This is the submitted version of a paper published in *Ethics & Behavior*.

Citation for the original published paper (version of record):

*Ethics & Behavior*  
http://dx.doi.org/10.1080/10508422.2015.1096207

Access to the published version may require subscription.

N.B. When citing this work, cite the original published paper.

Permanent link to this version:  
http://urn.kb.se/resolve?urn=urn:nbn:se:esh:diva-4954
National Human Research Ethics: A Preliminary Comparative Case Study of Germany, Great Britain, Romania and Sweden

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Abstract

Although international research is increasing in volume and importance, there remains a dearth of knowledge on similarities and differences in ‘national human research ethics’ (NHREs) i.e. national ethical guidelines (NEGs), institutional review boards (IRBs), and research stakeholder’ ethical attitudes and behaviors (EABs). We begin to address this situation by reporting upon our experiences in conducting a multinational study into the mental health of children who had a parent/carer in prison. The study was conducted in four countries: Germany, Great Britain, Romania and Sweden. Data on NHREs were gathered via a questionnaire survey, two ethics-related seminars and ongoing contact between members of the research consortium. There was correspondence but even more so divergence between countries in the availability of NEGs and IRBs, and in researcher’ EABs. Differences in NHREs have implications particularly in terms of harmonization but also for ethical philosophy and practice, and research integrity.

Keywords: ethical guidelines, institutional review boards, ethical attitudes, ethical behaviour, national human research ethics
Introduction

There is extensive agreement as to the principles - respect for persons, beneficence, non-maleficence and justice - by which research with human participants should be conducted to ensure it is ethical (London, 2007). Inconsistencies start to become apparent when efforts are made to interpret these principles and translate them into ethical procedures (Emanuel, Wendler and Grady, 2000; Mishna, Antle and Regehr, 2004). These inconsistencies are part of a much more extensive pattern of convergence and divergence in ethics, which exist in three main domains: ethical guidelines, institutional review boards (IRBs), and research stakeholder’ ethical attitudes and behaviors (EABs) (Carrington, Neville and Whitwell, 2014). We refer to these three domains collectively as human research ethics (HREs). Intranational similarities, but more commonly differences, have been identified in the content and status of ethical guidelines (Powell and Smith, 2006); the membership and decision-making of IRBs (Hedgecoe, 2008); and the EABs of research stakeholders (Graffigna, Bosio and Olson, 2010).

Similarities and differences in HREs have been reported also at the international level. There are conflicting assessments as to the degree of overlap between national ethical guidelines (NEGs) (Blake, Joffe and Kodish, 2011). There is evidence of some conformity in the existence and organisation of IRBs (Klitzman, 2008), but the indication from most research is of major variations between national IRB systems (Hearnshaw, 2004). Agreement but also notable discrepancy has been revealed in the EABs of different national research stakeholders (Ries, LeGrandeur and Caulfield, 2010).
Although conformity and deviation in HREs are important at the intranational level, they are especially relevant in the international context. International research is subject to the same socio-demographic and organisational factors that produce divergence in HREs in intranational studies but it is exposed to a range of additional social, political, economic and cultural variables that can create divergence in HREs. The amount of international research being conducted is also burgeoning (Garrafa, Solbakk, Vidal and Lorenzo, 2010).

There are contesting philosophical perspectives on the implications of similarities and differences in national HREs (NHREs) (Benatar, 2004). Ethical Universalists argue that there are established ethical procedures that should be adhered to in all situations and that any deviation from these is unethical. Moral Relativists counter that the way in which ethical procedures are interpreted has to take account of local conditions, such as culture and values. Other writers, adopting a more applied stance, have claimed that differences in ethical behavior may signify unethical research practice (Hearnshaw, 2004). There has, within these critiques, been a particular concern surrounding research sponsored by organisations in HICs but conducted in low and medium income countries (LMICs) - work which may involve ‘ethical imperialism’ (Hyder, Wali, Khan, Teoh, Kass and Dawson, 2004). This charge of ethical imperialism has come to incorporate a series of fundamental ethical and political issues, including equipoise (Freedman, 1987), the standard of care (Edejer, 1999) and the 10/90 gap (Garrafa et al., 2010). Variations in ethical procedures can lead to adverse consequences for research both methodologically (Graffigna et al., 2010) and practically (Hearnshaw, 2004).
There has been considerable debate over the appropriate response to differences in NHREs (Freed-Taylor, 1994). Much of this debate has revolved around the issue of harmonization, which has been discussed in relation to NEGs (Freed-Taylor, 1994) but even more so IRBs (Hedgecoe, Carvalho, Lobmayer and Raka, 2006). There have been a number of major initiatives towards harmonization, for example the International Conference on Harmonisation (ICH) (Hirtle, Lemmens and Sprumont, 2000). Opponents of harmonization have challenged the basic premise that differences in EABs are problematic (Edwards, Ashcroft and Kirchin, 2004); pointed out that there will always be variance in the extent to which research stakeholders support harmonization and interpret its associated directives (Hedgecoe et al., 2006); and suggested that harmonization may be incompatible with European law (Hedgecoe et al., 2006).

