Dear Colleague

Re The influence of Environmental Factors on the Participation and Quality of Life of 8-12 year old children with cerebral palsy in 6 EU countries

I have prepared this summary as an introduction to the above project for those interested to know in general terms about the study.

The project that is funded by the EU Research Framework 5 Programme. It will begin late 2002.

It is only a summary and I would be pleased to supply further details of any aspects, including methodology.

Yours faithfully

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### Project Administrative Overview

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**Project abstract (maximum 1000 characters)**

Cerebral palsy is the commonest cause of physical impairment in childhood and associated with cognitive and sensory impairments. It occurs in 1 in 500 births, or 10,000 new cases a year in the EU. Average life expectancy is at least 40 years. Children with cerebral palsy continue to be seriously disadvantaged with respect to social relationships, education and employment prospects. A collaboration of 14 cerebral palsy registers, funded by the EU, has already registered 6500 children and standardised the identification and assessment of children (including severity of impairment).

In children with stable impairments (as compared to children with illness), the two key outcomes of Participation and Quality of Life are especially influenced by physical, social and attitudinal Environmental Factors (EFs) as well as medical interventions. Our principal hypothesis is that children with similar severity of impairment will experience variable outcomes in different countries due to variation in EFs. This will allow the identification of EFs which, if improved, will yield the greatest benefits for children and their families. Such knowledge will inform EU policy in the health, educational and social sectors and generate protocols to optimise outcomes.

It is a further hypothesis, testable in a subsequent study, that successful management of these EFs will have long-term impact into adult life, including function in the labour market.
Objectives (maximum 1000 characters)

Children with impairments such as cerebral palsy continue to be seriously disadvantaged with respect to social relationships, education and employment prospects. There are infrastructures and systems in place in European countries to respond to child and family needs. However, the arrangements vary considerably and it is not known which work because they have rarely been evaluated against well-defined outcomes. The two key outcomes are Participation and Quality of Life (QOL). Our principal hypothesis is that children with similar severity of disability will experience variable outcomes in different countries due to variation in Environmental Factors (EFs). This will identify EFs which, if improved, will yield the greatest benefits for children and their families.

The study aims:
1. To generate knowledge about optimal environments to inform EU policy in the health, educational and social sectors.
2. To generate protocols for carers and professionals to optimise participation and QOL.
3. To interest children and families in a future study to test the hypothesis that successful management of EFs has long-term impact into adult life

Description of the work (maximum 2000 characters)

Definitions
Participation (formerly called handicap) is an individual’s involvement in life situations. QOL is a person’s self reported, subjective experience of their life’s quality. EFs are the physical, social and attitudinal environment in which people live. Examples are: Arrangements for educational provision - special or mainstream school, Legislation on access to buildings, Social attitudes and norms, Anti-discrimination legislation, Transport design, Rehabilitation and therapeutic services, Assistive technology.

Work already completed
A collaboration of 14 cerebral palsy registers, funded by the EU, has already registered 6500 children and standardised the identification and assessment of children (including severity of impairment). A preliminary survey has confirmed there are major differences between EFs in the participating countries. We have identified suitable instruments to measure Participation and QOL. We have developed a preliminary description of relevant EFs.

Proposed work
In order to meet our objectives we will:
1. Ascertain the Participation and QOL of approximately 1000 children aged 8-12 years with cerebral palsy in 8 centres in 6 European countries. The chosen assessment instruments will be translated according to international guidelines. The sample of children will come from the collaborative register and permission sought from families and children. Research associates, appointed in each centre and then trained together, will undertake a pilot of all procedures in each centre. Following a workshop, at which the lessons of the pilot will be incorporated into the procedures, all families will be visited.
2. Develop and administer instruments to assess EFs. This will be informed by ICIDH-2, a systematic review of literature and policies, and discussions with parents. The instruments will assess EFs at the three levels of national policy, local implementation and actual delivery to families.
3. Prepare descriptive and analytic reports of our data according to a work package already drawn up.
4. Disseminate internationally through presentation to EU committees, articles in academic journals and an international conference; and nationally through articles in professional journals, reports to voluntary organisations and government departments of health, education and social care.

