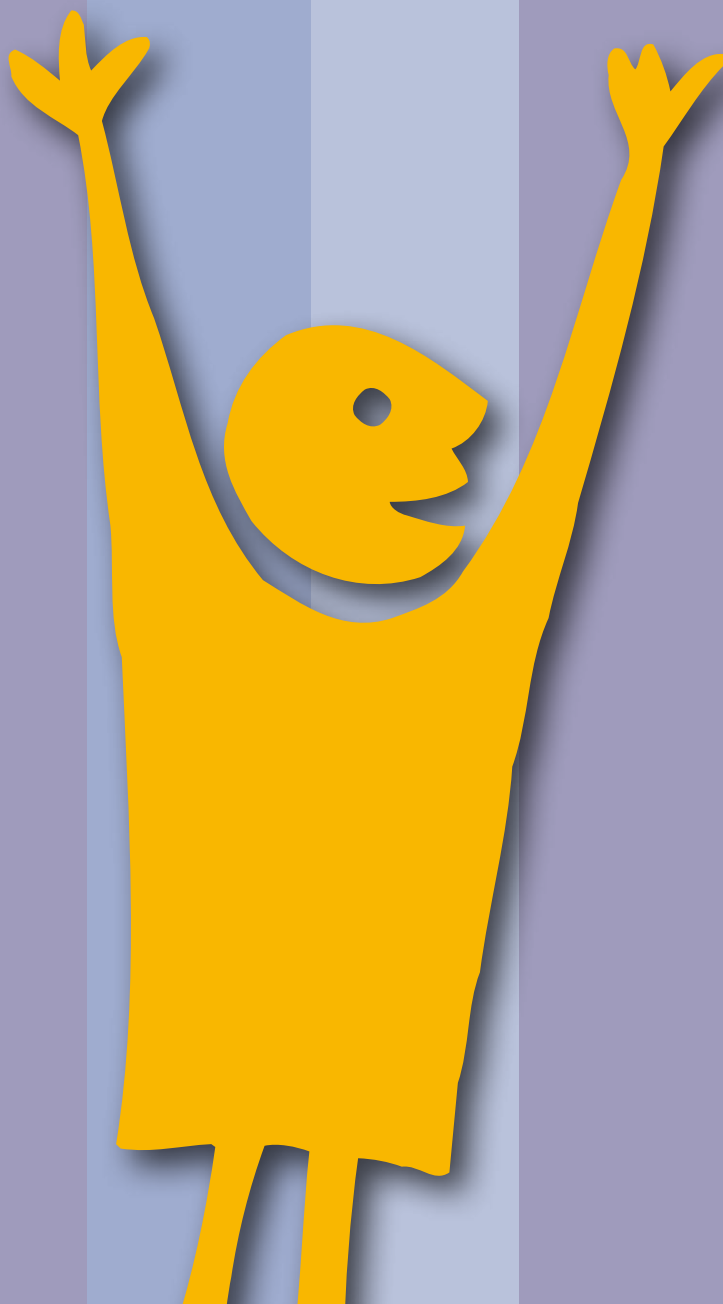




Children's research and ethical review: Executive Summary

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Children's Research and Ethical Review

Executive Summary

The National Children's
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Children's Research and Ethical Review