There is limited research on similarities and differences in NEGs and IRBs, and even less on agreement and disagreement in research stakeholders’ EABs (Giacobbe and Segal, 2000). A large part of the extant research is based upon a small number of English-speaking countries; namely, Australia, Canada, New Zealand, the UK and in particular the US, and much of it is drawn from biomedicine (Leach and Harbin, 1997). Analyses of ethical procedures tend to be neither extensive nor in-depth (Fisher, 2006).

Our aim was to address some of this shortfall in knowledge. We intended, more specifically, to assess more fully than had been done before the extent and depth of similarities and differences in NHREs. This would then enable us to contribute to the
debate surrounding convergence and divergence in NHREs, and in particular: how they should be interpreted; what they might signify in terms unethical practice; and the response with which they should be met.

We sought to accomplish these aims by describing and analysing the similarities and differences in NHREs that became apparent in the course of a study into the mental health of children and young people (hereinafter referred to as ‘children’) who had a parent/carer (‘parent’) in prison in Germany, Great Britain (GB - England, Scotland and Wales), Sweden or Romania. The research was located in behavioural science and the social sciences (criminology and social work); two distinct methods (questionnaire surveys and interviews) were employed; and a range of participants were used - comprising practitioners, policy makers and members of the public (both adults and children). Members of this last group could be deemed vulnerable on account that they were children, imprisoned and/or in families where a parent was imprisoned. We begin by examining the existence of NEGs and IRBs before turning to the main focus of the study - the researchers’ EABs in respect of participant-related ethical procedures. There is an additional focus upon vulnerable groups on account that HREs are especially germane to them.

**Methods**

**Background**

A substantial (Robertson, 2007) and increasing (Walmsley, 2008) minority of children experience parental imprisonment. Such loss of a parent can have adverse
consequences on a child’s development (Murray, Farrington, Sekol and Olsen, 2009), but it appears that services for these children and families may be deficient (Jones, Gallagher, Manby, Robertson, Schützwohl, Berman, Hirschfield, Ayre, Urban and Sharratt, 2013). There is a paucity of data on how children are affected by parental imprisonment; what their subsequent needs are; and how these are being, and should be, met (Johnson and Easterling, 2012). The COPING (Children of Prisoners, Interventions and Mitigations to Strengthen Mental Health) project was designed to tackle some of this dearth of information.

COPING was an EU-funded study, carried out across four member states between January 2010 and December 2012. It involved a consortium of six non-governmental organisations and four research institutions from: France (Children of Prisoners Europe); GB (the University of Huddersfield (project lead) and Partners of Prisoners and Families Support Group); Germany (Technische Universitaet, Dresden and Treffpunkt e.V.); Romania (Universitatea Alexandru Ioan Cuza and Asociația Alternative Sociale); Sweden (the Karolinska Institutet and Bryggan); and Switzerland (Quaker United Nations Office, Geneva). COPING comprised: a questionnaire-based survey conducted among children aged 7-17 years, who had a parent in prison, and their non-imprisoned parent; interviews with a sub-sample of these children, and their imprisoned and non-imprisoned parents; interviews with stakeholders; and a service mapping exercise.
Sample

The four study countries were chosen on the basis that they represented a diverse range of European states in terms of criminal justice policy and practice - including that relating to imprisonment (International Centre for Prison Studies, 2013) - and wider political, economic, social and cultural characteristics (International Monetary Fund, 2013).