Milestones and expected results (maximum 500 characters)

Month 11 Agreed and translated instruments
Month 15 All personnel, samples and instruments ready
Month 25 All data collected
Month 32 Completion of analysis
Month 35 Report and initial dissemination

The expected results contribute to Area 11 - Research relating to persons with disabilities
11.1 The study will increase understanding of the determinants of Participation
11.4 The study will yield recommendations about the optimal environment for children with disability to live in
11.2 The study will have explored how QOL can be assessed in children with disability
Present Situation and Innovative Aspects

Definitions.
The Final Draft of ICIDH-2 (1, Page 16) states, “ICIDH does not model the process of functioning and disability. Rather, it provides building blocks for users who wish to create models and study the process; it is a language whose texts depend on the creativity and scientific orientation of the users”. We shall use these building blocks and there are four main blocks:
- Impairment – Problems in body function or structure.
- Activity - The execution of a task or action by an individual. Activity limitations are difficulties with such tasks or actions
- Participation – An individual’s involvement in life situations. Participation restrictions are problems in achieving Participation
- Contextual factors – The complete background to an individual’s life and living, and consisting of Environmental and Personal factors. Environmental Factors are the physical, social and attitudinal environment in which people live and conduct their lives. They will strongly influence a person’s opportunity to participate.

Throughout this document we shall use the term Participation rather than handicap.
This implies a full acceptance of a social model of disability.

Quality of Life is a person’s self reported, subjective experience of their life’s quality and how their Activities and Participation influence it. Early instruments to measure Quality of Life often equated it with functional disability or with Participation (2). However it is now recognised that Activity and Participation are objective measures of health status whilst Quality of Life is a subjective measure; the objective and subjective should not be combined in a composite score of health status.

Background
Children with impairments such as cerebral palsy continue to be seriously disadvantaged (3, 4); and adults with cerebral palsy are disadvantaged with respect to employment and social relationships (5,6). There are infrastructures and systems in place in every European country to respond to child and family needs. The rationale for these arrangements arises from theoretical standpoints and from qualitative studies with children and their families. However, the arrangements vary considerably between countries and it is not known which actually work because they have rarely been evaluated against a well-defined outcome. In the comprehensive review “What works in Services for families with a Disabled Child?” (7), the authors had to take a needs based approach because of the lack of research-based evidence on the effectiveness of interventions for families. There is a therefore a need for, high quality scientific evidence to inform national and EU policies for disabled children. EU Communication 284:2000 also emphasises the “need for a strong knowledge base on prevalence of disability and on its implications to participate fully in all aspects of society”.

Participation and Quality of Life are the two outcomes against which to judge different models of provision for disabled children. There have been a number of qualitative studies that have sought directly the experience of families and children and yielded important insights into the lives and views of such children (4, 8, 9). However larger populations of disabled children should now be studied to discover how much Participation and Quality of Life vary between children with comparable severity of impairment and compared to children without impairment.

This proposal builds on recent innovative work
- The adoption by the European Union of the ICIDH and its revisions (1) has generated a conceptual framework that can be shared across countries.
- The applicants are already part of a European collaboration of registers of children with cerebral palsy (10, 11), funded by the EU, which allows categorisation of impairment (by type and extent) of children with cerebral palsy. The registers cover all children in a defined geographical area. They therefore allow studies that are epidemiologically sound. Further, the collaboration also involves sufficient numbers of children for conclusions to be drawn that are statistically sound.
The European Academy of Childhood Disability is raising the profile of the needs of disabled children and organised a recent meeting (12) at which descriptions of service provision for disabled children were collated for many countries.

The measure of Participation (13) we shall use has been developed in French and English translations and is being further refined and validated by its designers during the second half of 2001.

**Measurement of Quality of Life in children.**
This has lagged behind work with adults because of a sense that parents should represent their child’s views and that childhood was just a temporary state on the way to becoming an adult. However the United Nations Convention on the Rights of the Child (14) is changing such attitudes so that childhood is now recognised as an important state in its own right rather than as a stage passed through; and that children’s views should be sought directly rather than inferred from the views of their carers.

Measurement of Quality of Life has also lagged behind because of conceptual and practical difficulties such as the reliability of children’s self reports, the status of reports from proxy respondents (15, 16) and the different values which children place on particular health states as compared to adults (17, 18).