Executive Summary

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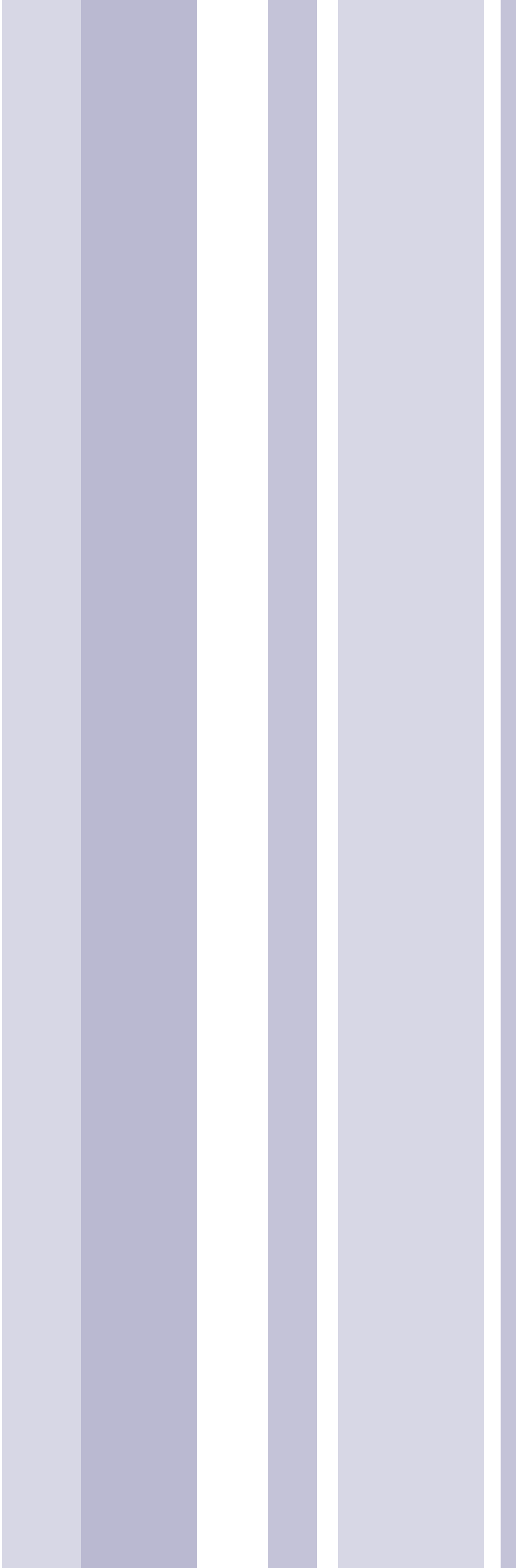
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Abbreviations

CFR	Code of Federal Regulations (USA)
CIHR	Canadian Institutes of Health Research
DHHS	Department of Health and Human Services (USA)
EU	European Union
HSE	Health Service Executive
ICB	Irish Council for Bioethics
NHMRC	National Health and Medical Research Council (Australia)
NPSA	National Patient Safety Agency (UK)
NRES	National Research Ethics Service (UK)
NSERC	Natural Sciences and Engineering Research Council (Canada)
NZHDEC	New Zealand Health and Disability Ethics Committees
REC	Research Ethics Committee
SOP	Standard Operating Procedures
SSHWC	Social Sciences and Humanities Research Ethics Special Working Committee (Canada)
SSHRC	Social Sciences and Humanities Research Council (Canada)
WHO	World Health Organisation

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Background

A substantial increase in research into the lives of children has been experienced in Ireland over the last few years. This increase is not only in the amount of research undertaken but also in the multi-disciplinary range of such research. Compared to requirements in research with adult research participants, research with children faces additional ethical challenges. These challenges are related especially to children's decision-making capacity, their vulnerability and the particular role of parents or guardians in the research process. The strong demand for protecting children from harm needs to be balanced with the equally urgent need for well-founded research findings that can help improve services for children.

While there is a tradition of highly formalised and professionalised research ethics review procedures in North America, the development of comparative structures has proceeded at a significantly slower pace in Europe and other continents. In Europe, increased attention has been paid to research ethics committee (REC) procedures after the 2001 European Clinical Trials Directive came into effect. Overall, Ireland has been comparatively slow in adopting formalised ethics review procedures. However, the publication of the *Operational Procedures for Research Ethics Committees* (2004) by the Irish Council for Bioethics led to more widespread attention to the implementation of structures and procedures to support good practice. The evolution of Irish research ethics review committees in a relatively unregulated environment coupled with the increase in multi-disciplinary research on children's lives warrants investigation. The main aim of this research is to provide an overview of the current mechanisms for applying for and achieving ethics approval for studies being undertaken with children in Ireland.