Data collection

Data on NHREs were collected in three main phases. The first phase involved two linked seminars that were held for all members of the research consortium; the first at the launch of the project, and the second shortly before the onset of fieldwork. An Ethical Protocol was drafted following on from these seminars. The second phase consisted of ongoing communications in which consortium members informed the first author of any ethical issue they encountered and/or any instances where they departed from the Ethical Protocol. The third phase comprised a questionnaire survey administered to the four national research leads towards the end of the COPING study. The survey was intended to check what ethical procedures had been followed and whether there had been any deviation from the Ethical Protocol.

Ethical approval

Each research team abided by any institutional, professional and legal requirements in its respective country regarding ethical approval.
Findings

National ethical guidelines

The GB researchers were able to refer to at least one set of research relevant NEGs for each of the disciplines and sub-disciplines represented in the COPING project. These included the British Psychological Society *Code of Ethics and Conduct* (BPS, 2009) and the British Society of Criminology *Code of Ethics* (BSC, 2006). These NEGs contained only limited advice regarding vulnerable participants. Research relevant NEGs did not exist in any of the three remaining countries.

IRBs

Researchers in Germany and Sweden are required by law to obtain ethical approval for studies with human participants (European Network of Research Ethics Committees, 2013). Ethical approval – through a local health service-based IRB - is a legal requirement for most, but not all, biomedical research in GB. There is no corresponding legal requirement to achieve ethical approval for social research, although there are policy and professional expectations that this be done, usually via a university-based IRB (Health Research Authority, 2013). All of these IRBs expected special attention be paid to vulnerable groups, including child participants and imprisoned parents. There was no equivalent IRB system in Romania but researchers in this country conducted their work in accordance with the major ethical procedures adopted by the three other research teams.
The research consortium identified a total of 16 participant-related ethical procedures that needed to be taken into account in the process of ensuring the COPING study was ethical. These procedures can be divided into three broad groups according to the degree of agreement or disagreement that existed between the four national research teams.

**Similarities in researcher’ EABs**

Written, non-general informed consent was obtained from all adult participants (Table 1). Special care was taken when developing the written research materials for imprisoned parents and their family members, and in face to face meetings with them, to ensure they fully understood the nature and purpose of the study, and the conditions under which it was being conducted.

Table 1 about here

The age of majority in all four countries was 18 years. Written, non-general assent was obtained from all minors in GB, Germany and Romania, and all under 15 year olds in Sweden (even though Swedish IRBs did not require this). (The lower maximum age for assent in Sweden is explained by the particular rules in that country governing minor consent - see below.) A minimum age for gaining assent from children was not set, with the youngest participants being 7 years of age.
Children were excluded from COPING if they did not know the reason for their parents’ absence.

If a child dissented to take part in the research, then his or her wishes were always respected.

Every participant was informed that they could refuse to answer questions or could withdraw from the research, without adverse consequences. This assurance was made especially clear to members of prisoners’ families.

Organisational permission or approval\(^1\) for the research was sought from relevant research stakeholders. These stakeholders varied between the four countries but they consisted of one or more of government departments or agencies, or local statutory services (Table 1). All members of the research consortium understood that it was particularly important to work with these stakeholders given the vulnerability of some of the participant groups, in particular the imprisoned parents and children who were in state care.

All the research teams provided participants with information on psychological and social support services – including the local collaborating NGO - and also facilitated contact with these agencies where appropriate. These arrangements were

\(^1\) ‘Permission’ refers to situations where the head of an organisation had to decide whether the research took place in the setting for which he or she was responsible. ‘Approval’ refers to situations where a stakeholder expressed an opinion as to whether research should take place in the setting for which he or she had an advisory or regulatory role.
considered especially important for prisoner’ families as it was anticipated that some of them might have unmet needs and/or might become distressed through their participation in the research.

*Relatively modest differences in researcher’ EABs*

All research teams were committed to the principles of data confidentiality and participant anonymity but they also concurred that disclosures should be made where they received information that a child was at risk of harm (Table 2). There were, in Sweden, no additional circumstances under which confidentiality or anonymity would be breached. Disclosure could, in GB and Romania, also occur if researchers were informed of a risk to prison security and in Germany if they were told of or any planned criminal offence. Each research team informed its participants of its respective disclosure policy. None of the fieldworkers, in any of the four countries, received information that they felt should be passed on to an authority.