In the child with chronic illness, early work tended to develop measures specific to particular diseases such as cancer (19) or asthma (20) for the purpose of contributing to the evaluation of medical interventions. There is now the need to measure Quality of Life in children with relatively stable impairment whose health status and Quality of Life are likely to be influenced more by social and Environmental Factors than by medical interventions. A generic instrument rather than an impairment specific instrument should be used because we wish to assess Quality of Life in the same context and with the same instrument in all children. There are now a number of well-validated generic Quality of Life instruments from which we have chosen the most suitable instrument for our study.

**Measurement of Participation of disabled children and their families.**
Although the concept of Participation has been well articulated for over 20 years, there have been few attempts to operationalise it. This is partly because ICIDH has been criticised for being too medical and not taking account sufficiently of the social construction of disability (21). However in the Final Draft of ICIDH2 these competing theoretical frameworks are largely reconciled by the formal introduction of contextual factors.

The Final Draft ICIDH-2 classifies Participation as follows:
- Learning and applying knowledge
- General tasks and demands
- Communication
- Mobility
- Self-care
- Domestic life
- Interpersonal interactions and relationships
- Major life areas
- Community, social and civic life

There are even fewer attempts to operationalise Participation for children but one instrument LIFE-H (13) has been developed within the ICIDH framework and is presently being modified and tested for specific use in children.

**Contextual Factors**
Context arising from Environmental Factors is classified in the Final Draft ICIDH-2 (1). This classifies Environmental Factors as: Products and technology, Natural environment and human-made changes to environment, Support and relationships, Attitudes, Services, systems and policies. However, final Draft ICIDH-2 (Page 5) is about all people not just those with disabilities. Its classification of Environmental Factors is therefore very large and only some of the factors are relevant to children and even fewer are likely to impact on disability.

We shall study Environmental Factors that are relevant to the majority of children with cerebral palsy. Factors that are relevant uncommonly will not be considered because their manipulation would have less potential overall benefit; and it would be unlikely that statistical significance would be achieved in any analysis.
Further we shall be concerned with Environmental Factors that might reasonably be capable of manipulation through policy changes or education. Examples are: Arrangements for educational provision - special or mainstream school, Legislation on access to buildings, Social attitudes and norms, Anti-discrimination legislation, Transport design, Rehabilitation and therapeutic services, Assistive technology.

In our study we shall undertake both the description of Environmental Factors relevant to childhood disability and the development of a classification that can be used in an analysis where the factors are used as explanatory independent variables.

Context arising from “personal factors” such as family relationships, family mental health are recognised by Final Draft of ICIDH-2 to be important but they vary with culture, may fluctuate markedly within the same family over the years and are not readily amenable to change by social policy. They are not therefore capable of manipulation at EU or nation level. In our study, we shall not use them as explanatory variables but will need to take into account any which are potentially confounding – i.e. are associated independently with the proposed explanatory variables as well as the outcome.

**Summary of innovative elements**

The principal innovative aspect of this proposal is that we shall provide scientific evidence to demonstrate how factors in the environment are related to the Participation and Quality of Life of children with cerebral palsy. We do not at present know which Environmental Factors are the most important because they have not been evaluated against well-defined outcomes.

The proposal is the first study to assess the Participation and Quality of Life of a large sample of children with significant relatively stable impairment generated from whole population databases. The numbers are sufficiently large to provide sufficient statistical power to direct the study to 8-12 year olds and to control for severity of impairment. Systematic description and assessment of relevant Environmental Factors across six EU countries has not been undertaken before.

The 8-12 year old age group are rarely studied as most studies look at children up to 5 where the needs of parents are explored in detail; or young adults over 18 years of age.
References

11. SCPE. Prevalence and characteristics of cerebral palsy in thirteen European centres. Submitted
Objectives and Expected Achievements

Background
Cerebral palsy is the commonest cause of physical impairment in childhood and associated with cognitive and sensory impairments. There are 10,000 new cases a year in the EU and average life expectancy is at least 40 years. Children with cerebral palsy continue to be seriously disadvantaged with respect to social relationships, education and employment prospects. The environment may hinder or promote Participation and Quality of Life. It is not known which Environmental Factors should be promoted because they have rarely been evaluated against a well-defined outcome.

