Project No.: 044406

Project Acronym: PROMENPOL

Project Title: Promoting and Protecting Mental Health – Supporting Policy through Integration of Research, Current Approaches and Practices

Instrument: Co-ordination Action

Call Identifier: FP6-2005-SSP-5A

ProMenPol Ethical Vision and Guidelines (Ad-Hoc Deliverable)

Project Start Date: 01/01/2005 **Duration:** 36 Months

Organisation name of lead contractor for this deliverable: Work Research Centre (IRL)

Revision [2]

Project co-funded by the European Commission within the Sixth Framework Programme (2002-2006)		
Dissemination Level		
PU	Public	**X**
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission	
CO	Confidential, only for members of the consortium (including the Commission Services)	

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Document History						
Edi	**Rev**	**Date**	**Confidentiality**	**Description**	**Action**	**Pages**
01	01	06/2007		Ethical Vision – Ad hoc Requirement	C	2-11

(*) Action: I = Insert R = Replace C = Creation

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1. Introduction

The ProMenPol project is structured into three phases of activity. In the first, a conceptual framework will be developed for understanding and organising methods and tools to promote mental health within the three settings for the project (educational institutions, workplaces and residential facilities for older people). In the second, a set of tools for the promotion of mental health will be developed while in the third these tools will be piloted in a range of settings within the participating countries and amended on the basis of their evaluation in these settings. Dissemination of the outputs of all three phases will also take place.

A number of ethical issues arise within the ProMenPol project particularly in Phase 3 – particularly relating to informed consent, data security & confidentiality and relevant guidelines & regulations. What is required is an ethical vision that can inform the partners and the pilot sites that will ensure that the implementation of the study complies to best practice in ethical decision making. There are a number of relevant national and international guidelines and regulations that can assist the ProMenPol partners to develop such an Ethical Vision that can assist all participants to adhere to an appropriate approach to the intended beneficiaries throughout the life of the project.

The Statement of Ethical Vision is intended to set out the approach to be adopted by ProMenPol partners, and participating pilot sites, to ensure ethical excellence in all project activities.

2. Ethical Issues within ProMenPol

The project's focus is on developing useful tools to assist relevant practitioners/professionals, in three settings, create mental health positive environments and activities with a view to promoting and protecting the mental health of participants in each context, i.e. schools, workplaces and residences for older people. This involves collecting data relating to the Mental Health Promotion and Protection tools that are available and classifying them in a way that make more amenable to application in each of the contexts. From this perspective, the greatest proportion of data collected related more to the instruments themselves rather than to the intended beneficiaries. In fact, there will be no direct contact with either patients or the general public within the first two project phases – these phases being concerned with either information collection or information production.

Even in Phase 3, there will be no contact with psychiatric patients within the school or workplace settings – the target groups for the mental health promotion activities are teenagers or adults of working age. No one with a psychiatric diagnosis will be accepted as a participant in a pilot project. It is less clear with regard to older people in residential homes and particularly where an older person is under professional care. In this regard, it is important the ProMenPol partners agree on the ethical framework which will constrain Phase 3 activities and which will be disseminated to all potential pilot sites. The Ethical Vision will be transformed into a Guideline for all those professionals implementing the pilot studies. Thus the proposal below is intended to set out the general principle that should underpin these guidelines.

It is worth exploring the key ethical issues that need to be addressed in the vision and make explicit the reasons why these are of concern. A number of the main concerns are outlined below. The intention is to provide the partners with an opportunity consider these issues and to bring their views to the next meeting.

2.1 Informed Consent

The ProMenPol Phase 3 pilots are being carried out in three different contexts – educational establishments, workplaces and residences for the elderly. In each of the contexts the focus of the ProMenPol tools is always upon Mental Health, not upon Mental Illness. Thus, in the case where a potential participant for a pilot project has a clinical diagnosis of acute Mental Illness, participation in the pilot study is counter-indicated. As such a person with a diagnosis would not be permitted to participate. Hence the issue of informed consent within mainstream settings will operate according to the principles elaborated below interpreted in terms of the lifespan developmental stage of the participant. In education settings this will involve obtaining consent from a parent or legal guardian of under age participants. In workplaces, it will involve gaining consent from employees.

It is within residences for older people that the issue of 'capacity to consent' may well arise. This is particularly so in relation to residents with early onset Alzheimer's. There is little doubt that these individuals are likely to gain positively from the tools and techniques proposed by ProMenPol but it is still essential that the procedures to ensure 'informed consent' are followed carefully. Thus where there is any doubt about a person's 'capacity to consent', the support of an advocate or a family member must be sought to determine 'informed consent' or to consent on behalf of the person where this is

appropriate and legal. In the case where there is any doubt in the matter, the person in question, should not be permitted to participate in the pilot.

During the training of Phase 3 action researchers, i.e. the responsible persons in the pilot site, and during pilot site development, these ethical issues will be raised and appropriate procedures agreed. The application of these procedures will be the responsibility of the Austrian Red Cross. These procedures must include an application for ethical approval to an appropriate body where this exists.