Table 2 about here

*Relatively major differences in researcher’ EABs*

Parental consent was gained for all minors in Germany, GB and Romania (Table 3) but in Sweden only for under 15 year olds. Parents in all four countries - with the exception of those in one particular situation in Sweden (see below) - had to give active consent.
Consent was required of only one parent in GB, Germany and Romania, but both parents in Sweden. The Swedish researchers were concerned that it might be difficult, for practical reasons, to obtain the consent of imprisoned parent. The Swedish IRB agreed to a streamlined consent process whereby imprisoned parents were informed of the research, their right to remove their child and that non-responses would be taken as consent.

Researchers in Sweden obtained (autonomous) consent from minors aged 15-17 years.

Researchers in GB, Germany and Sweden were generally quite positively disposed towards the idea of compensating non-imprisoned parents and their children. They also agreed that the amount, and form, of compensation had to be sufficient that it achieved its intended purpose but not be so generous that it had an unwarranted influence upon any participant. There were discrepancies even between these three teams as to the precise amount and form of compensation that was appropriate (Table 3). The Romanian researchers felt that it would be unethical to offer compensation as the economic conditions of many of its families were such that this proposition would almost compel them to participate.

Researchers in GB, Germany and Romania believed it was ethical to ask non-imprisoned parents about the incarceration record of the imprisoned parent. The Swedish researchers, by contrast, felt that this practice was unethical. All the
families taking part in the COPING study were vulnerable by virtue of their having a parent in prison but the Swedish policy meant that it was not possible, in that country, to examine the relationship between parental incarceration history and children’s mental health.

The GB and Romanian researchers asked participants to define their ethnicity according to their physical appearance. (The Romanian team was under a legal obligation to obtain participants’ consent before asking them about their ethnicity.) The German and Swedish researchers were more cautious about collating information on ethnicity and believed that it should be categorised according to some aspect of a participant’s culture i.e. their nationality, the language(s) they spoke and/or their country of birth (or that of their parents). Membership of a black or minority ethnic (BME) group can render an individual vulnerable but it was not possible to make comparisons, across the four countries, as to the role of this variable, owing to the varying classificatory schemes.

Researchers in GB, Germany and Sweden requested checks of official information sources (largely police-based) to verify that it was not inappropriate for any given individual to have contact with children. These systems did not exist in Romania. There were, though, safeguards in place in Romania (and the other three countries) to help prevent untoward behavior on the part of any fieldworker. This included the supervision of fieldworkers and the setting up of systems for participants to report any concerns they might have.
Discussion

NEGs were available in only one country and IRB systems existed in three countries. The EABs of the four national research teams were similar in respect of six ethical procedures, but there were relatively modest or major differences between them in relation to three and seven ethical procedures respectively. There was, in general, little consistency between particular countries and research teams in their NHREs.

National ethical guidelines

Many countries have NEG, often covering biomedical research and sometimes other disciplines, but a considerable number do not. There does not appear to be any especially distinct patterns by country, although NEG may be more common in English-speaking HICs. (Alahmad, Al-Jumah and Dierickx, 2012). There are other NEG’ dimensions that were not examined in the COPING research but for which either correspondence or divergence, between countries, has been reported; namely, the content (Mishna et al., 2004; Taylor, 2008) and specificity of codes (Powell and Smith, 2006); the positions that are taken within them (Elger and Caplan, 2006); and their status (Freed-Taylor, 1994). There is reference to vulnerable groups in some, but not all, NEG. Children are especially likely to be discussed, but there is variation between the codes in the other groups that are mentioned (Alahmad et al., 2012). Coverage of vulnerable groups in NEG is, overall, limited.
IRBs

Issues over the availability (Uys, 2006), use (Glickman, McHutchison, Peterson, Cairns, Harrington, Califf and Schulman, 2009) and operation (Calain, Fiore, Poncin and Hurst, 2009) of IRBs are more likely to arise in LMICs. Some LMICs have effective IRB systems, and the number and quality of IRBs in these countries is increasing (Nyika, Kilama, Chilengi, Tangwa, Tindana, Ndebele and Ikingura, 2009). LMIC’ IRBs sometimes work to more robust standards than their HIC equivalents (Klitzman, 2008). Commonalities and discrepancies have been identified in the IRB systems of HICs (Graffigna et al., 2010). There can be differences between countries in the types of research that are required to go to ethical review (Cleaton-Jones and Wassenaar, 2010). Many IRBs exhibit a special concern over vulnerable groups but there is variation between them as to: who is defined as vulnerable; the level of attention they receive; and the reason for this attention (London, 2002). HIC’ IRBs tend to be more concerned with child participants (Balen, Blyth, Calabretto, Fraser, Horrocks and Manby, 2006), whereas their LMIC’ counterparts are more anxious over participants who are in poverty or poor health (Nyika et al., 2009).

