

Ethics Guidelines for International, Multicenter Research Involving People with Intellectual Disabilities^{1,2,3,4}

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Abstract This position statement endorsed by the International Association for the Scientific Study of Intellectual Disabilities is designed to promote and facilitate research projects affecting and involving people with intellectual disabilities. The paucity of dedicated research infrastructure and expert ethical review processes to oversee research in this field, especially in developing countries, is asserted as a major issue to be addressed by both the scientific community and governments. International multicenter collaboration has been proposed as a means of addressing these problems. The statement draws on internationally recognized documents outlining the ethical considerations involved in human research activities. It interprets these documents in light of the particular needs and interests of people with intellectual disabilities and incorporates international consultation involving researchers from a variety of disciplines. It affirms the importance of ethical decision making in local communities. Specific recommendations are made concerning ethical review processes, research design considerations, consent processes and the conduct of research involving and affecting people with intellectual disabilities, their families and communities. Research proposals, especially those for international, multicenter projects, need to take into account cultural diversity among participants and differing legal requirements across jurisdictions, while at the same time maintaining the scientific rigor of the research protocol. Promoting partnerships between researchers and people with intellectual disability, together with their families, advocates and local communities are important considerations when developing research projects. Similarly, the development of strategies to both communicate findings to participants and their communities, and to promote their community's access to the benefits of these findings are all important ethical considerations.

Keywords: Research, ethics, intellectual disabilities

PREAMBLE

The International Association for the Scientific Study of Intellectual Disabilities (IASSID) identified the need for a position statement on research and ethical review issues associated

with research projects affecting and involving people with intellectual disabilities. The need for such a position statement was foreshadowed by Dr. Harvey Stevens (1967) in his Presidential Address to the Inaugural IASSID World Congress at Montpellier, France:

If this field is to continue to reserve support for its research activities, it must assure its supporters and the public that adequate safeguards have been delineated and are being rigorously applied, particularly when using the mentally deficient [*sic*] as a research subject (pp. xxxi–xli).

More recently, IASSID President Dr. Neil Ross called for the establishment of an IASSID Ad Hoc Committee to investigate contemporary issues affecting international, multicenter research and to prepare a position statement.

This position statement is designed to assist with the protection of people with intellectual disabilities and their advocates who participate in research. Furthermore, it is intended to promote and provide guidance for the development and execution

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³This document incorporates contributions from members of the IASSID Ad Hoc Committee on International, Multicenter Research Ethics and other interested persons. The names of contributors are listed at the end of this document. It should not be assumed that anyone of the contributors endorses the document in total.

⁴Editor's note: Citations were not included in the text of these guidelines but are found in the References section at the end of the article.

of research projects affecting and involving people with intellectual disabilities, especially projects that cross national boundaries and involve participants in developing countries. In particular, the statement is intended to aid the establishment and operation of “ethics committees”/“institutional review boards” to oversee international multicenter research projects, especially in developing countries and jurisdictions where there are no well-established mechanisms for this purpose. It is also designed for use in the education of new researchers and practitioners in the field of disability.

Furthermore, IASSID asserts that one of the major ethical issues to be addressed by the scientific community and governments alike is the lack of both theoretical and applied research in this field. This problem, in part, is linked to a lack of funding at both national and international levels. Thus, IASSID calls upon the research community and government agencies, at both national and international levels, to consider how issues affecting people with intellectual disabilities and their families can be included on research agendas and funded appropriately.

For the purpose of this position statement,

- *Research* is understood to be any systematic investigation or inquiry involving human participants intended to discover clinical, social or theoretical knowledge and/or verify previous findings or assertions. It can vary in its form according to the methods employed (e.g., a controlled experimental study, a clinical trial, a quantitative survey, or qualitative interviews), the degree of intrusion into the lives of the participants, and the degree to which participants are at risk of adverse events.
- *Multicenter research* is understood to be a research conducted according to a single protocol, but at more than one site and therefore supervised by more than one investigator. Such research could be conducted at more than one site within a particular country or in different countries. In the latter case, it is commonly designated as “international, multicentre research”.

IASSID asserts that when evaluating the ethical merit of proposed research projects, and conducting research involving people with intellectual disabilities as participants, or research that is intended to affect the lives of these participants, the three fundamental ethical principles identified by the Council for International Organizations of Medical Sciences (CIOMS, 2002) should apply:

1. respect for persons, including their autonomy and right to self-determination;
2. beneficence for participants and the community, that is, maximizing benefits and minimizing risks; and
3. justice, both legally and morally, in the treatment of those involved in research and in the treatment of the communities to which the participants belong.

In preparing this statement, IASSID endorses the four ethical duties in conducting multinational, multicenter research identified by the Nuffield Council on Bioethics (2002):

1. the duty to alleviate suffering, especially in developing countries;
2. the duty to show respect for persons;
3. the duty to be sensitive to cultural differences; and
4. the duty not to exploit the vulnerable.