Environmental Factors are defined as the physical, social and attitudinal environment in which people live and conduct their lives; they include such factors as: Legislation on access to buildings, Social attitudes and norms, Anti-discrimination legislation, Assistive technology, Educational provision, Transport design, Rehabilitation and therapeutic services.

Within any one locality or even country, such EFs are relatively constant and therefore it is difficult to study their influence. However by comparing different countries, significant associations may be identified between certain EFs and outcome.

Overall purpose
In children with stable impairments (as compared to children with illness), the two key outcomes of Participation and Quality of Life (QOL) are especially influenced by physical, social and attitudinal Environmental Factors (EFs) as well as medical interventions. The principal hypothesis is that children with similar severity of impairment will experience variable outcomes in different countries due to variation in EFs. The study will allow the identification of EFs, which, if improved, will yield the greatest benefits for children and their families. Such knowledge will inform EU policy in the health, educational and social sectors and generate protocols to optimise outcomes.

The objectives are:
- To generate knowledge about optimal environments for children with disability to inform EU policy in the health, educational and social sectors.
- To generate protocols for carers and professionals to optimise Participation and QOL.
- To interest children and families in a future study to test the hypothesis that successful management of EFs has long-term impact into adult life on health, Participation, QOL and role and function in the labour market.

Expected achievements
- Participation and QOL will have been measured in approximately 1200 children with a range of severity of impairment of cerebral palsy across the European Union.
- Environmental Factors across the European Union relevant to 8-12 year old children with cerebral palsy will have been described and assessed
- The correlation between Participation and QOL for different severities of impairment will have been described; and how these differ in children without impairment.
- A model to represent the influence of EFs on Participation and QOL will have been developed.
- Recommendations will have been made about the optimal environment in which children with cerebral palsy should live to ensure they enjoy the same level of Participation in society as their non-disabled peers; these will inform European Union policy making.
- Protocols will have been proposed for workers in the health, social and educational sectors to help them identify with families how the environment can be best modified to optimise Participation and QOL.

Children and families will have been interested in a future study to test the hypothesis that successful management of EFs has long-term impact into adult life on health, Participation, QOL and role and function in the labour market.
**Community Added Value and Contribution to European Union policies**

**Community added value**
The study will benefit all EU countries because:

- This study is directed to a large and disadvantaged group of children. Cerebral palsy occurs in 1 in 500 births, or 10,000 new cases a year in the EU. Average life expectancy is at least 40 years. There are approximately 400,000 people with cerebral palsy in the EU. On average four family members are directly affected by a person with cerebral palsy, giving a total of approximately 2 million people affected either directly or indirectly by cerebral palsy in the EU. Their needs are great and policies to help them are not well informed by scientific research.

- Many people with disability have physical impairments or combined physical/sensory, cognitive impairments which yield similar disabilities to those in people with cerebral palsy. The study therefore had added potential benefit for the wider group of people with disability.

- The findings will inform policy and service development in the disability sector across the European Union – particularly as the EU expands and countries join where policies and services have been underdeveloped.

This study must be undertaken in a multi-country setting because:

- Involvement of many countries is necessary to provide the diversity of Environmental Factors necessary to investigate our principal hypothesis that optimisation of environmental variables can increase Participation and QOL.

- There are insufficient children linked to a register in any one country to provide sufficient numbers of 8-12 years in different severity categories.

- Key staff in the different registers possess essential skills in epidemiology, rehabilitation, paediatrics, statistics, assessment of Participation and Quality of Life.

**Contribution to EU policies**
The study promotes children’s interests and rights, in line with obligations in the 1989 UN Convention on the Rights of the Child and the 1997 Amsterdam Treaty which included for the first time in EU history specific reference to children. The study aims to promote for European children with disability their right to participate fully in the life of their communities. Further, employment rights for migrant workers and their children within the EU should not be undermined by unacceptable variation in the adequacy of environmental provision for their disabled child in different EU countries.