Researcher’ EABs

Primary ethical procedures

We categorise ethical procedures into one of three groups: primary, secondary or tertiary. Primary ethical procedures are the most prominent in discussions of HREs and they have been subject to a fairly substantial amount of research. These ethical
procedures are generally respected and followed by national researchers. Differences in EABs become apparent when the detailed implementation, and additional dimensions, of these procedures are examined.

Difficulties with informed consent are more likely to arise in LMICs, especially in relation to vulnerable groups (Emanuel, Wendler, Killen and Grady, 2004; Glickman et al., 2009). These problems do not always arise in LMICs (Oduro, Aborigo, Dickson Amugsi, Anyorigiya, Atuguba, Hodgson, Koram, 2008) and differences with HICs should not be overstated (Allmark and Mason, 2006). Similarities and differences between national researchers have been highlighted in the breadth of the informed consent they obtain (Ries et al., 2010) and the format in which they request it (Suhonen, Saarikoski and Leino-Kilpi, 2009) but particular patterns by country have not been reported.

Researchers in HICs appear to attach equally high importance to ‘protecting respondent anonymity/confidentiality’ and ‘maintaining client confidentiality’ (Giacobbe et al., 2000). Disclosure in LMICs tends to be in the interests of the relatively powerful (Beyrer and Kass, 2002), whereas in HICs it is usually motivated by a concern for people who are at risk or who are a risk to others (Ensign, 2003). There can be disparities between HIC researchers in the precise circumstances in which they disclose and whether they inform participants of their disclosure policy (Fisher, 2006).

There is some inconsistency and even confusion as to what HIC’ researchers’ EABs are, or should be, regarding child-related ethical procedures (Helweg-Larsen and
Bøving-Larsen, 2003). Many researchers in LMICs and HICs recognise the importance of parental consent (Powell and Smith, 2009) and routinely seek it in practice (Ries et al., 2010) but there are differences between national researchers in the likelihood of their seeking active consent (Bogolub and Thomas, 2005). There is a facility in many HICs for parental consent to be waived (Balen et al., 2006) but this is uncommon in LMICs (Ahsan, 2009).

Minor consent is particularly likely to be sought by researchers in HICs conducting psychosocial studies of sensitive topics with adolescents (Flicker, Haans and Skinner, 2004) but there are differences in the conditions under which it is obtained (Moodley, 2007). There are distinctions between researchers in the minimum age for minor consent (Powell and Smith, 2006) but there does not appear to be any particular patterns by country (Taylor, 2008).

There is fairly extensive agreement between researchers in HICs that they should obtain assent from children (Mishna et al., 2004) and the criteria to be used in determining whether a child is capable of giving assent (Vitiello, 2003). There is a fair amount of variation between national researchers in their EABs in respect of the minimum age for child assent (Ries et al., 2010).

There is a consensus among researchers, especially those in Europe and the US, that children should not be involved in a study if they have dissented (Sheahan, Da Silva, Czoli and Shaul, 2012), although there are contradictions within the literature as to whether this holds for therapeutic research (Sheahan et al., 2012).
Secondary ethical procedures

Secondary ethical procedures are recognised by many - but not all - researchers and have received only modest coverage in the literature. There is agreement between HIC researchers concerning participants' right to withdraw (Giacobbe et al., 2000) and the extent of withdrawal they should be offered (Ries et al., 2010). There is quite widespread recognition of the need to pay special attention to respecting the rights of vulnerable groups regarding withdrawal (Scheyvens, Scheyvens and Murray, 2003).

There are conflicting views as to whether compensation is ethical (Singer and Bossarte, 2006; Thomas, 2007). There is particular disquiet over the use of compensation with vulnerable populations (including prisoners) (Pont, 2008), and especially those who are disadvantaged (Denny and Grady, 2007) and even more so those living in LMICs countries (Creed-Kanashiro, Oré, Scurrah, Gil and Penny, 2005).