IASSID calls on those in both scientific and political spheres to recognize the power imbalance that can exist between researchers and those who are either direct participants in research or who are members of communities whose interests are the focus of research. Such power imbalances can be particularly evident where people with intellectual disabilities live or work in congregate care or institutional facilities, where they can be particularly vulnerable to coercion and exploitation. Furthermore, IASSID calls upon those involved in the development of research protocols and those responsible for the oversight of research (including members of “ethics committees”/“institutional review boards”) to, wherever possible, work in partnership with people with intellectual disabilities, their families and advocates in the development of research goals, questions, strategies, methodologies and information dissemination (National Health and Medical Research Council, 2002).

IASSID affirms the primacy of ethical decision making in local communities, where research is to take place. However, IASSID also acknowledges that the infrastructure and expertise available to facilitate the ethical review and approval of proposed research projects varies from country to country. Therefore, IASSID asserts it is important to draw upon a number of internationally accepted principles to guide the development, ethical review and implementation of research. Subsequently, this statement has been developed with reference to a number of internationally accepted documents, including:

- Nuremberg Code, 1949
- the *Universal Declaration of Human Rights*, 1948
- the *Declaration of Helsinki*, 1964/2000
- *International Ethical Guidelines for Biomedical Research Involving Humans*, 1993/2002
- the European Union Directive on the Conduct of Clinical Trials, 2001

Other documents informing these guidelines are listed in the bibliography.

IASSID acknowledges the diversity, internationally, of ethical values and legal requirements. In publishing the current guidelines, IASSID intends to promote a wider debate among researchers, practitioners, people with intellectual disabilities and their advocates from a variety of cultures, which will contribute to the future revision of these guidelines.

INTRODUCTION

The International Association for the Scientific Study of Intellectual Disabilities (IASSID) exists for "... the worldwide promotion of the scientific study of intellectual disabilities and related developmental disabilities and of the conditions of persons with such disabilities and their families" (IASSID By-laws, Article 1.1). In this endeavour, IASSID encourages international cooperation and multicenter research involving members of the scientific community, people with intellectual disabilities and their advocates.

IASSID is aware that developing countries in particular are in urgent need of research to assist them devise and implement appropriate programs and strategies to support people with intellectual disabilities and their advocates. For this reason, consistent with the findings of the Nuffield Council on Bioethics (2002), IASSID asserts that it is appropriate for those in wealthier countries, both in the government and non-government sectors, to assist and sponsor research in developing countries.

Also, IASSID wishes to ensure that the needs and priorities of people with intellectual disabilities throughout the world are represented in all research activities designed to advance the health and well-being of the general community. IASSID asserts that people with intellectual disabilities should not be excluded (discriminated against) as potential participants in generic research and every effort should be made to include their perspectives, priorities and needs in generic research activities.

However, IASSID is aware that people with intellectual disabilities and their advocates can be vulnerable to exploitation and even abuse when they participate in research. Consequently, before research can proceed, rigorous ethical safeguards must be in place to promote and protect the health, safety and human rights of participants; and to prevent their exploitation.

IASSID is concerned that not all jurisdictions in which research could be conducted have established infrastructure and protocols to monitor and regulate ethical issues, and in turn safeguard and protect the interests of people with intellectual disabilities and their advocates involved in research activities. Also, in the case of international multicenter research, different ethical standards or principles could apply in different countries and across different cultures. If not addressed, these differences could pose a significant barrier to, or compromise international, multicenter research activities.

IASSID endorses the principle that for research involving human participants, "... the well-being of the human subject should take precedence over the interests of science and society" (World Medical Association, 2000; Declaration of Helsinki, Article 5). IASSID maintains that those persons proposing research involving people with intellectual disabilities as participants need to justify to both their peers and their community (including people with intellectual disabilities and their advocates) that what they propose is in the interest of people with intellectual disabilities, and the means by which they intend to

achieve it is acceptable in light of the highest international standards, both ethically and legally.

Importantly, in multicenter research, the onus is on those initiating research to justify to those communities in which they propose to conduct the research, both the ends and the means of their research activities. This process will usually involve preparing an ethically based research protocol or a stand-alone document that discusses the ethical considerations within the research protocol (i.e., an ethics proposal), to be reviewed in both their own country and other countries in which they propose to conduct the research. The ethics proposal process will ordinarily involve the researchers explaining to an independent and competent authority what they intend to do; why such an investigation is important; what potential benefits there are to society; what dangers might be involved; how they intend to proceed; what safeguards they will establish to protect the participants' rights and safety; and how they will make their findings available.

The independent and competent authority to which the ethics application is to be made (i.e., the ethics committee/institutional review board) will ordinarily consist of men and women, who provide expertise in research processes from varied disciplines, the law, religion and ethics, as well as lay persons from the general community, and wherever possible, people with intellectual disabilities. In the case of institutional-based ethics committees, there will usually be at least one person who is independent of the institution or the organization from which the ethics application originates. Ideally, there should be at least one committee member who can represent and advocate for the interests of those persons identified as potential participants for the study. Such representation or advocacy is particularly important where the proposed research involves participants who could be considered vulnerable or disadvantaged in some way or from a cultural background different from that of those proposing the research.

