Balancing Benefits, Burden, Risks and Limitations; how to do Design when Human Beings are involved…

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The Netherlands Code of Conduct for Research Integrity and the, derived, Code of Ethics of Eindhoven University states that for both students and staff: “In their research and design, they adhere to the ethical codes for activities in which human subjects and animals are involved.”. This paper tries to give a short introduction what this means for research and design projects in the field of Industrial Design. It centers around four central themes: Benefits, Burden, Risks and Limitations. This paper is, by far, not complete; it aims at creating awareness and providing connections to other, more detailed, material.

Since the mission of our department explicitly includes “designing in a societal context” many researchers and designers want to do research on- or to design systems and products for- use by human beings; often to alleviate certain societal problems including health, wellbeing, mobility and social inclusion. It is important to realize that in this process things can and will go wrong; this is a normal part of research and design. It is, however, important that this process is handled with great care in order to avoid that human beings (or animals) are hurt unnecessarily and that, if things go wrong, adequate processes are in place to handle possible consequences. In this context it is always important to balance Benefits and Burdens; there can be projects with limited benefits where the actual burdens to (end-)users and/or test-persons are limited but there can also be projects, for example in the medical fields, where the burdens (and related risks) to people can be considerable but where the (potential) benefits outweigh these disadvantages; both types of projects are normal in an academic research/design environment but it is obvious that the latter process requires more attention than the first. It is important, in all cases where humans are involved, that before a research or design plan is submitted a careful consideration is made on Benefits, Burdens, Risks and Limitations. The following paragraphs will address each of these topics more in detail.

Benefits

In analyzing the benefits of a research/design project it is always important to distinguish the perspectives from all (potential) stakeholders involved. This includes of course the possible users but also the researchers themselves. Next to this there can be a wide range of (secondary) stakeholders such as (in healthcare) caregivers, (in industry) suppliers/customers, etc. Benefits can include alleviating (societal) problems, making profit etc. For the designers/researchers it can be gaining knowledge, satisfying curiosity, learning, setting-up a business etc. It is, however, important to describe these expected benefits explicitly so that they can be used to balance possible burdens for people involved in the design/research process.

Burdens

The process of research and design for human beings always will always include activities where (potential) users and/or stakeholders become involved. This will result in a burden for these people. The burden is, of course, different for a short interview than for participation in an extended longitudinal use study. However, even short interviews can cause serious stress or harm for the participants involved when certain (controversial) questions are asked. Generally speaking, it is possible to distinguish four different types of burden that can occur for human subjects involved as (test-)participants in a design process: Effort, Spending resources, Discomfort, Danger.

The following section will address these aspects more in detail:

- Effort: The mere fact that people participate in design/research requires effort. Effort can be expressed in time but also in physical effort or otherwise. It is important that both the designer/researcher as well as the participant acknowledge this effort and that participants are compensated accordingly. Compensation can have different forms: from appreciation (from the researcher) for the help provided to an actual monetary compensation or an equivalent.
- Spending resources: In many cases participants are required to spend resources to participate. Examples can be transportation costs, taking leave in order to participate or even to buy consumables (food/drinks) as a consequence of participating in a design or research project. Also, here adequate compensation is required.
- Discomfort: Asking people to participate in a design or test may create discomfort for the users. Discomfort can be both of a psychological or physical nature. Discomfort can occur when participants are brought in a situation where they feel stressed, do not feel comfortable or just do not want to be in. Examples of psychological discomfort can result from, for example, unpleasant, intrusive or annoying questions while physical discomfort can result from unpleasant environmental factors such as (unpleasant) sounds, light signals, temperature but also several forms of physical exercise can create discomfort. Test persons will always have to have the option to opt-out or cancel the test when experiencing discomfort. Next to this they will have to be briefed on beforehand and will have to be adequately compensated.
- Danger: the difference between discomfort and danger can, in many cases, be difficult to distinguish. Generally speaking, tests are “dangerous” when there is the likelihood of highly undesirable, sometimes irreversible, side effects. Generally speaking, dangerous situations should be anticipated and mitigated as much as possible (see also section on Risks) but there are situations where also the likelihood of dangerous situations is accepted since alternatives are not available.

In principle there is nothing wrong with imposing, even considerable, burdens to (test-)persons in a design process provided that

- The benefits outweigh the burdens
- Alternative strategies, with less burden involved, are not available
- Adequate compensation is provided
- Potential risks (see also following paragraph) are explicitly described and, where appropriate, risk mitigation plans are in place

In this context it definitely makes sense (especially with tests with considerable burden for the test-persons) to explicitly look for results of earlier tests and see in how far they can be used instead.

Risks

In setting-up a design and or research plan every researcher/designer will hope that everything will develop exactly as planned. Since both design and research are process with unpredictable outcomes things can also go wrong. The mildest form of a risk is that a test does not result in the expected outcome with no further side-effects. However, it is also known that tests can have undesired or even dangerous side effects that can cause a considerable burden or even danger for the people involved. In setting-up a design or research project with people involved it is important to try to anticipate these risks as much as possible on beforehand. Tools, such as Failure Mode and

Effect Analysis (FMEA) provide a systematic way to anticipate risks and to develop adequate risk mitigation plans.

However, even the most detailed risk prediction tools cannot predict everything. It is important to recognize that in every research and design project things can and will go wrong; sometimes with serious consequences for the people involved. Therefore, it is good to think already on beforehand on Out of Control Action Plans (OCAP): what to do in unanticipated situations. An OCAP always should include: when to stop, how to limit fall-out and how to learn for the future.

Special attention is required when vulnerable people are involved. Examples of vulnerable people are children, elderly people an people/patients with relevant medical conditions. There are special provisions in the law to protect vulnerable people since they may not always oversee the impact or consequences of participating in a test. This will often result in approval, not only of the participants themselves (if this is possible) but also of an overseeing authority such as (for children) parents and (in a school context) the school authorities, for elderly also from the relevant caregivers and for patients from the medical authorities (most often a Medical Ethical Approval Committee, METC).

Limitations

In order to mitigate risks during design and research processes it can be helpful, for example as part of an Out of Control Action Plan, to explicitly define limitations; situations that are clearly undesirable and will be avoided. As an example: unless the research/design project explicitly requires this, avoid situations where traumas or religious, ethnical or other sensitive topics play a role. Concentrate on what is really relevant on the research or design project at hand. Avoid, when possible, situations that may cause strong emotions. When these situations can not be avoided as part of the research/design process: take care that qualified, registered, professionals are actively involved in the tests. When undesired situations unexpectedly occur: be prepared to stop the test and assure adequate follow-up (see also OCAP).

Conclusion

It is obvious that how much preparation is required strongly depends on the situation at hand. Low risk, low burden tests require less preparation than high-risk, high burden tests. Nevertheless, also the latter are a very important part of the process of research and designing; certain, important, challenges can only be addressed by taking considerable risks and/or imposing considerable burdens to the people involved. Therefore, also these tests are a normal and essential part of research and design. It is obvious, however, that the latter requires careful study of possible alternative and, if these are not available, a most careful preparation.