

The logo for 'enable' is displayed in a white, lowercase, sans-serif font on a dark blue rectangular background. The letters are slightly shadowed, giving it a three-dimensional appearance.

A large, stylized version of the 'enable' logo. The word 'enable' is written in a white, lowercase, sans-serif font with a thick outline. It is set against a blue, wavy, ribbon-like background that curves under the letters.

Experiences in Project on Informed Consent, Ethical Dilemmas and Procedures

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Research among people experiencing dementia

- **People experiencing dementia face a double jeopardy [Rodeheaver and Datan, 1988]**
- **Ageism and stigmatisation [Proctor, 2001]**
- **Societal place of isolation and exclusion [Cotrell and Schulz, 1993]**



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- **Redress in the way people can be included and heard [Wilkinson,2002]**
 - **How far has Enable sought to promote appropriate inclusive practises ?**
 - **To bear witness to the person as an active participant and place at the core of the Enable project**



Ethical Procedures: cross country **experiences**

- **Enable ethical approval unique cross culturally**
- **Diversity of systems operating nationally**
- **Similarity: detailed and thorough research outline and proposal required and how to obtain informed consent**



NATIONAL LEVEL

- **Norway – one committee approved after three weeks, and one notified**
- **Finland – own organisational ethical committee and the Alzheimer's Association with research and protocol plan.**
- **Lithuania – Attend meeting of Bio – medical Research Ethic Committee**



Ireland and England

- **Extensive application forms**

England

- **reported greatest challenge to approval 8 different committees– 11 months**
- **Committee unfamiliarity with research type**
- **‘Scientific validity’**
- **People viewed as secondary in consent process**
- **Highlight need for informed multi disciplined committees**



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- **Carers often sought as advocates**
 - **To obtain information essential to include the person experiencing dementia as an active participant**
 - **Involves seeking informed consent**
 - **How is this possible?**



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- **Health, social welfare and housing**
 - **Recruit potential participants**
 - **‘ Gatekeepers’**
 - **Key to gaining access to participants**
 - **Crucial to the consent process**



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- **Identifying key participants through telephone and visits to day centres**
 - **Visits at home to introduce Enable**
 - **Crucial that interest in product derived directly from participant**
 - **Home visits allow verbal and non verbal communication and expression to be observed and assessed for motivation and interest**



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- **Gaining potential participant approval**
 - **Expression of interest**
 - **Written consent with researcher allowing for questions and concerns to be raised**
 - **Crucial to inform participant is allow to withdraw at any stage of the research, and that consent is a *continuous process***



Consent Experience

- **Unique research situation afforded an interview situation in which trust and rapport could be fostered**
- **Participants felt safe to and state whether or not they wanted to continue in the project**
- **Contact with carers and health professionals to ensure privacy and respect for participant and to proceed with up and coming interviews**



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- **Researchers' aware that obtaining intimate information that could evoke emotion**
 - **Highly relevant, ethically, people with dementia reassured**
 - **As individuals and as participants that they were VALUED.**



Dementia Specific

- i. Rapidly changing home life situations and in health conditions of participants**
- ii. Consent could be difficult to ascertain in these circumstances**
- iii. Person's needs V that of the carer**
- iv. Wanting to please**



Carer Specific

- ✍ **Concern by carers that they should not begin the study knowing that they may not be able to complete the project**
- ✍ **Carers protective - for fear of distress**
- ✍ **Resulted in withdrawal prior to consent from person experiencing dementia**



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- **Significant interest and high expectations**
 - **Matching individual need to device**
 - **Delays in informed consent due to delays in devices**
 - **Parts arrived - participants lost interest**
 - **Devices arrived – participants vacationing for summer months**



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- *Availability* - not all products available
 - *Prototypes* – High expectations and faulty devices
 - *Levels of motivation* – Health carers began to lose interest with faulty devices impacting upon further recruitment



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- **Impact upon recruitment**
 - **Impact upon level of interest**
 - **Person's needs V carers'**
 - **Person's needs V other agents**
 - **Potential impact upon quality of feedback – statements differ to engineers/researchers/carers/ health workers**



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- **Advisory networks and panels**
 - **Continuous informed consent**
 - **Listening and hearing the person**
 - **Consultation with carers and professionals**
 - **Multi disciplined consultation**
 - **Positive view of ethical procedures**
 - **Commissioners' awareness**