An ethics committee/institutional review board, or equivalent local committee, will have the authority to approve, propose modifications or reject an ethics application. Also, such committees will ordinarily have a right to request regular progress reports concerning any research activities they have approved. They will have the authority to withdraw approval for research that fails to comply with an agreed protocol or local regulations.

If local ethics approval is withdrawn, then all local research activities should cease immediately, or whatever local sanctions in place against researchers would apply. In the case of multicenter research, if the sponsor or originating authority is no longer approved to continue, then all research should cease. In any event, many funding bodies require current ethics approval for projects they fund. Failure to obtain such approval or the withdrawal of ethics approval will ordinarily result in the suspension or forfeiture of funding. In addition, research that has not been approved by an ethics committee/institutional review board, or for which approval has been withdrawn, will not ordinarily be accepted for publication in peer-reviewed, scientific journals.

In making a determination, an ethics committee/institutional review board will consider a number of issues:

- a. how the research is to be explained to the participants;
- b. how participant consent (and/or proxy consent) is to be obtained;
- c. how participants are to be treated during the research;
- d. what safeguards are in place to minimize any potential harm to participants;
- e. what mechanisms are in place to respond to any adverse events;
- f. how participants' personal information and research results pertaining to them as an individual are to be kept private and confidential;
- g. what mechanisms are in place to report findings to the participants and allow for peer review by the scientific community; and
- h. what mechanisms are in place to maximize any benefit to participants (and their community) of research findings.

Where inter-jurisdictional or cross-cultural conflicts of procedural or ethical standards arise, the ethical standards or principles maintained by the country or cultural group in which the research is proposed to be conducted would ordinarily prevail. In particular, local laws and regulations cannot be ignored. In the case of international, multicenter research, researchers need to consider if by incorporating different local standards into their research protocol, they are not compromising the ethical framework within which they ordinarily work; that they are not going to act in a way they believe could compromise or harm their participants; and/or act in a way that could undermine the scientific credibility of their research activities. Where resolution of such conflict is not possible, it could be that it is inappropriate for the research to proceed.

There follows recommendations to assist with ethical review processes for research involving participants with intellectual disabilities, and in particular research involving international, multicenter trials investigating support needs and treatment options for people with intellectual disabilities.

RECOMMENDATIONS

General

1. That international organizations, national and local governments, together with the scientific community recognize people with intellectual disabilities to be among the least privileged and most vulnerable in the community and that if their circumstances are to improve, there is an urgent need to facilitate rigorous and ethical research into issues of importance to people with intellectual disabilities, their families and support systems.

2. That those involved in funding and conducting research recognize the advantages of international, multicenter collaboration; including broader funding bases, together with additional infrastructure and expertise to progress and monitor research activities.

3. That organizations involved in research and service provision for people with intellectual disabilities have established written policies and procedures to promote ethical conduct in their activities, including wherever possible, strategies for working in partnership with people with intellectual disabilities, their families and advocates.

Ethics Review Processes

4. That international, multicenter research involving people with intellectual disabilities and/or their advocates be subject to independent review by appropriately constituted ethics committees/institutional review boards or equivalent local committees (i.e., independent committees consisting of men and women who provide expertise in research processes from varied disciplines, the law, religion and ethics, as well as lay persons from the general community).

5. That where research involving people with intellectual disabilities is proposed as an international, multicenter project, ethics approval should ordinarily be obtained in both the country in which the principal investigators work and those countries in which the research is proposed to be conducted.

6. That where an international, multicenter research project involving people with intellectual disabilities is proposed to be conducted in a country where ethics committees or institutional review boards are not yet established, the ethics committee or institutional review board in the country of the principal investigator will take into account the local laws and customs of the communities in which the research is proposed to be conducted. However, to assist ethics committee/institutional review board deliberations, it remains the responsibility of the principal investigator to provide the ethics committee or institutional review board with relevant information concerning local laws and customs of the communities in which they propose to conduct research (as they should have already familiarized themselves with these information as part of preparing their research proposal).

7. That local ethics committees/institutional review boards be established in such a way that they have the authority to approve or disapprove, recommend amendments to, and withdraw approval for research projects within the area of their jurisdiction, and that local laws provide sanctions for noncompliance.

8. That ethics committees/institutional review boards be established in such a way that they can act as independently as possible of government and/or industry (especially where government or industry are involved in the sponsorship and/or conduct of research). These bodies should provide a forum for critical reflection and a mechanism to address potential power imbalances between researchers and those who are either direct participants in research or who are members of communities whose interests are the focus of research.

9. That ethics committees/institutional review boards include men and women who provide expertise in research processes

from varied disciplines, the law, religion and ethics, as well as lay persons from the general community and those in a position to advocate the interests of people with intellectual disabilities.

10. That ethics committees/institutional review boards recognize the expertise of people with intellectual disabilities, their families and advocates and, wherever possible, consult with and involve people with intellectual disabilities, their families and advocates in their deliberations. For this purpose, appropriate mechanisms could include, but not be restricted to, the forging of links between ethics committees/institutional review boards and self-advocacy groups and/or family support organizations.