Tertiary ethical procedures

Tertiary ethical procedures rarely feature in discussions of research ethics and have been subject to little research. The indication from reviews of NEGs and related instruments is that researchers from a range of countries obtain solo parental consent (Hens Nys, Cassiman and Dierickx, 2009). There is a small number of countries where researchers are expected to acquire joint parental consent (Vitiello, 2003) - an expectation which is greater where risks are higher, the research is therapeutic and both parents are available (Axelin and Salanterä, 2008).
The US is the only country where there has been any appreciable discussion concerning the collation of sensitive third party information (Lounsbury, Reynolds, Rapkin, Robson and Ostroff, 2007). US researchers tend to be cautious about gathering third party information without the consent of the individual in question.

Gathering information on participant’s ethnicity and classifying ethnicity according to physical appearance are standard practices in English-speaking HICs (Afkhami, 2012). Researchers in continental Europe are more wary of collecting data on participant’s ethnicity and tend to categorise ethnicity by the country of origin of, and/or the language spoken by, participants and/or their parents (Verkuyten, 2009). Ethnicity can be an important variable in terms of vulnerability but these definitional inconsistencies raise issues over the validity of given categorisations and inter-country comparisons (Salway, Higginbottom, Reime, Bharj, Chowbey, Foster, ... and O’Brien, 2011).

Researchers in many HICs seek permission from non-family member ‘gatekeepers’ (Savage and McCarron, 2009). Some of participant groups, including children and prisoners, may be deemed vulnerable and gatekeepers may have a safeguarding role in relation to them (Emmel, Hughes, Greenhalgh and Sales, 2007). Researchers in a number of HICs complain that gatekeepers often present unwarranted impediments to legitimate studies, and more particularly do not respect participants’ right to engage in research (Heath, Charles, Crow and Wiles, 2007).
Many different national researchers believe they should identify sources of support for participants (Swain, Heyman and Gillman, 1998), especially if the research involves vulnerable groups (Jewkes, Watts, Abrahams, Penn-Kekana and García-Moreno, 2000) and sensitive topics (Lees, Procter and Fassett, 2014).

There has been an increasing commitment among researchers from HICs towards requesting ‘police checks’ on fieldworkers collecting data from vulnerable participants, particularly children but also people with disabilities and the elderly (Jacobs and Blitsa, 2012).

Limitations

The countries in the COPING study do not comprise necessarily a representative cross-section of all nations in Europe (Karamessini, 2007), let alone the world (Inglehart, 1997). The COPING countries make up a quite modest proportion (9%) of all European states (n=45) and a very small proportion (2%) of all nations (estimated n=196) (Rosenberg, 2014). The data in this paper were obtained from a single study, with a quite specific focus and restricted range of methods. The study was also limited in terms of the disciplines and subject areas it drew upon. NEGs and IRBs were examined in the course of this research but in relation only to whether or not they existed. There was a more detailed exploration of researcher’ EABs but this was in respect just of participant-related ethical procedures and even this was not comprehensive (McGuire, Colgrove, Whitney, Diaz, Bustillos and Versalovic, 2008). It is likely that, had the research been more wide-ranging, more similarities but an even greater number of differences in NHREs would have been identified, rendering
this phenomenon yet more complex. There was no analysis to verify the exact factors that accounted for the similarities or differences in NHREs, or to establish the extent to which the prevailing EABs applied to all individuals within a given country’s research team.

Conclusion

This work represents an important first step towards a broader recognition of the existence of similarities but even more so differences in NHREs. There is, within the wider literature, support for our findings but also an indication that there are other dimensions of NHREs where there is convergence but much more commonly divergence. Many of these differences exist between LMICs and HICs but there is also variance within these groupings (Glickman et al., 2009), plus a number of other axes around which there are discrepancies, including Europe-US, US-other HICs and continental Europe-English-speaking HICs.

Similarities in EABs lend support to the universalist view of ethics (Grodin, 1992), whereas differences in EABs reinforce a relativist stance (Gostin, 1991). A more appropriate response to IHREs might be that proposed by Mzayek and Resnick (2010), whereby ‘a middle-ground solution is offered in the form of ethical pluralism’ (p.3). We did not feel that differences in behavior, within COPING, were a reflection of unethical research. Similar conclusions have been reached in reviews of other research (Blake et al., 2011). These differences have, instead, been interpreted as a product of legitimate distinctions between national researchers. There are, though, some actions by national researchers that have been adjudged to be unethical (Lurie
and Wolfe, 1997). Further differences in ethical behavior and instances of unethical practice may be identified with the increasing focus on the conduct of national researchers.