The following resolutions or articles take account specifically of children with disability:

- Resolution of Council 31/5/1990 Integration of children with disabilities into ordinary systems of education
- Resolution of Council 20/12/1996 Empower and enable people with disability to participate fully by removing barriers …Take account of the needs and interests of families and carers.
- Article 13 Amsterdam Treaty Combat discrimination based on grounds of… disability, age …
- Communication (2000) 284 …needs a strong knowledge base on prevalence of disability and on its implications to participate fully in all aspects of society …
- Article 137 Amsterdam Treaty. Encourages the development of policies to “combat social exclusion”.
Contribution to European Union Community Social Objectives

Quality of Life
This study is directed to assessing the Quality of Life children with disability in the European Union and increasing our understanding of how to promote it.

Social model of Participation
Until recently, state services catered predominately for the medical needs of children with disability on the assumption that Participation depended upon something within the child that could be helped by medical intervention. The social, educational and recreational needs are arguably of far greater relevance to the child with respect to influencing Participation and improving Quality of Life. The social model recognises that Participation results from the circumstances in which a person lives rather than being restricted by a problem in the person. Our study is of these circumstances.

Involving citizens in planning the study
The development of this study has been discussed with voluntary organisations and disabled people:
- Focus groups of parents of children with cerebral palsy in Newcastle, United Kingdom
- SCOPE– the UK voluntary organisation for people with cerebral palsy. It thinks it is very important to compare Quality of Life between disabled and non-disabled (as we are doing), as well as differences between disabled children.
- A group of parents of children with cerebral palsy in Cork, Ireland.
- The Danish Society for Cerebral Palsy. It welcomed the study and made two principal points. First that Participation is vital and that most adults with cerebral palsy think that cognition, communication and vision are more important for Participation than mobility. Will this be true for children as well? Secondly the Society indicated that the trauma of cognitive the diagnosis could still affect the family many years later.
- The Northern Ireland Cedar Foundation for people with cerebral palsy and other physical difficulties. This organisation “welcomed the proposal particularly because it will have implications for improving services for children with cerebral palsy”.

In the study, voluntary groups and disabled children will be involved in focus groups to assist the development of the classification of Environmental Factors.

Seeking children’s views directly
The EU has emphasized that more account needs to be taken of the views of its citizens. Children and especially children with disability are often excluded from expressing their views. In assessing Quality of Life, we shall ask children themselves about their lives, and not rely on reports of parents or caregivers.

Education, Training and the Labour market
The findings of the study should enhance Participation in education and learning programmes of children with cerebral palsy. In about 50% this will link to appropriate training and then part-time or full-time Participation in the labour market. In the 50% who cannot participate fully in the labour market, other employment is likely to be created for trainers and carers. The following EU resolutions or articles are relevant:
- Article 136 …promotion of employment
- Article 150 ..facilitate co-operation between education and training
- Article 125 …improving the employment prospects of EU citizens
- Article 153 …protecting economic interests of consumers
Economic Implications

Employment consequences of implementation of potential findings

Individuals and economies benefit from the fullest Participation of citizens. At least half of people with cerebral palsy do not have significant mental impairment and should be able to participate in the labour market when adult. Their carers will thus be less occupied with caring and therefore available for other economic activity. The half of people with cerebral palsy who cannot participate in the labour market still have rights to optimal social inclusion and this requires services and care packages.

Our study should yield important information about the type of environmental modification and assessment instruments needed by people with different severities of disability. Application of this knowledge will need the appointment of skilled assessors, such as social workers, to assess individuals. Many people with cerebral palsy will need extra education and training because they will not be able to enter manual employment. Necessary environmental modifications will need appointment of skilled technicians to modify workplaces (eg computer screens and keyboards) and skilled carers for those who cannot live independently. Jobs will have to be adapted and often be location-independent so that people with disability do not have to travel.

Strategic impact

The strategic knowledge base will be enhanced in the following ways:

- There will be accurate data about the Participation and Quality of Life of a substantial group of children with cerebral palsy. Cerebral palsy leads to physical disability but it has associated cognitive and sensory disabilities. The data will therefore will applicable to a wider group of disabled children.
- The data will cover whole populations of children with cerebral palsy rather than groups of a particular socio-economic class or who attend a certain school or clinic. Compared to the many small qualitative studies, there will for the first time be quantitative data on a large complete group, systematically collected and analysed.
- The analysis will take advantage of differences between countries to yield for the first time objective data about the relative importance of different Environmental Factors on Participation and Quality of Life; further it will show how the relative significance of different Environmental Factors will vary with the type and severity of disability.
- This knowledge will provide a strategic knowledge base for policy development across the EU and practitioner training.