11. That in the course of their deliberations, ethics committees/institutional review boards acknowledge people with intellectual disabilities can be vulnerable to coercion and exploitation. Furthermore, they acknowledge that this vulnerability can be exacerbated where people live independently of their family, in institutional care and in countries where social and legal infrastructure to protect individual human rights, and especially the rights of people with intellectual disabilities, is not well established.

12. That in their deliberations, ethics committees/institutional review boards considering proposals to involve people with intellectual disabilities as participants take into account the principles and standards detailed in:

- the United Nations *Universal Declaration of Human Rights*, 1948
- the World Medical Association *Declaration of Helsinki*, 1964/2000
- the United Nations *Declaration on the Rights of Disabled Persons*, 1975
- the United Nations *Standard Rules on the Equalisation of Opportunities for Persons with Disabilities*, 1993
- the CIOMS and The World Health Organization *International Ethical Guidelines for Biomedical Research Involving Humans*, 1993/2002
- the European Union Directive on the Conduct of Clinical Trials, 2001

13. That approval for an international, multicenter trial involving participants with intellectual disabilities should only be given, where the ethics committee is satisfied that:

- a. the proposed research is in the interests of people with intellectual disabilities;
- b. the methods proposed are scientifically sound and are both culturally appropriate and legal in the communities in which the research is proposed to be conducted; and
- c. those who are to conduct the research are competent to do so and/or will be supervised by appropriate specialists.

14. That the usual standard for measuring the merit of any proposed research project be a comparison with either “*the best current intervention*” or the “*established effective intervention*”

available internationally for people in a comparable circumstance. Alternatively, where the proposed protocol is not related to an “intervention”, that wherever possible, it be assessed against evidence-based best practice (e.g., Cochrane Collaboration, 2003) at an international level.

15. That ethics committees and institutional review boards involved in the approval of international, multicenter research projects concerning people with intellectual disabilities acknowledge the complexity of coordinating such projects and work collaboratively, minimizing cost to researchers in terms of both time and money.

Research Design Considerations

16. That in designing international, multicenter research proposals, researchers take into account the diversity of cultural values and beliefs that could be encountered in the execution of their project. Furthermore, that their protocols be designed in such a way as to accommodate cultural variations, while at the same time minimizing the need to adapt the protocol in a way that could adversely affect the meaningful comparison of data between research sites.

17. That as part of the process of designing an international, multicenter research proposal, where interest groups are established in local communities (e.g., self-advocacy organizations or family support groups), researchers consult with these groups and that this process of consultation be documented as part of any subsequent ethics application.

18. That the option of collaboration with indigenous/traditional practitioners in the participants’ communities of origin be considered in the development of any research protocol, but that any such collaboration be ethical insofar as it reflects an evidence-based approach or best practice in research.

19. That research proposed by external sponsors (i.e., government or nongovernment sponsors from a country other than the country in which it is proposed to conduct the research) be informed by and in keeping with the national and/or local priorities concerning the development and implementation of services for people with intellectual disabilities, unless the reason for doing so can be justified to the ethics committee in that country or local community.

20. That sufficient resource for the proper execution of research projects is provided by the sponsoring agencies/investigators, to minimize any diversion of limited local resources from the existing day-to-day support of people with intellectual disabilities, especially where research is proposed to be conducted in developing countries.

21. That international sponsors of research involving participants with intellectual disabilities have an obligation to ensure adequate training and on-going support for those who will conduct research on their behalf in a host country and that wherever possible, the development of sustainable local research and clinical expertise is to be considered integral to the establishment and

operation of any research project, especially where research is proposed to be conducted in developing countries.

22. That prior to commencing any research project, provision should be made to ensure that, wherever possible, benefits to participants as a result of their involvement in the project are sustainable and that established benefits can later be made available to any participants who were involved in a control or alternative treatment group.

23. That prior to commencing any research project, researchers endeavour to ensure that, wherever possible, post-trial access to any effective treatments or interventions is available to others in the participants' community, especially where research is proposed to be conducted in developing countries.

24. That the rationale for selecting people with intellectual disabilities as participants in research be that the research is related to the needs of people with intellectual disabilities and that the research has the potential to benefit people with intellectual disabilities. This is understood to include nontherapeutic research, such as the development of diagnostic scales or assessment tools. Alternatively, it could be that the proposed participants with intellectual disabilities constitute a representative sample of the general population, which is subject to the same research protocol.

25. That the selection of a control or comparison group be such that any potential disadvantage to persons assigned to those groups are minimized, and that mechanisms are in place to ensure that these persons have access to any benefits later established as a result of the study, especially where research is proposed to be conducted in developing countries.

26. That the methods employed to address the subject matter of the research be the least intrusive possible and involve the minimum risk to participants with intellectual disabilities, their advocates and others in their local community.