Methodology

A multi-method approach to overall research design was employed.

Documentary review

A literature review was undertaken to identify ethical issues in research with children, international good practice regarding review processes, institutional structures and the analyses of challenges encountered in establishing and implementing ethical review procedures.

Stakeholder perspectives

Stakeholder perspectives were ascertained through both quantitative and qualitative approaches to data collection. All data collection tools were piloted prior to use. All interviews and focus groups used a topic guide format and all were digitally recorded and transcribed verbatim. Analysis was undertaken through a template approach as described by Robson (2002).

Postal survey

A quantitative postal survey of all operational RECs listed by the Irish Council of Bioethics, with additional committees identified through the documentary review process, was undertaken. The aim was to gather information on REC remits, procedures and specific practices and extent of applications relating to research with children. This component of the empirical data collection was conducted in collaboration with a research team from the HSE (Health Service Executive Research Ethics Committee Review Group, 2008). Responses were received from 32 RECs in total, resulting in a response rate of 64%.

Interviews, focus groups and participatory workshop

Members of RECs: Semi-structured telephone interviews were undertaken with 26 Chairs and eight administrators of RECs. Two focus groups were undertaken with members of RECs and four individual interviews with REC members, two of whom were also children's researchers.

Children's researchers: Researchers of children in Ireland were identified through web-based searches of organisations and institutions expressing an interest in research with children. Six focus groups were conducted with children's researchers based in three institutions in Dublin, Cork and Galway: two academic and one medical. In addition, eight individual interviews with children's researchers from five institutions were conducted.

Children: Young people were accessed through schools. The Principals of primary schools who were known to have participated in any children's research were contacted. Four schools agreed to participate. In total, 47 students aged 11–13 took part in the study. A participative workshop protocol was designed and pilot-tested. The areas focused on were those consistently highlighted in the literature as important in relation to ethical issues in children's research: consent, confidentiality and risk/burden.

Parents: A list of 113 schools known to have participated in research was generated from the Department of Education and Science data-file of schools. Twenty primary schools were randomly selected from the compiled list. Fifteen of the 20 Principals from each of the 20 schools identified recruited a parent, 13 of whom participated in the study. A semi-structured telephone interview was undertaken with each parent.

Health Service Executive (HSE) consultation: The HSE research initiative into RECs included a consultation day with invited members of RECs, researchers, patients' representatives, experts and policy-makers. The data collected were subsequently shared between the research teams.

Ethics

Approval for conducting the research was sought and granted from the Research Ethics Committee, National University of Ireland, Galway.

Results

Research ethics governance: International context and issues for current models

International examples of national research ethics governance demonstrate the range of models that have developed. These models generally fall along continuums from more to less centralised and more to less standardised. Any governance approach to research ethics has to address the problem of balancing diversity and locality issues on the one hand and the issue of standardisation and quality assurance on the other. Standardisation is not restricted to the case of thoroughly centralised review systems. In many countries research ethics governance systems do not treat all research equally; in most countries the area of clinical trials research is governed quite strictly, which in the EU falls under the European Clinical Trials Directive (EU, 2001), while other forms of research are frequently under less ethical scrutiny. There is a concern that, as a consequence, not all research participants receive the level of protection that they should be entitled to (Evans, 2004).

Much of the research ethics literature on governance issues from the researchers' perspective focuses on the extent to which research ethics committee review requirements represent an undue burden that impedes rather than facilitates research and does not fulfil its stated primary goal of protecting research participants (Burriss and Moss, 2006; Fleischman, 2005; Fost and Levine, 2007; Wald, 2004). This problem is particularly evident in the area of multicentre studies; these concerns have been one of the main drivers for research ethics governance reforms. Researchers argue for the need of looking beyond a mere compliance model towards increased efforts of constructive cooperation with researchers (Connolly and Reid, 2007).