One primary objective is to involve children and families so that they understand the significance of this project and future work. A further hypothesis, testable in a subsequent study, is that successful management of environmental variables will have long-term impact into adult life, including function in the labour market. Such a hypothesis, if confirmed, would yield further scientific evidence necessary for sound policy development.
Ethical Aspects

The study will be undertaken in full accordance with the principles specified in the Declaration of Helsinki (World Medical Association; Edinburgh Revision 2000) and in accordance with the legal, ethical and regulatory requirements of each participating member state. Confidentiality will be guaranteed by all contractors and sub-contractors.

Justification for the methodology of the research

The objective of the study is to find out the extent to which environmental factors impact on the quality of life and participation experienced by children with cerebral palsy and their families in six European centres. The overall approach will necessitate the identification of a representative population of children with cerebral palsy and their families in a number of European countries for reasons related to the measurement and experiences of participation and quality of life. Existing case registers and surveys of children with cerebral palsy in each of the participating centres will be used as a sampling frame to identify the children with disability. The project may also require information on a random sub-sample of children without cerebral palsy but this will depend on whether the instruments eventually chosen already have been standardised in that country. Healthy volunteers would be recruited from the school population in the same area as the register in each country. Given the main interest of the study is in the views of children with cerebral palsy and their parents, the most appropriate method of data collection will take place at a time and place that is convenient for families (this may include evenings and weekends).

Potential benefits and risks to society

In accordance with the recommendation of the Helsinki Declaration (Part B; para 19) this study is justified on the grounds that it will clearly benefit the population of children with CP and their families in Europe. More specifically, the study will lead to an improved understanding of the factors affecting quality of life and participation and lead to recommendations and further hypotheses for future testing. The study will improve understanding about the relationship between quality of life and interventions (e.g. rehabilitation services) and will lead to recommendations about how existing resources and new configurations of services and policies could be developed to facilitate participation and improve the quality of life for children with CP and other types of disability.

One of the main risks to society stems from the potential for unreliable or invalid results related to the problems of measuring quality of life. The choice of instruments used to measure quality of life will be based on thorough knowledge of the scientific literature and will be made in consultation with experts in the research team and the external Advisory Board to the project (as recommended in the Helsinki Declaration; Section B; paragraph 11).

Potential benefits and risks to families and children

In the short term families and children with cerebral palsy are unlikely to benefit directly from the study (except from a cathartic type experience as a result of sharing their views and problems with the researcher/s). We recognize that this position is worthy of special attention (Part A; paragraph 8 of the Helsinki Declaration) and must be made clear in the information given to parents as part of the informed consent process. Participating families, if they wish, will be kept informed of the outcome of the study in terms of outputs (reports, conferences, papers) and policy and practice developments. Similarly, parents and children without cerebral palsy are unlikely to benefit directly from the study but their role will be clearly explained in relation to the possible future benefits for children with disabilities.

Children with cerebral palsy and indeed children with other types of disability will benefit indirectly and in the long term as this study will produce substantial recommendations about the way future services should be organised and policies developed to help ensure disabled children enjoy the same level of participation in society as their non-disabled peers (Helsinki Declaration; Part B; para 19).

In terms of risks it is possible that families and children could experience psychological adverse effects through interviewing although this is considered unlikely. The researchers also recognize that the assessment of quality of life could be a sensitive topic and may have an impact on participants – for example generating heightened awareness of and dissatisfaction with their current quality of life. Safeguards taken here to
minimise these possibilities will include the recruitment of experienced professionals as interviewers (social workers, psychologists, nurses or health visitors for example); the recruitment of interviewers local to each country to ensure fluency in the language, familiarity with the culture - in particular attitudes towards disability; and an additional period of training for the interviewers to ensure sensitivity and competence in administration of the instruments. Also the accuracy of the translated versions of the instruments will be checked and validated in each of the countries.