Consent Processes

27. That consent to participate, to the maximum degree possible, be informed and that in all circumstances, consent to participate be voluntary and free from any deception or coercion. However, due to their limited experience of research processes, it might be that gaining the participants' fully "informed consent" at the outset of the project is not possible. In such circumstances, a mechanism of "process consent" should be formally incorporated into the research protocol. For example, each new phase of the research process (or session) should be explained and the participants' involvement renegotiated (including affirming their right to withdraw at any stage, without compromising their current support services).

28. That the consent process include the provision of information concerning:

- why the research is being proposed;
- who is to conduct the research;

- how the research is to be conducted and what it involves;
- the possible outcomes to the research for the person, including any potential benefits, potential risks or possible adverse consequences;
- how individual information will be kept and who could have access to it;
- the person's rights with respect to their declining or agreeing to participate and, if they agree to participate, their right to later withdraw at any time; and
- that there will be no adverse consequences to them if they decline to participate or later withdraw.

29. That an adult person with intellectual disability should be assumed capable of providing informed consent, unless it has been established otherwise; for example by formal assessment and/or legal determination. Where adults with intellectual disabilities are recognized as decision makers in their own right, every precaution should be taken to ensure that people with intellectual disabilities, especially those living or working in congregate care/institutional facilities are not subject to coercion or exploitation. To this end, people with intellectual disabilities could be encouraged to consult with a family member or another independent advocate, prior to consenting to involvement in a research project.

Note: Children (i.e., minors) with intellectual disabilities should be afforded the same rights and protection as children without cognitive disabilities. Their parents or legal guardians should be involved in any consent process. However, even where a parent or legal guardian has given consent to their participation, children should not be coerced or forced against their will to participate in research activities.

30. That where an adult with intellectual disability provides informed consent to participate in research, that their decision be respected and support provided to assist them to participate.

31. That when determining if a person can give informed consent, consideration should be given to:

- the person's previous experience of participation in research, if any;
- the form and extent of their decision-making capacity in every day situations;
- their propensity to acquiesce and/or demonstrated ability to say "no" in circumstances not to their liking;
- their ability to interpret and explain in their own words the protocol that has been presented to them, including their appreciation of any risks and their right to decline participation without any adverse consequences to them or the services they receive. However, they do not need to understand "technical information" pertaining to the design or methods adopted in the research protocol;
- the culture and legal jurisdiction in which the person lives.

Note: Advice and the assistance in clarifying a person's capacity to provide informed consent could, for example, be obtained

from a Guardianship Tribunal (or its equivalent), a psychologist, medical practitioner or lawyer familiar with people with intellectual disabilities.

32. Where a person is able to provide informed consent but unable to read and sign a consent form, oral consent in the presence of at least one independent witness could be acceptable. However, where implemented, this process needs to be formally documented.

33. That where a person is unable to provide informed consent, their spouse, parent, legal guardian, family elder or community leader (as local laws and culture dictate) should be consulted. However, it must be acknowledged that family members and advocates can vary in their experience and subsequent effectiveness in providing or withholding informed consent. Researchers therefore need to exercise caution when relying on such persons to safeguard the interests of potential participants. In some instances, especially where a nominated family member or legal guardian do not have regular contact with the potential participant, collective decision-making processes, involving a number of advocates, can be more effective in safeguarding the potential participant's best interests.

34. That in some circumstances, it might be a legal and/or a cultural imperative that consent to participate include reference to a proxy (e.g., a person's spouse, parent, legal guardian, family elder or community leader). This could be especially important for participants from cultures that emphasize a collective (e.g., family) identity, as opposed to an autonomous individual identity. However, in such circumstances, genuine assent to participate (which can be either explicit or implied) must always be obtained from individual participants with intellectual disabilities. The process by which this is obtained should be documented. The refusal or resistance to participate by a person with an intellectual disability must be respected, whatever the view of others involved in the consent process is. That is, even where a legal guardian has provided consent to participate in a research project, a person with an intellectual disability (be they an adult or a child) should not be coerced or forced against their will to participate in research activities.

35. That the information provided to potential participants (and/or those providing proxy consent) about a research project be accurate and in a format that takes into account the participants' (or proxy's) first language and/or local dialect, and wherever possible any comprehension difficulties that might be associated with the participants' intellectual disabilities. To this end, the information process could include the use of visual cues and practical demonstration of research procedures.

36. That the consent process and supporting documentation takes into account the participants' first language (and local dialect), and wherever possible, any comprehension difficulties that might be associated with their intellectual disabilities. To this end the consent process could include the use of visual cues and practical demonstration of research procedures.

The Conduct of Research

37. That in international, multicenter research, researchers provide sufficient monitoring of research activities at a local level so as to ensure both participant safety and the integrity of the research protocol.

38. That researchers involved in international, multicenter research projects ensure that participants with intellectual disabilities and their advocates have access to an independent authority to which they can easily direct inquiries and/or complaints concerning the research project. Furthermore, that mechanisms exist to ensure any complaints are conveyed in a timely manner to all ethics committees involved in the approval and monitoring of the project. Note: In some countries or local communities, the provision of a telephone contact number alone might be insufficient. Personal follow-up by an independent authority (e.g., a local health visitor, not involved with the research team) could be necessary.