RECs and the Irish REC landscape

RECs have been a much less prominent part of the research landscape in Ireland than in other countries. Currently, 72 RECs in Ireland have been documented, 46 of these contributing to this study.

Ethical review structures

RECs in Ireland can be classified into three main categories:

- **Health and social care committees**, which include 29 HSE committees and 11 committees in the voluntary and private sector. Thirteen committees have been approved to review clinical trials, the majority of which are also HSE committees.
- **Academic committees**, of which 27 are currently on record.
- **Other types of committees**, such as those linked to relevant professional associations and other bodies. Currently 6 RECs fall into this category.

REC structures

Existing guidelines on REC membership often stipulate a minimum number of members, frequently somewhere between 5 and 8 (CIHR, NSERC and SSHRC, 1998/2005; DHHS, 2005; DK, 2003; ICB, 2004; NHMRC, 2007). Survey data indicate that membership of RECs in Ireland ranges from 2 to 21 members, with a mean of 13.0 (sd 4.2). Common guidelines regarding the composition of RECs concern the inclusion of members with expertise in the areas of: law, ethics, research and members whose experience qualifies them to act as subject advocates. Guidelines frequently stipulate the inclusion of lay members (Department of Health and Children, 2004; Holm, 1992; HRC, 1996; ICB, 2004; NHMRC, 2007; WHO, 2000). From the survey data it was established that over 70% of Irish RECs had membership from the following professional backgrounds: legal adviser (81%), medical doctor (78%), nurse (75%) and lay person (72%).

The day-to-day operation of the committees requires administrative support and a certain level of resources for other aspects of the running of the committee, which is explicitly acknowledged by most research ethics guidelines (CIHR, NSERC and SSHRC, 1998/2005; DHHS, 2005; NHMRC, 2007; WHO, 2000). While most committees have some access to administrative support, in many cases this is minimal. According to the survey data, resources represent a major challenge for the work of RECs in Ireland. From the stakeholders' perspective, it was acknowledged that a wide range of levels of resourcing was experienced by different RECs. According to the survey data, in Ireland RECs met 2–11 times per year, with a mean of 6.3 (sd 3.2). The majority of committees (72%) reviewed up to 50 submissions, while two committees reported a very high workload (196 and 278 reviews respectively). The overall median was 36.

The work of RECs requires a certain degree of specialist ethical expertise. While training of REC members is generally considered important (Hanna, 2000; Silberner, 1998) and is mandated by some guidelines, in many committees no specialist training is provided. The provision of dedicated research ethics training for members is not the norm in Irish RECs. There was great variation amongst RECs as to the extent and form of training received. While stakeholders are not unanimous in considering lack of training as problematic for the functioning of the RECs, the lack of training and wish for better training opportunities is a topic that was raised frequently in interviews with stakeholders.

Research ethics review processes

Most committees work on the basis of Standard Operating Procedures (SOPs), which document the organisational framework and the procedures according to which the REC operates and require that applicants fill in a standard application form. In the Irish context, 90% of committees reported that they have a standard application form, but only 68% of the surveyed committees operate on the basis of SOPs. Stakeholders reported a wide range of procedural differences in the review process after receipt of the application for ethical approval; 74% of committees facilitate expedited review.

Following review, the REC comes to a decision on how to proceed, usually indicating some version of the following: approval, provisional approval that is subject to conditions, deferral and resubmission, or rejection (ICB, 2004; NRES, 2007; NZHDEC, 2006). According to survey data, and in keeping with international experience, the vast majority of submitted research proposals are ultimately granted approval. If a submission is refused, 66% of committees state that they give the researchers the option to appeal the decision; however, there is little clarity on the implementation of such appeals procedures.