Where researchers encounter families in a state of distress independent of the interview process, a mechanism for referring such families to the appropriate support services in each country will be agreed in advance. There will also need to be a clear mechanism for advising the family who to contact if a major unmet need is identified.

Providing information (written and oral material)

Approaching families

This study will comply with the guidelines issued by each of the Registers on contacting families and the researchers will satisfy the requirements of the local ethical, legal and regulatory requirements of the participating member states. However, in addition the researchers also recognize the following principles are ‘good practice’ in any follow up study of vulnerable groups:-

- Families will be approached in a sensitive manner and ideally initial contact will be made on behalf of the researchers by a professional known to the family who will seek their ‘permission to be contacted’ by the researchers. This method will provide a double check that each child is still alive and well, as well as giving the families an opportunity to opt in or out of the study at an early stage without feeling compromised. It also helps to give families confidence about the legitimacy of the researchers and the study and helps to provide them with a context about how they have been identified and why they have been approached.

- Parents of children with CP and other forms of physical disability should generally be kept informed of the project. This could be achieved by distributing information leaflets about the study to voluntary agencies, in-patient and out-patient facilities and schools. It may also be possible and desirable to access the local media in the various regions.

Written material

Once permission to contact the families has been secured, each family will be sent a letter inviting them to take part in the study. The written material to be sent to families specifically seeking their consent to participate will include a standardised information booklet (developed through focus group work with parents of children with cerebral palsy) and a written consent slip for the parent/guardian and child and a return envelope. Parents will be asked to sign and return all consent slips before a visit to the family takes place. Material sent to families including the consent slip will be developed in Workpackage 2c. The materials will be subject to approval by each of the local ethics committees and will comply with the recommendations specified in the Helsinki Declaration (Part B; para 20, 22) as follows. The letter and information will state: -

- participation is voluntary;
- the aims, methods, funding, possible benefits and risks of the study;
- that the study has been passed by a local ethical committee (including the name of the committee and application number);
- the researchers, their affiliations, any conflicts of interest;
- participants have the right to withdraw from the study at any stage without giving any reasons;
- taking part, or not, will in no way affect the family and child’s access to or uptake of services;
- information gained as part of the study will be treated as confidential;
- the research may not directly benefit their child but could make a difference to other children with cerebral palsy;
- there will be no payments or inducements as a result of taking part in the study;
- expenses will be reimbursed in full;
- parents/guardians have the opportunity to discuss the study and to ask any questions of the relevant researcher before consenting.
Obtaining informed consent
The researchers involved in this study recognize that the main study participants are vulnerable members of society - disabled children and their parents. In all cases the informed consent of the parent/legal guardian will be sought (Helsinki Declaration; Part B; para 24) and this will include written consent. In all cases where the child is able to provide informed consent, the researchers will seek consent from the child as well as the parent/legal guardian (Helsinki Declaration; Part B; para 25). However, the researchers also recognize that those children with severe intellectual impairment who will be unable to give consent are a particularly vulnerable subgroup and worthy of special consideration. Their position is discussed more fully below.

Persons unable to give consent
This study will include children with profound intellectual impairment who will be unable to give informed consent. In this case informed consent from the parent/legal guardian will be sought in accordance with the applicable law (Helsinki Declaration; Part B; para 24). It is important to include this subgroup of children to ensure the representativeness and relevance of the study given the likelihood that these are the children with the greatest need for care and most likely to experience social exclusion. The degree of risk and burden to the person unable to give consent is likely to be minimal and no more than previously described for children who can give consent.

National legal/ethical requirements of the member states
As part of Workpackage 1, researchers at each participating centre will be responsible for obtaining the consent of appropriate local and national ethical committees, which conforms to the law and regulations of each country, before carrying out the research. As part of the application each local co-ordinator will submit a copy of the scientific protocol, including the information to be sent to parents/families, the consent slip and informed consent statement and all of the instruments to be used (Helsinki Declaration; Part B; paragraph 13). The local ethical committees will be kept informed about the progress of the study (on an annual basis or as specified by each committee) and will be informed of its completion and outputs (as specified by each committee).