39. That "appropriate standards of care" for participants with intellectual disabilities in research projects should be established in consultation with those who work within the country or local community in which the research is to be conducted. However, "appropriate standards of care" should also be informed by internationally accepted, best practice.

40. That any potential risks to participants with intellectual disabilities be distributed as equitably as possible between participants in all jurisdictions involved in any international, multicenter research project.

41. That any risk should not ordinarily exceed those that are attached to the provision of routine support or therapy, medical or psychological treatments. For a project to proceed where risks are deemed to be in excess of those attached to routine practice, the ethics review committees/institutional review boards would need to find (consistent with CIOMS, 2002; Guideline 9) that:

- a. the research is designed to be responsive to the problems or issues affecting the prospective participants;
- b. the risks of the research protocol are at least comparable with those associated with routine support, medical or psychological examination of such persons in the circumstances under investigation;
- c. the objective of the research is sufficiently important to justify exposure of the participants to the increased risk;
- d. the research activities are reasonably commensurate with support activities and/or clinical interventions that the participants have experienced or may be expected to experience in the course of their life; and
- e. safeguards are in place to minimize consequences of risk should they arise.

42. That it might be appropriate to compensate participants for their involvement in a project. For example, compensation for travel expenses for inconvenience such as time away from their usual work or activities, or for incurring risk. However, no induce-

ments should be offered to participants and compensation must not be coercive, with reference to local cultural norms and circumstances. In particular, where a person provides proxy consent, no inducement should be made. Here it should be noted that, depending upon the person's circumstances, even small sums of money and/or the provision of specialist services could be considered a major inducement, especially in developing countries.

43. That provision is made for the secure storage, transport and exchange of consent documentation and individual data.

44. That prior to storage and/or transport, data is de-identified.

45. That only those directly involved in the research (i.e., the collection and analysis of data) have access to raw and/or identifiable data.

46. That international, multicenter research projects involving participants with intellectual disabilities, wherever possible, provide for the dissemination of findings in ways that promote access by participants, their advocates and local communities. This could include, for example, conducting post-project information sessions, the production of a plain language summary of the findings (where appropriate, in multilingual formats and/or augmented by pictures), or briefings provided to local practitioners or community leaders who could in turn report findings to participants in a culturally appropriate way. However, the cost of such processes needs to be taken into account when planning projects.

47. That any potential benefits to participants with intellectual disabilities be distributed as equitably as possible between participants in all jurisdictions involved in any international, multicenter research project.

48. That ownership of personal information pertaining to individual participants who reside with the individual contributing those data and that on request of participants and/or with their consent, relevant individual data will ordinarily be available at the conclusion of a research project to assist with the participants' on-going support or treatment.

49. That research involving participants with intellectual disabilities submitted for publication identifies the ethical standards that have been applied in the conduct of the research (e.g., the name of the ethics committee/institutional review board approving the protocol and/or the set of ethical standards applied, such as those of the World Medical Association, 2000).

50. That in the documentation and publication of any research findings, those involved in conducting research in a host country on behalf of a principal researcher or international sponsor be given appropriate acknowledgment for their contribution to the project.

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The following individuals have provided specific comments on previous drafts. However, no single contributor to the Working Group necessarily endorses the document in total.

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APPENDIX 1

Model Ethics Application Form

- To assist with seeking ethics approval, there follows a model ethics application form.
- It is intended that local ethics committees adapt this form as they determine.
- The purpose of the model application form in its current format is as a tool for education.

MODEL APPLICATION FOR ETHICS APPROVAL

1. Date of application

Day/Month/Year

2. Place(s) of application

Provide the full name and contact details of the principal ethics committee/institutional review board to which the application is made.

Provide the full name and contact details of all other ethics committees/institutional review boards to which the application is made (or to which it is intended to be made).

3. Full title of the project

Provide the full scientific title for the project, as it will be identified in the literature.

4. Short title of the project

Provide a short, plain language title by which the project will be introduced to participants.

5. Principal investigator

Provide the full name, qualifications and address details for the principal investigators. Note any impediment, legal or otherwise, to any of these people working with people with disabilities. Each person is to sign the ethics proposal.

6. Co-investigator(s)

Provide the full name, qualifications and address details for all the co-investigators; that is, any person who will be involved in carrying out any of the procedures detailed in this proposal and/or collecting data in relation to this project. Note any impediment, legal or otherwise, to any of these people working with people with disabilities. Note what safeguards will be in place to ensure that any additional personnel, such as research assistants who are recruited later, are appropriate persons to work with people with disabilities (e.g., references obtained and/or police checks conducted).

7. Endorsement of the project

Provide the full name, title and contact details of a person at the principal institution, other than one of the investigators, who has authority to endorse/approve the project proposal. This person should sign the ethics proposal.

Provide full contact details of any individual or organization, representative of the proposed participant group with which you have consulted when developing this project proposal. Attach supporting evidence.