Monitoring and RECs

RECs usually keep a record of the proposals that they review. In some jurisdictions, detailed instruction is given on what records are required (e.g. CFR 46.115 in the US). The scope and authority of such monitoring or auditing activity is often unclear and it has been debated how effective RECs are in this role and how exactly the role of RECs should be understood (Bankert and Amdur, 2000; Bortolussi and Nicholson, 2002; Faden *et al*, 1980; Heath, 1979; Saver, 2005). Few stakeholders referred to any monitoring function of RECs beyond acknowledging that it did not occur or was underdeveloped.

Ethical issues in children's research

Ethical issues in research with children and adolescents are similar to those with adults but are compounded by further complications due to the following factors:

- the legal status of minors;
- the inclusion of additional parties (i.e. parents and/or guardians) in the consent process;
- potentially, but not necessarily, reduced psychological competence (as opposed to legal competence) for consent in minors;
- significant inter-individual differences in maturity, even within the same age group or study population; and
- significant differences of knowledge and maturity between children of different ages and different study populations, with adolescents given increasing rights of self-determination in many areas of their lives.

Informed consent

International guidelines frequently address informed consent requirements in considerable detail (DHHS, 2005; NPSA, 2007). Challenges in the practical implementation of procedures, especially regarding the problem of ensuring participants' understanding of study information, are highlighted. A decision by a minor to participate in research is considered to constitute assent, defined as '*a child's affirmative agreement to participate in research*' (DHHS, 2005, p. 1). A child's assent needs to be complemented by a decision of a '*legally recognised surrogate decision-maker*' (Baylis *et al*, 1999, p. 6), i.e. the parents and/or guardians. However, how exactly this assent process is realised in child research is not always clear from published literature and might indicate a need for further clarification for the research community (Range and Cotton, 1995a, 1995b; Roberts and Buckloh, 1995). Stakeholders focused on this area in the interviews and focus groups, recognising the difficulties particularly in relation to: adolescence, the lack of coherence nationally in the legal age of consent, conflict between parents and children in decisions over research participation, research in the school setting and the role of the school in informed consent. Parents highlighted the need for clear information to facilitate their decision-making. Children identified that a child's consent should precede parental consent, acknowledging there is a role for others in the process.

Confidentiality

Confidentiality issues are usually governed by certain legal data protection requirements and ethical research requires familiarity with such requirements (SSHWC, 2007). The main concern about confidentiality in research relates to information that has been provided by the participant to the researcher or to data that can be traced to the participant. The responsibility of the researcher is to make sure that data are not available to unauthorised persons. This includes several different issues:

- safe data storage (physical and electronic);
- removing identifying information from data sets, for example by encryption, anonymisation or modification of identifying information; and
- receiving approval from a participant for any disclosure of information to other parties.

In the case of research with children, all of the above concerns should be taken into account, but there are also some challenges specific to children's research. One area that is particularly prominent is child protection. In most jurisdictions, including Ireland, mandatory reporting laws and relevant child protection guidelines are in place (Department of Health and Children, 1999/2004). It is considered good practice to communicate these limitations to research confidentiality to both parents and children during the informed consent process (Neill, 2005). Stakeholders generally recognised the limitations of confidentiality in research with children, both implicit and explicit. Confidentiality in relation to visual images was identified as a particular issue. Parents made limited reference to confidentiality but did refer to the need for anonymity. Children were presented with an example of a research dilemma – an account of a child disclosing sensitive information to a researcher – and in response they expressed a range of perspectives on confidentiality.