The issue of ethical imperialism is complex. Some unethical practice in LMICs is perpetrated by local researchers as opposed to ‘visiting’ HIC’ investigators. Unethical research has also been conducted in HICs (Blake et al., 2011). All research stakeholders will have to be more mindful of the risk of ethical imperialism as the volume of international research grows and the number of differences in ethical behaviors being revealed increases.

There are greater social, political and cultural differences between LMICs and HICs than there are within HICs, which have been the focus of comparative HREs studies (Louw and Delport, 2006). It is likely that as more complete knowledge of NHREs emerges, so harmonization will be rendered even more challenging. This raises questions over the extent to which harmonisation can be achieved and the degree of effort that should be invested in striving towards it.

The need for research on similarities and differences in NHREs is growing. This is a result of the dynamic nature of HREs and of research more generally, which is leading to ever-increasing situations for both convergence and divergence. There are three major sources for this dynamism: the emergence of novel areas of study, sources of data and research methods (Sampson, Caldwell, Taylor and Taylor, 2013); the rising amount of research being undertaken in an ever-wider range of
countries (Kamalski and Plume, 2013); and ‘ethics creep’ (Haggerty, 2004). We believe future work should be concerned with:

- Africa, Asia, Central and South America, Eastern Europe (including Russia) and the Middle East (Alahmad et al., 2012).
- Biomedicine but even more so behavioural science, the social sciences and the humanities (Leach and Harbin, 1997).
- Multidisciplinary research, in order to determine the moderating effect, if any, of a discipline in the nation—HREs relationship.
- NEGs and IRBs but even more so the EABs of researchers – (in relation to participants, other researchers and stakeholders, and society more generally) and participants (Valdez-Martinez, Garduño-Espinosa, Martinez-Salgado and Porter, 2004; Vitiello, 2003).
- The full range of ethical procedures and all dimensions of NHREs (Fisher, 2006).
- The causes of similarities and differences in NHREs (Suhonen et al., 2009).

Researchers engaged in intranational or international studies more generally should be encouraged to report on HREs and NHREs, respectively. Existing efforts to build ethics awareness and capacity (Lavery, 2004) should be continued and expanded not only in LMICs but also in HICs (Zachariah, Ford, Maher, Bissell, Van den Bergh, van den Boogaard, ... and Harries, 2012).
The extent of the void that exists in the appreciation of NHREs is well illustrated, perhaps, through Pipi, Cram, Hawke, Hawke, Huriwai, Mataka, ... and Tuuta’s (2004) account of the principles that underpin the Māori ‘code of conduct’:

It is important to remember that in Māori society knowledge and learning are associated with being tapu (sacred). In discussing learning and tapu, Te Uira Manihera (1992:9) of Tainui describes the sacredness of learning and the struggle elders have in “the handing down of knowledge”. The fear is that “by giving things out they could be commercialised. If this happens they lose their sacredness, their fertility…” (p.151)

The study of NHREs is a major and challenging task but it is also - for what it can reveal about the diversity and richness of human thought and action - a fascinating one.

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http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/


