PIA Project and Ethics

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PIA Project Ethics Manager
Relevance of Ethics for PIA project

research activity:
user involvement and field trials

system design
Ethics, a definition

*ethics*: ensuring the dignity, rights, safety and well-being of research participants and of users of technology
Project to Use RESPECT Code of Conduct for Research

Minimum standards and a framework for the conduct of ethical research in Europe

Based on three main principles:
• Upholding scientific standards
• Avoidance of social and personal harm
• Compliance with the law
Compliance

We need to ensure compliance with

• any relevant regulations - European and those within each country
e.g. Mental Capacity Act 2005 in UK

• ethics approval systems (academic, local and/or national).
Ethics Approval

Action: all need to find out who need to apply to and when / timings.

May need to apply in two stages,
1) Initial user involvement in focus groups etc
2) Field trials.

Each participating country is responsible for applying for any relevant ethical approval.
Ethics Approval Requires submission of research materials to be used, e.g.

<table>
<thead>
<tr>
<th>Focus Groups</th>
<th>Trials</th>
</tr>
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<tbody>
<tr>
<td>Non-Disclosure Agreement</td>
<td>✓</td>
</tr>
<tr>
<td>Consultation / Focus Group Topics</td>
<td>✓</td>
</tr>
<tr>
<td>Information Sheet for participants</td>
<td>✓</td>
</tr>
<tr>
<td>Eligibility Questionnaire for primary users</td>
<td>✓</td>
</tr>
<tr>
<td>Consent Forms for primary and secondary user</td>
<td>✓</td>
</tr>
<tr>
<td>Consent Form - Information about the Tablet – agreement regarding ownership, usage and responsibilities</td>
<td></td>
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<tr>
<td>Background Questionnaires for primary and secondary user</td>
<td>✓</td>
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<tr>
<td>Well Being Questionnaires for primary and secondary user</td>
<td>✓</td>
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<tr>
<td>Interview Guides for primary and secondary user</td>
<td>✓</td>
</tr>
<tr>
<td>Questionnaires – Feedback on Experience and Satisfaction – for secondary user</td>
<td>✓</td>
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<tr>
<td>Tick Box Diaries for primary and secondary user</td>
<td>✓</td>
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<tr>
<td>Questionnaire – Willingness to Pay</td>
<td>✓</td>
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Also Necessary

for project and for ethics approval applications:

• **Guidelines for Tests and Trials** to include Recruitment Plan

• **Code of Conduct for Fieldwork**
Compliance - Data Protection

- Charter on the fundamental rights of the European Union (2000/C364/01)
- EU Data Protection Directive 1995
- Any other requirements within each country.

For info:

New European Data Protection Regulation proposed designed to harmonised data protection law across Europe, & account for changes in technology since - should be introduced in 2014
Recommend –
Develop Ethical Framework

e.g.
- Privacy
- Autonomy
- Integrity and dignity
- Reliability
- E-inclusion
- Role of technology in society
- Equality of access
... and a Risk Matrix

Help us to reach sound decisions about the ethical acceptability and optimal regulatory controls for the PIA system

- *balance between the benefits and risks*
- *balance of differing stakeholder needs*
- *balance between autonomy, freedom and privacy, and responsibility, sustainability and beneficence*

Recruitment
Information to users
Field trials
Communication with users

Dignity /privacy

Exit strategy
Data use and storage
Use of results
After-trial use of equipment