Risk, burden and benefits

The primary goal of existing research ethics structures and practices is to ensure that participants, adults or children, will not be exposed to undue risks and, where possible, will receive some benefit from their research participation. In research with children, the protections are significantly stricter than in research with adults, due to their perceived vulnerability, and most international guidelines agree that children require particular protection in research and accordingly set fairly strict criteria regarding the issue of risk (e.g. in the US as documented in DHHS, 2005). A complication is that it appears that lay persons generally find it extremely difficult to conceptualise risk. From the researcher's perspective, it is notoriously difficult to assess psychological risks, and there is evidence both of significant conservatism and risk adversity in relation to identified psychological risks (Corbin and Morse, 2003), but also, on the other hand, of lack of awareness of certain psychological risks or harms (Hadjistavropoulos and Smythe, 2001). It is important not only to consider the risk of harm as a consequence of research interventions, but also the burden of research participation itself.

In addition to avoiding risk and burdens, researchers also face the demand to allow participants, where possible, to benefit from their participation in research. Among the more frequently mentioned benefits of research participation are the following:

- access to otherwise not available services, diagnosis or treatment (Edwards, 2006);
- gaining novel experience and information through research participation and feedback; and
- altruistic satisfaction of being part of a process that might contribute to improvement in therapies and services or an increase in knowledge.

Stakeholders made limited reference to benefits, although some cautioned against overstating any benefit to children through participation in research. Participants referred to risk and benefit in terms of a relationship between the two, often referring to the need to enable children to take part in research that relates to them, some referring to this as a *'right'*, and the need to reduce exposure to any risk. The majority of parents do not feel that their children need to be direct recipients of any benefits from the research they are involved in. The majority of children expressed an attitude of altruism in relation to research participation.

The ethics of children's research in Ireland

While developments in relation to ethical review appear to be progressing, participants identified gaps both at the level of overarching governance of RECs and in the provision of independent ethical research review, particularly in relation to some schools-based research with children. There is a lack of consistency in relation to operating procedures and review processes between RECs, and the range of structural models of RECs in the Irish context is striking. Procedures need to do justice to children's and parents' right to consent or refuse to participate, with due regard to the autonomy, but also to the varying range of levels of maturity and vulnerability, of children and potential cases of disagreement between parents and children. The specific role of children themselves in the consent process requires further exploration, including the specification of exact legal requirements of informed consent for mature minors. The difficulty of navigating these generic and specific tensions and challenges to the ethical review of children's research was identified by stakeholders. While there is diversity in research ethics review, there are points of commonality at three levels:

- the primary goal of the ethics review process for all RECs is the protection of research participants;
- ethical review, as practised in contemporary RECs, is usually based on consideration for respect for autonomy and dignity, non-maleficence, beneficence and justice; and
- RECs share the need to develop procedural mechanisms for the review process.

Conclusion

With the increase in research into the lives of children, which reflects an increase in research generally, the research ethics review landscape is continually developing. The majority of Irish RECs identified that they reviewed research with children as part of their function. The diversity and range of research with children reported reflected the range of general research reviewed in every way. While consensus was not expressed by stakeholders regarding the centralisation of REC governance, the commonalities identified, especially regarding the implementation of a central information resource, the desirability of wide-ranging standardisation, and specific needs for information and guidelines in relation to children's research, could form the basis of the beginning of dialogue in the further development of effective and efficient research ethics review in Ireland. It is imperative for all stakeholders, including children, to be able to voice their respective views at the beginning of such a necessary dialogue.

As a starting point for such dialogue, the following suggestions arising from the research could be considered in order to ensure that children's research in Ireland is conducted ethically and reviewed adequately by Irish RECs. These recommendations in relation to the general research ethics governance system are largely in agreement with previous Irish reports on the issue, with the exception of the assessment of the benefits of a centralised, non-localised review system with a strictly limited number of committees, which was not generally supported by the stakeholders consulted. This difference was likely to be due to the nature of the research that these RECs and other stakeholders engaged in. The majority of stakeholders consulted were strongly, if not exclusively, involved in research outside the clinical trials sector, and, especially for the children's research stakeholders, a significant proportion of these were working either in social science research or in health research based on social science methodologies.