2.2 Guidelines and Standards

During the development of the tools and instruments ethical guidelines will be compiled and integrated into the operation of the tools. The basis for these guidelines will be derived from current best practice and existing ethical codes and guidelines (for example, CIOMS guidelines (2003)1, EU Ethics Research Code (2003)2, the Irish National Disability Authority's Guidelines for Ethics in Disability Research (2005)3 and the European Science Foundation policy for Good Practice in Research and Scholarship (2000)4).

The aim of the guidelines will be to ensure:

- That those operating the tools know what is expected of them and know where to find appropriate guidance
- That ethical issues have a high profile within the tool sets
- The dissemination of good ethical and professional practice amongst those using the tools
- That the requirements of appropriate agencies for formal ethical policies and procedures are met

When it comes to the Phase 3 Pilot Sites, an extra ethical dimension comes into play. This arises because the tools are still in a pilot phase and thus, although they will have been developed on the basis of documented best practice, it can not be assumed that the impact of the tools will be without risk, however minor.

On this basis, the Phase 3 action researchers will have responsibility for:

- Their own ethical conduct
- Conducting or managing all work in accordance with the project's ethical principles
- Seeking expert advice where appropriate (This will be available within the project)
- Developing and maintaining awareness of relevant ethical issues and rules of conduct amongst those with whom they work.

In this regard, the ProMenPol principles incorporate the core values of:

- Respect for human rights, equality and diversity
- Social responsibility

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[1] *Council for International Organisations of Medical Sciences (CIOMS), The International Guidelines for Biomedical Research Involving Human Subjects (Geneva, 2003).*

[2] *Dench S, Iphofen R, Huws U (The Institute for Employment Studies), An EU Code of Ethics for Socio-Economic Research (Brighton, U.K., 2003).*

[3] *National Disability Guidelines, Ethics in Disability Research (2005), National Disability Authority (Dublin, 2005).*

[4] *European Science Foundation (ESF), Good Scientific Practice in Research and Scholarship (Strasbourg, France 2000).*

- ✓ Beneficence
- ✓ Non-malfeasance
- ✓ Inclusivity and voice
- ✓ Professionalism
- ✓ Legality

Various national and international documents have been taken into consideration in finalising these core values, such as the Charter of Fundamental Rights (2000)[5] and the Universal Declaration of Human Rights (1948)[6], in addition to the guides and codes mentioned earlier.

The final safeguard to put in place is the adoption of an ethical review policy within the project. This would provide for the possibility that any pilot study, undertaken within the context of the ProMenPol project, can be subject to ethical review by a relevant appropriate body in accordance with commonly agreed standards of good practice such as are laid down in The Nuremberg Code (1949)[7] and the Declaration of Helsinki (2002)[8], plus the guidelines and codes mentioned earlier.

These may be broadly categorised as follows

- Beneficence - 'do positive good'
- Non-malfeasance – 'do no harm'
- Informed consent
- Confidentiality and anonymity

2.3 Beneficence and Non-malfeasance

- The research should be scientifically sound and the purpose should be to contribute to knowledge
- Research should be preceded by a careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others
- Adequate facilities and procedures should be in place to deal with any potential hazards

2.4 Informed Consent

- Each potential subject must be adequately informed of the research
  - ✓ aims
  - ✓ methods
  - ✓ anticipated benefits

[5] *European Union, Charter of Fundamental Rights of the European Union, Official Journal of the European Communities (Nice, 2000).*
[6] *United Nations, The Universal Declaration of Human Rights, (Adopted and proclaimed by General Assembly resolution 217 A (III) 1948).*
[7] *The Nuremberg Code [from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949. Washington, D.C.: U.S. G.P.O, 1949–1953.].*
[8] *World Medical Association, Declaration of Helsinki Ethical Principals for Medical Research Involving Human Subjects (Amended by the 52nd World Medical Association General Assembly, Edinburgh Scotland October 2002).*

  - ✓ potential hazards and any discomfort it might entail
- Participants must be given the right to refuse to participate
- Documentation given to potential participants should be comprehensible
- Participants must be given the opportunity to raise issues of concern
- Consent should be required in writing
- Records of consent should be maintained
- A complaints procedure must be available and comprehensible to all subjects
- All participants must be volunteers
- Consent must be obtained from others where the subject does not have the legal competence to give informed consent

2.5 Confidentiality and Anonymity

- All research should conform with current data protection legislation
- All confidential details must be securely stored and only accessible to named individuals
- Explicit consent must be gained from a subject to publish where details in a publication might identify that individual

2.6 Ethics Management During the Project

The monitoring and review of all ethical and data management procedures will be carried out by a sub-committee of the project co-ordination committee. This committee will be made up of a representative from each of the participating countries and the members will be:

Country	Member	Qualifications
Germany	Dr. Karl Kuhn (Project Manager)	PhD in Social Science; chairman of the European Network for Workplace Health promotion and other high level positions
Ireland	Dr. Donal McAnaney	Higher Diploma in Education, Diploma in Remedial Education, Ph.D in Psychology; Director of Research & Innovation for the Rehab Group
Netherlands	Dr. Frans Nijhuis	PhD in Psychology in Work and Health; Director of the Hoensbroeck Centre for vocational rehabilitation; Professor of 'Psychology of work rehabilitation' ;
Austria	Mag. Gert Lang	Degree in Sociology and numerous research related further education; extensive research experience; research fellow and project manager at FRK.
Finland	Dr. Juha Lavikainen	PhD in Psychology; Director of WHO Collaborating Centre on Mental Health Promotion, Prevention and Policy
Estonia	Dr. Airi Varnik	PhD in Psychiatry; Head of Estonian-Swedish Mental Health and Suicidology Institute
Belgium	Dr. John Henderson	Registered Medical Practitioner and specialist in Psychiatry; policy advisor to Mental Health Europe.
Ireland	Joe Keane	User Representative Advocate, Irish Advocacy Network

This committee, which will be led by the project manager, will have the role of directing, managing and reviewing the development and implementation of a project policy on ethics and data management. A representative of the Irish Advocacy Network will augment this committee, which will meet on a regular basis and will undertake to inform the Commission (through the project management structures) of all relevant developments in relation to these issues.

3. Data Security and Confidentiality Issues

Data confidentiality issues potentially do apply to the data collection activities for evaluation purposes within all three settings of Phase 3 of the project.

3.1 Where will Data be Collected in the Project?

Phase 3 of the project will see the only primary data collection to take place within the project. This will be done not through the researchers within the project, but through 'action researchers' within a set of pilot sites which will be identified through the main project dissemination activities.

These pilot sites will, in return for usage of the materials produced by the project, undertake to field trial them within their own settings. These action researchers will be supported by the project researchers in terms of:

- Provision of an evaluation protocol for the tools and methods that they will use
- Provision of ethical guidelines with regard to informed consent, where applicable
- Provision of guidelines on data security and confidentiality

3.2 Types of Respondent

Data security and confidentiality issues therefore only arise with regard to the collection of data from within these pilot sites. There are three potential types of respondent within these pilot sites:

- Professionals and practitioners
- Client representatives or advocates
- Older residents/workers/students

Different mechanisms for ensuring the confidentiality of data from each of these types of respondent will be needed and will be fully elaborated as part of the work of the project.

3.3 The Nature of the Data to be Collected

It should be noted that at no stage will personal or health related data be stored on any of the clientele within the three settings of concern to the project. Instead, the project will focus on collecting data related to the evaluation of the tools developed within the project. It is probable that the vast majority, if not all of these evaluations will focus on the utility and effectiveness of these mental health promotion tools rather than on the assessment of mental health. In the unlikely event that a pilot site wishes to assess the effectiveness of tools through obtaining health sensitive data directly from their clientele, special data management procedures will be developed for these sites.

3.4 Data Protection Procedures

The data protection and security features to be adopted within the project will be consistent with the following EU and national regulations:

- European Commission Directive No. 95/46 on the protection of personal data
- The Data Protection Act (Ireland)
- Law 2472/1997 on the protection of individuals with regard to the processing of personal data (Greece)

- German Research Foundation Guidelines [Deutsche Forschungsgemeinschaft *http://www.dfg.de/*] (Germany)
- Central Ethic Commission at the German Bundesärztekammer [Federal Chamber of medical Doctors *http://www.zentrale-ethikkommission.de/10/15Ethikberatung.html*] (Germany).
- Medical Research Involving Human Subjects Act (WMO) [Wet medisch-wetenschappelijk onderzoek met mensen] (Netherlands)
- WBP; Personal Data Protection Act [Wet Bescherming Persoonsgegevens] (Netherlands)
- Statutes of the Austrian Ethics Commission [Statuten Forum Österreichischer Ethikkommissionen] (Austria)
- Personal Data Protection Act and the Databases Act (Estonia)
- Other relevant national regulations depending on the countries which run pilot studies

The data security features to be adopted within the project will also be consistent with best practice guidelines and codes such as those mentioned earlier.

The sequence of events in setting up the pilot sites which will govern data protection and security are:

- Contacting potential pilot sites through the project dissemination activities
- Characterising the nature and type of pilot site and the type of evaluation study to be undertaken (setting, types of tool to be evaluated, nature of respondents in the pilot evaluation, study design to be used etc.)
- Provision of evaluation protocol and guidelines on data protection and security
- Obtaining evaluation data from the pilot site
- Combining data from multiple pilot sites for tool evaluation purposes
- Producing evaluation report

3.5 The Procedures of Data Protection & Security to be Applied

The following procedures will be applied to the collection and storage of data:

- Obtaining ethical approval according to national law and practice, where applicable
- Obtaining informed consent where applicable according to national practice and guidelines
- No personal identifiers to be attached to either paper based or electronic data collection and storage forms
- Identification data to be kept separately to evaluation data
- Action researchers and project researchers to be bound by national law on data protection and confidentiality and to make declarations to that effect
- Storage of data to be held in secure conditions
- Paper and electronic versions of data to be held in separate secure locations
- Pledge not to use data for purposes other than which it was collected for
- Data providers (respondents) to have the right to view data or withdraw data from the pilot studies