8. Previous consideration by the current ethics committee

Note if the current project was previously submitted to this ethics committee and what was the determination at the time: approved; request for modification; not approved; approved, but later terminated. Attach supporting evidence. Provide the date and any reference number pertaining to the previous application.

9. Previous or concurrent consideration by any other ethics committee

Note if the current project was previously, or is currently being submitted to any other ethics committee and what, if any, has been the outcome: approved; request for modification; not approved; approved, but later terminated. Attach supporting evidence. Provide the date and any reference number pertaining to any such application(s).

10. Expected duration of the project

If approved, when will the project commence and when is it anticipated to end.

11. Site or location for the project

Provide the name, physical address, postal address, e-mail address and telephone contact details of the institution or organization primarily responsible for overall management of the project. Detail other sites where research activities are to be conducted. If possible, provide physical address, postal address, e-mail address and telephone contact details. Describe how research sites will meet the needs of participants with disabilities.

12. Plain language description of the project (250 words or less)

Provide a plain language/lay description of the project.

13. Sources of funding

Outline the sources of funding for the project, together with any contractual obligations related to funding, any potential conflicts of interest and how it is proposed to address these.

14. Potential conflicts of interest

Outline any conflicts of interest or potential conflicts of interest for any of the investigators or their respective organizations and the strategies proposed to address these. Describe any anticipated or potential benefits to those conducting the research, either directly or indirectly, financial or otherwise. Note who will own the findings or any intellectual property resulting from the project and/or have control over their publication/dissemination.

15. Background and rationale for the project, including an outline of potential benefits (maximum 1 page, single spaced in 12pt type)

Describe the proposed project in detail. Justify the project; outline why the project is important, what benefits it is likely to produce, for individuals and the community. Include key references to related projects and findings in the literature. Provide a reference list.

16. Aims and hypotheses for the project

State what you expect to achieve as a result of the project. State any hypotheses you intend testing or research questions you will be addressing.

17. Method

a. Recruitment of participants (including inclusion/exclusion criteria)

How will the project be publicized? Attach proposed publicity material.

How many participants are required to make the project viable (justify)? How will potential participants be identified? How will they be invited to participate? Will there be any exclusion criteria, and if so what are the criteria? Will potential participants be offered any compensation for their participation or enticement to participate? How will language/communication issues be addressed?

Will any of the potential participants be persons living independently of their family, in institutional settings or resident in any country or community in which there is minimal or no social and/or legal infrastructure to safeguard their individual and human rights? If so, what strategies will be established to address such circumstances and to safeguard the social and legal interests of participants?

Are there any other research projects known to the investigators that could be competing for participants and if so how will equitable recruitment be negotiated?

Attach the Participant Information Sheet for each participant group (and any other proposed information formats), including any prepared form in the first language of participants whose preferred language differs from that of the investigators. Provide details of how the translation was obtained and verified to be correct.

b. Process for obtaining consent

How will consent be obtained and documented? Where consent cannot be obtained directly from participants (e.g., due to their comprehension skills), how will formal consent be obtained and participant assent obtained? Will participants be blind to any aspects of the protocol (e.g., the use of a placebo), and if so, how will this be handled and how will participants later be de-briefed?

Attach the Consent Form for each participant group (and any other proposed consent record formats), including any prepared form in the first language of participants whose preferred language differs from that of the investigators). Describe how the translation was obtained and verified to be correct.

c. Data collection strategies

Describe precisely the procedures you intend to undertake either directly with the participants or in obtaining participant data (e.g., accessing records or interviewing proxy respondents). Will any data be recorded (e.g., audiotape or videotape) or gathered electronically; and if so, what steps will be taken to ensure confidentiality of others who could be captured on the recordings? Could the protocol interfere with the person's usual lifestyle or treatment? Do these strategies conflict in any way with local laws, values or customs and how will any such conflict be addressed? Will any comparison or control group be employed and if so, how will this be implemented?

d. Monitoring and quality assurance

What procedures will you have in place to monitor the project and ensure that it proceeds as it has been designed? What procedures will you have in place to monitor those procedures that are intended to address any unforeseen adverse consequences?

What facilities will be established at a local level for participants who require additional information about the project or those who wish to make a complaint about the project? How will this information be communicated to the Ethics Committee of Record and other authorities with a legitimate interest in such complaints?

e. Potential risks and management of adverse events

Outline any potential or foreseeable risks (e.g., physical, emotional, social or legal) to participants and the strategies proposed to either prevent these or to respond to them should they arise. How are any potential risks to be distributed among the different groups or communities involved in the project? How will others involved in conducting or supervising the research (including any ethics committee or institutional review board involved in approval of the project) be notified of any adverse events?

f. Termination criteria and protocol

Under what circumstances would individual trials be terminated? Under what circumstances would the entire project be terminated?

g. Data transport/exchange and storage

How will data be transported or exchanged between sites? Where will the data be stored and how will the security of identifiable data be ensured? What steps will be taken to de-identify individual data? How long will data be stored; and how does this comply with local laws or regulations concerning the preservation of research data?

h. Data analysis

How will the data be analyzed; what approach will be adopted or techniques employed? Will interim results be analyzed as part of quality and safety assurance? Will a monitoring/review committee be involved in the process?

