Ethical Review in the FRR Project – A Continuous Process

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Ethical Peer Review in FRR

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Background: Fifth Framework Program

Decision of the Parliament and the Council:

“All research activities conducted pursuant to the Fifth Framework Program shall be carried out in compliance with fundamental ethical principles, including animal welfare requirements, in conformity with Community law.”
Wider Effects of Ethical Review

Ensure that all ethical questions have been adequately addressed before the funding of the project.

Ethical review serves to:

• Raise awareness of ethical issues in life sciences and duty of scientists to address them
• Keep ethical issues high on the agenda
• Encourage Member States to develop or reinforce legal and ethical frameworks in relation to research
How to deal with the involvement potentially frail users in testing prototypes of a toilet that are located in an office space?

- Safety
- Respect, integrity
- Privacy and confidentiality

None of us wanted to try out the prototype in the presence of others!
The FRR Approach to Ethical Review

Descriptive – Continuous - Enlarged

- Less normative and evaluative
- Not relying solely on existing research and professional guidelines or principles of medical ethics
- Active participation, continuously addressing the ethical dimensions:
  - Special user group
  - Sensitive area of research, “taboo”
  - User-driven nature of FRR research
- Action research aspect: approach facilitates learning about ethical aspects of one’s work
Methods

Ethnographic fieldwork

- Participation in meetings, observation of user tests
- Interviews with users and developers
- Analysis of project materials and reports

Conceptual clarification
Ethical Review in Practice

Normative work
- Identification of ethical issues in the test and research design – common approach
- Awareness raising of ethical dimensions
- Background work – comparison of existing guideline documents
- Feedback to URBs and Consortium, Reporting

Guidance work
- Sensitive area of research - how to remove the taboo effect of testing a toilet?
- Process of informed consent, gradual, step-by-step increasing familiarity with the FRR

Empirical work
- Observation of user tests
- Interviews with users
- Focus group with users
- Feedback to the URBs and Consortium, Reporting

“Developing Friendly Rest Rooms for the elderly and the disabled people”
FRR Final Conference Vienna, 17th March 2005
Peeling away the Taboo: Step-by-Step Informed Consent

1. At home
   Information Kit
   Peer information
   Do I want to Participate?

2. Meeting room
   More information.
   Would you like to see the FRR?

3. Lab
   Developers show, tell, and try out the FRR.
   Would you like to try it out?

4. Lab
   User tries out the FRR.

Renewal & Exit
Observations-
Test
Situations

Carefully prepared and rehearsed
  – a script was prepared and rehearsed
  – pilot tests were performed
  – meaningfulness of tasks to be performed was discussed

Good atmosphere and rapport were created through
  – humor
  – refreshment breaks
  – Small, important signs of caring about the user

A good practice, “ethics”, was kept high on the agenda
Observations - Participants Displayed

Trust in the project, institutes and developers
– open, active, courageous participants
– “This could embarrassing, but everything has always been handled delicately.”
– “There are no secrets here.”

Confidence
– Felt confident giving feedback: “If it is made for us it must be made properly.”

Well-being in the test situation
– Spontaneous comment: “It is really great here with you.”
– “This is fun.”
– “I have felt safe and important here.”

Understanding the limits of benefit
– “I am doing this to benefit future pensioners, like you.”
Feedback on Informed Consent Procedure

“I liked the information very much. It was serious and important.”

“Information gives a good feeling and it needs to be provided for the users in advance.”

“We were always very well informed.”

“We were always asked if everything was ok.”

“I found it good that I was told how long the test would take and that I was reminded that it is the prototype, not me, that is being tested”
Lessons Learned

Despite all our efforts…

...to act responsibly toward the users and their needs, protect their integrity, privacy and wellbeing, good preparation of the users and ourselves...

…the unexpected can happen, as the test situation can:

– trigger an emotional response - it can be a reminder of one’s disability or of loss of autonomy
– be physically strenuous (many transfers)
– be interpreted by the test persons as a test of their capacities (“how many did I get right?”)

Additional challenge:

There is limited control in presenting the project outside the consortium.
“Developing Friendly Rest Rooms for the elderly and the disabled people”

FRR Final Conference Vienna, 17th March 2005

Prototypen-Test: „Toiletten mit Hirn“!

Der Gang aufs WC stellt für viele Menschen mit physischer Behinderung ein Problem dar. Damit das „natürlichste Bedürfnis“ keine unnatürliche Anstrengung mehr kostet, forscht die TU-Wien nun an einer „intelligenten“ Toilette. Das Bezirksjourn-

al berichtet exklusiv vom ersten „Probesitzen“!

von Hannes Wieser


Jedem sein „High-Tech-Klo“

Man muss sich das so vorstellen: Schon beim Betreten der Toilette stellt sich diese automatisch auf die von der jeweiligen Person als optimal erachtete Position ein. Nach dem Verlassen sorgt ein vollautomatisches Reinigungssystem für optimale Hygiene, und die vielen nützlichen Hilfssysteme der intelligenten Toilette fahren wieder in einen unauffälligen Ruhezustand zurück.


Das Forschungsprojekt wird von 11 Partnern aus 7 EU-Ländern durchgeführt. Mehr Informationen zur Intelligenten Toilette: www.fortec.tuwien.ac.at/frr
Concluding Thoughts

Ethical peer review helped put ethical questions continuously on the agenda of the FRR project.

The cooperation with the ethical review team appeared to raise project workers’ awareness of ethical issues in their work. The cooperation was considered useful.

Influence on work practice: the process of informed consent is a tangible and probably lasting input for future work with users.

Based on our experience we propose: R&D projects that involve frail persons and that deal with a sensitive area or research should adopt a continuous ethical peer review.
Thank you!

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