1. Creation of a central research ethics resource

The general perception of stakeholders was that there is a need for a central research ethics resource, its functions to include in particular provision of authoritative advice, training and networking for REC members and researchers. In relation to children's research, such an ethics resource would provide information, guidelines and training on the ethical conduct of research with children. Details regarding the implementation of these will be further explained below.

2. Comprehensive governance system and national standardisation

While many participants strongly valued the independence of their own RECs, it was also common for participants to express the view that the existing system was suboptimal in relation to its current lack of governance. The Clinical Trials REC system was perceived as reasonably functional (despite some significant misgivings on some aspects of the system), but the review of other research, especially but not exclusively other types of multi-centre studies, was perceived to be urgently in need of reform. Those participants who addressed the issue tended to favour a governance model that would provide standardisation of review without centralisation and loss of review authority by local committees. Nevertheless, they acknowledged the need for extensive standardisation and a governance system that would ensure consistency across RECs. Aspects of such governance that were identified as desirable include:

- standardisation of application forms across Irish organisations, allowing for adequate differentiation between research sectors and methodologies;
- implementation of standardised online submission procedures;
- standardisation of review procedures, including expedited review, and timelines across Ireland;
- creation of binding procedures for the review of multi-centre research that does not fall under the clinical trials directive;
- implementation of clear and consistent appeals procedures within RECs and review feasibility of external adjudication;
- guidelines for membership, including increased clarity on role of lay members; and
- use of the same or compatible software for record-keeping.

In the absence of a governance body with the authority to implement review guidelines, it is urgently required to conduct a consultation regarding the review of multi-centre studies that do not fall under the clinical trials directive, with the goal of coming to an agreement on binding, streamlined review procedures across Ireland. Such a consultation should ideally be conducted across the different sectors – academic, HSE and voluntary.

3. Creation of suitable structures for the review of children's research

While very few stakeholders identified the implementation of completely separate structures for the review of children's research as desirable, there was a widespread perception that REC members felt less competent to review children's research than research with adults. While general competence-building of REC members in this area of research would be one possible solution, an alternative step could be the implementation of a limited number of RECs with special expertise in children's research, as realised in the UK system, for example. Given concerns about overly narrowing down the scope of review activities of RECs, such RECs could remain open to the review of other types of research. Relevant elements in setting up such specialised structures would include:

- flagging ethics committees with special expertise in children's research, based on review load and membership;
- standardisation regarding application form and documentation requirements for children's research; and
- providing training for REC members, especially from such committees, regarding good practice, ethical concerns and common research methodologies in children's research.

4. Meeting specific information needs

Many stakeholders mentioned that there was uncertainty, both among committee members and researchers, in relation to the ethical requirements of children's research. This uncertainty can lead both to overprotectiveness and inadequate protection of children in research. The following recommendations emerged as particularly relevant during the course of the study:

- Create general guidelines of good practice in children's research and disseminate these online and through leaflets.

- Provide specific information on:
 - legal obligations and relevant documentation (e.g. Children First);
 - informed consent and assent procedures and the creation of information sheets;
 - confidentiality in children's research;
 - acceptable risk;
 - standards for school-based research, clarifying the role of Principals, parents and students, researchers' responsibilities, dangers of over-researching, etc.;
 - standards for dual role research (e.g. teachers engaging in research activities with their students); and
 - standards for student research with children.
- Develop and provide dedicated training modules (online or workshops) on important research ethical issues in children's research.

5. Involving children in the research process

While there is relatively broad endorsement of the participatory agenda, i.e. acknowledgment of the need for facilitating children's active engagement in the research process, there is so far no reflection of this in the Irish research ethics review process. As evident from the study and as supported by the literature, children and young people show a good understanding of ethical concerns in research. Accordingly, their input could be valuable:

- for the development of material and guidelines on children's research for Irish RECs; and
- for an exploration of the possibilities of involving children and parents in other functions in the design of ethical research, during the research ethics review process or in the research ethics governance system.

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