

# 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

## Concrete Challenge in Vienna

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

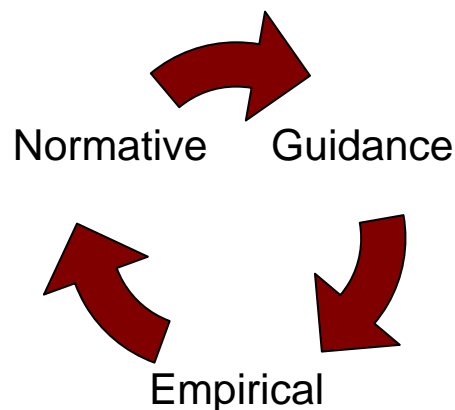
## Methods

### 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

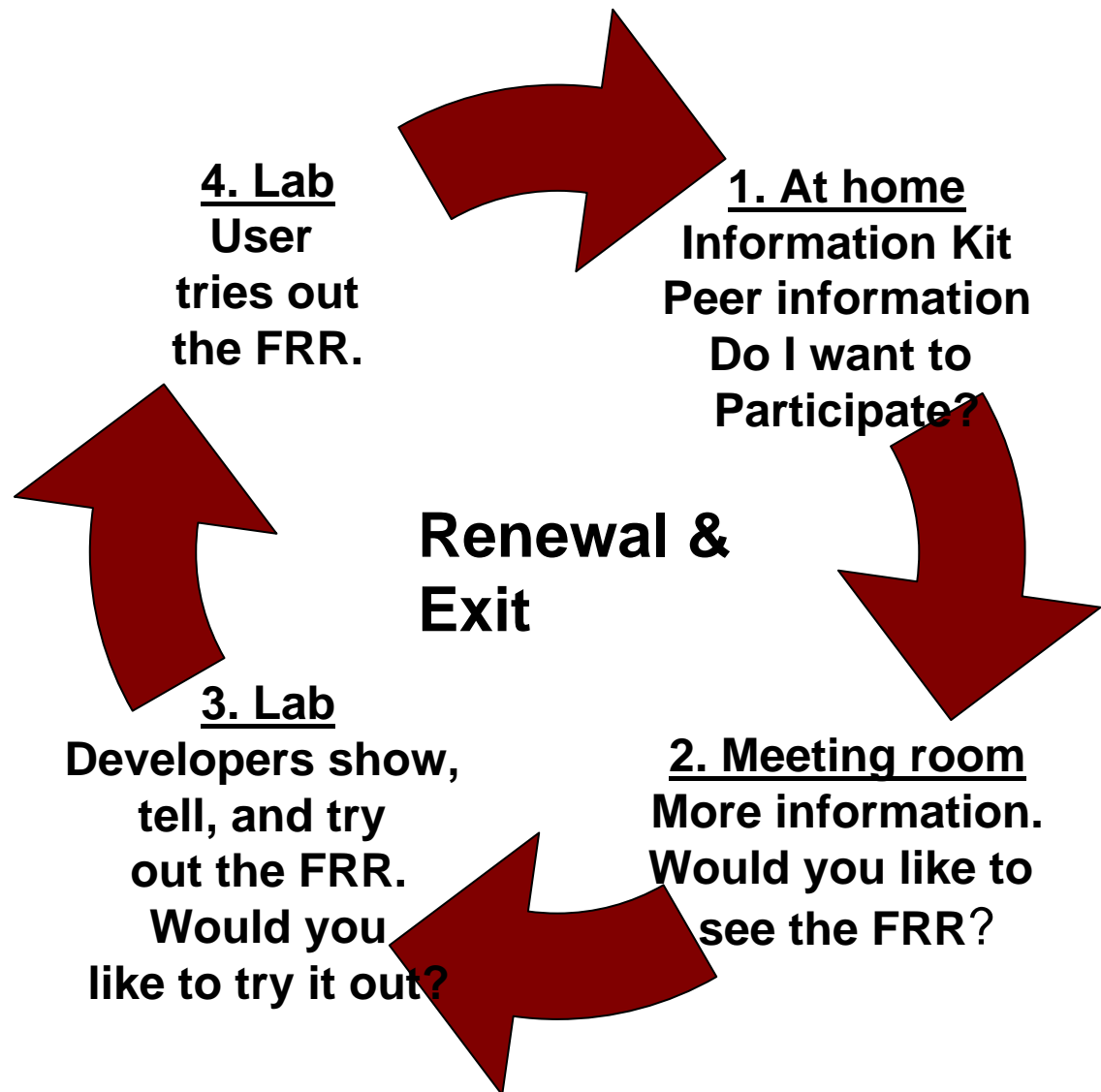
## Guidance work

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

## Peeling away the Taboo: Step-by-Step Informed Consent





## 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 be 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.

# **Prototypen-Test: „Toiletten mit Hirn“!**

Der Gang auf's 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 Bezirksjournal berichtet exklusiv vom ersten „Probesitzen“!

■ von Hannes Wieser

„Bei einer 'Toilette mit Hirn' passt sich jede ihrer einzelnen Komponenten an die unterschiedlichsten Bedürfnisse körperlich beeinträchtigter Menschen an“, erklärt DI Paul Panek von der Forschungsgruppe für Rehabilitationstechnik „fortec“ an der TU-Wien.

## **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 Hilffsysteme der intelligenten Toilette fahren wieder in einen unauffälligen Ruhezustand zurück.

Was die technologischen Herausforderungen betrifft, so kommen berührungslose „smart card“-Technologien mit Lese- und Schreibfähigkeit genauso zum Einsatz wie Sprachsteuerung, Bewegungssteuerung, Sensorsysteme und modernste Roboter-technik. Ob die Bedienbarkeit dieser Toilette auch verstanden wird, erforscht man



Name of  
Test person ■

**testete das erste Labor-Prototypensystem der neuen „intelligenten Toilette“ sprichwörtlich auf Herz und Nieren.**

gerade mit umfangreichen Anwender-Tests. Beim ersten Probesitzen im Versuchslabor gab's lediglich mit der Fernbedienung (kleinere) Probleme. Testperson Ernst Böck resümiert: „Die Symbolik der

Bedienungselemente an der WC-Fernbedienung ist noch nicht ganz eindeutig. Sonst funktioniert's aber ganz gut.“ DI Panek ergänzt: „Vor allem die Sprachsteuerung kommt bei den Testpersonen sehr gut an.“ Und: „Schon im Herbst wollen wir den endgültigen Prototypen in einem Caritas Socialis Tagesheim installieren.“

Das Forschungsprojekt wird von 11 Partnern aus 7 EU-Ländern durchgeführt. Mehr Informationen zur Intelligenten Toilette: [www.fortec.tuwien.ac.at/frr](http://www.fortec.tuwien.ac.at/frr)

Foto: Wieser

## 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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