18. Reporting results

Explain how (where) the results will be made available: to members of the scientific community for peer review; to persons who can implement change at a local level; and to the participants and/or people with disabilities generally. Are there any circumstances where findings could be withheld?

19. Follow-up to the research project

Describe how any benefits to participants gained through their involvement in the project could be sustained following the project. Describe how any benefits to one group of participants (i.e., an experimental group) will later be made available to others involved in the project (i.e., a control group). Describe how any benefits discovered or identified as a result of the project will be made available to members of the participants' local community and how the benefits could be made available to other persons with similar needs. Is any cost to the individual or the community anticipated? Will data from the current project be stored and used in any future project? What community capacity building activities/benefits are the project sponsors committed to in terms of either scientific or social endeavors?

APPENDIX 2

Checklist for Participant Information Form and Participant Consent Form

- An application for ethics approval should be accompanied by a copy of the Participant Information Sheet and Participant Consent Form that will be provided to potential participants and/or their advocates.
- Both the Participant Information Sheet and the Participant Consent Form should be designed to ensure comprehension/understanding by participants and/or their advocates. Plain language should always be used, with scientific terminology included only where absolutely essential. Consideration should also be given to the inclusion of visual and/or pictorial aids.
- Where participants are to be recruited from a cultural or linguistic background that is different from that of the principal researchers, an approved translation of the Participant Information Sheet and the Participant Consent Form should accompany the ethics application. Care should be taken that translations are accurate and take into account local dialects of any official language. Details of how the translation was obtained and subsequently verified should be included in the ethics application.
- In some circumstances, it could be appropriate for the information sheets to be augmented by audio or visual recordings to assist with the accurate dissemination of information. Also, standardized practical demonstration of some research activities and data collection procedures could be necessary.

The Participant Information Sheet and the Participant Consent Form should be on institutional/organizational letterhead and should include:

1. The short, plain language title of the project.
2. A brief, plain language statement of the project aims and potential benefits. The statement should acknowledge if the project is being conducted to meet the requirement of a qualification (e.g., university degree). Also, any sponsorship of the project by government or nongovernment organizations should be acknowledged.
3. The names and contact details of those responsible for the project; including those with overall administrative responsibility and those with local responsibility.
4. The name(s) and contact details of the authority/authorities that have approved the project.
5. A description of what the participants are expected to do, where they would be expected to participate and over what period of time. This description should include acknowledgment of any audio or video recording that could be involved in either research activities or data collection.
6. A clear statement of any potential risks or discomfort for participants or those with whom they live, work or socialize, and information about how any adverse events will be addressed.
7. A clear statement of any potential benefits to participants and any possible limitations to these benefits (e.g., for the duration of the project), including any compensation for their participation or costs they might incur as a consequence of their involvement in the research.
8. Details of how data are to be collected, stored, and later destroyed or preserved. Details of how the privacy and confidentiality/anonymity of participants are to be maintained. Also, any limitations on the maintenance of confidentiality and/or circumstances where information might need to be disclosed to a third party (e.g., reporting any disclosure of abuse).
9. Details of how the findings are to be disseminated, including how the confidentiality of individual participants is to be maintained. Also, a statement of how participants will be advised and/or can find out about the findings other than through the peer-reviewed literature. Information about if and how individuals can gain access to data to assist with their usual support or treatment.

10. A statement guaranteeing the participants' right to withdraw from the project at any time, without having to give a reason or in any way having an adverse consequence for them personally (e.g., the cancellation or alteration of any support service and/or treatment they would ordinarily receive).
11. A statement that the participant has been given a signed copy of the Participant Consent Form.
12. Contact details of an independent authority to which participants can direct any inquires or concerns they might have about their involvement in the project. The independent authority should be readily accessible at a local level. However, contact details for the principal ethics committee should also be included.
13. A signed statement (by the person or their legal guardian) that the participant has read, or had read to them, the Participant Information Sheet (which they can keep for their own records), that they understand what participation in the project involves and that they agree to participate on the understanding that they can withdraw their consent at any time without prejudice to their usual services and/or treatment.
14. The Participant Consent Form should also provide for the consent of a "Legal Guardian" or "Person Responsible", where the person is unable to independently provide informed consent; for example., in the case of a person whose disabilities limit their decision-making capacity or a minor (Note: The age of consent varies between jurisdictions and across cultures). The reason why someone other than the participant is signing the form should be documented (e.g., the person did not understand the consent process or was not deemed legally competent). In such circumstances, the relationship between the participant and the person providing the consent should be detailed. There should be a clear statement that the person providing consent on behalf of the participant does so without any inducement or likelihood of personal gain as a consequence of providing consent. Also, there should be a clear statement that even though someone else signed the Participant Consent Form, if the participant does not provide assent to proceed (i.e., they protest or choose not to comply with the procedure), their participation will cease immediately.
15. Pages on any Participant Information Sheet or Participant Consent Form should be clearly numbered in the format "Page 1 of 2", etc.