interest and the frequency of favorable opinions for the industry was not established.

Finally, no matter what the research organization (industrial company, public or private laboratory, etc.), scientific results are required to remain competitive and attractive, and this mainly relies on researchers. Moreover, as an individual, the researcher needs to publish to be recognized by the scientific community. Such pressure can lead to unethical behaviors, such as only considering results that can be further exploited; considering a partial result as a result; and believing that the faster a result is obtained, the better. A broader question is then: can an experiment be totally free of conflict of interest, i.e., avoid both industrial interests and personal interest?

## More Scientific Integrity Issues

Experiment results may correspond more or less exactly to what was expected. To embellish results, some questionable research practices are likely to be adopted,<sup>13</sup> e.g., failing to report all of an experiment's conditions, excluding data, stopping collecting data earlier than planned because one found the result that one had been looking for,<sup>14</sup> using inappropriate statistics to support one's hypothesis,<sup>13</sup> etc. Some researchers<sup>14,15</sup> have shown that such scientific misconducts are far from being rare. Moreover the temptation may be great to break up or segment data from a single study and create different manuscripts for publication (salami slicing),<sup>16</sup> which is also unethical.

## CONCLUSION

While some issues are often highlighted by the ethics committees that are in charge of reviewing experimental projects, others stem from biases inherent in the very research process. Consequently ethics should not boil down to box ticking, which does not stimulate thought, but rather should be a *process* to be implemented all along research and even inside research itself. As far as an experiment is concerned, its purpose and the way it is conducted must be questioned at every step, and each time new investigation or data-processing techniques appear. Indeed, ethics should not be perceived as a constraint to research and innovation, but rather as way of ensuring high-quality results.<sup>17</sup>

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