### Table 1 Similarities in researcher’ EABs

<table>
<thead>
<tr>
<th>Ethical procedure</th>
<th>Germany</th>
<th>GB</th>
<th>Romania</th>
<th>Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent</td>
<td>Each adult taking part in the research did so only after giving fully informed consent.</td>
<td>Same</td>
<td>Same</td>
<td>Same – except this applied only to under 15 year olds</td>
</tr>
<tr>
<td>Child assent</td>
<td>Each child (i.e. under 18 year old) taking part in the research did so only after giving assent</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Child dissent</td>
<td>If a child (i.e. under 18 year old) stated that he or she did not wish to take part in the research, then this wish was respected – even if parental consent had been given</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>Each individual taking part in the research was informed of his or her right not to answer particular questions or to withdraw from the research at any time without this having any adverse consequences for them or anyone else.</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Organisational permission or approval</td>
<td>Permission for the research to take place was obtained from the head of the prisons in which some of the research took place. Approval for the research to take place was sought from the following federal ministries and agencies: the Bavarian Ministry of Justice and Consumer Protection; the Saxony Ministry of Justice; and the Bavarian Commission for Data Protection.</td>
<td>Permission for the research to take place was obtained from the head of the prisons in which some of the research took place. Approval for the research to take place was sought from the following national ministries, and national and regional government agencies: the Ministry of Justice; the National Offender Management Service (NOMS); and Northwest England NOMS.</td>
<td>Permission was obtained from The National Administration of Prisons and the heads of prisons in which some of the research took place; Local Child Protection Services in Iasi, Botosani, Bacau, and Vaslui counties (to enable access to children in state care); Approval was required from the National Authority for Personal Data Processing, according to Law 677/2001 for the protection of persons with regards to personal data processing.</td>
<td>A collaborative agreement was signed between the Swedish National Prison and Probation Service and the Swedish university.</td>
</tr>
<tr>
<td>Participant support</td>
<td>All individuals taking part in the research - and in particular children and their parents - were informed that they could obtain psychological and social support from the NGO that was involved in participant recruitment. If a participant did not want this form of support or if they were not in contact with this NGO, then they were informed of alternative sources of support.</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
</tbody>
</table>
Table 2 Relatively modest differences in researcher’ EABs

<table>
<thead>
<tr>
<th>Ethical procedure</th>
<th>Germany</th>
<th>GB</th>
<th>Romania</th>
<th>Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidentiality</td>
<td>Participants were informed that the information they provided to the research would be treated in the strictest confidence – subject to the two exceptions given below.</td>
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<td>Participants were informed that the information they provided to the research would be treated in the strictest confidence – subject to the two exceptions given below.</td>
<td>Participants were informed that the information they provided to the research would be treated in the strictest confidence – subject to the one exception given below.</td>
</tr>
<tr>
<td>Anonymity</td>
<td>Participants were informed that they would not be identified or identifiable in any written or verbal report emanating from the research – subject to the two exceptions given below.</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Disclosure</td>
<td>Participants were informed that confidentiality and anonymity would be breached if they provided information that indicated: 1) a person had been harmed or was at risk of harm, or 2) a serious crime was planned.</td>
<td>Participants were informed that confidentiality and anonymity would be breached if they provided information that indicated: 1) a child (any person under 18 years) was at risk of coming to harm, or 2) there was a risk to prison security.</td>
<td>Participants were informed that confidentiality and anonymity would be breached if they provided information that indicated: 1) a child (any person under 18 years) was at risk of coming to harm, or 2) there was a risk to prison security.</td>
<td>Participants were informed that confidentiality and anonymity would be breached if they provided information that indicated: a child’s (any person under 18 years) physical or mental health was endangered.</td>
</tr>
</tbody>
</table>
Table 3 Relatively major differences in researcher’ EABs

<table>
<thead>
<tr>
<th>Ethical procedure</th>
<th>Germany</th>
<th>GB</th>
<th>Romania</th>
<th>Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parental consent</td>
<td>Parental consent was obtained before any child (i.e. person under the age of 18 years) was asked to take part in the research.</td>
<td>Parental consent was obtained before any child (i.e. person under the age of 18 years) was asked to take part in the research.</td>
<td>Parental consent was obtained before any child (i.e. person under the age of 18 years) was asked to take part in the research.</td>
<td>Parental consent was obtained before any child (i.e. person under the age of 15 years) was asked to take part in the research.</td>
</tr>
<tr>
<td>Solo or joint parental consent</td>
<td>Consent was obtained from only one parent for his or her child to take part in the research. This was always the non-imprisoned parent.</td>
<td>Consent was obtained from only one parent for his or her child to take part in the research. This was always the non-imprisoned parent.</td>
<td>Consent was obtained from only one parent for his or her child to take part in the research. This was always the non-imprisoned parent.</td>
<td>Consent was obtained first from the non-imprisoned parent for his or her child to take part in the research. Consent was assumed for the imprisoned parent except in cases where this parent opted out.</td>
</tr>
<tr>
<td>Minor consent</td>
<td>Minor consent was not obtained.</td>
<td>Minor consent was not obtained.</td>
<td>Minor consent was not obtained</td>
<td>Minor consent was obtained from young people aged 15-17 years inclusive.</td>
</tr>
<tr>
<td>Compensation</td>
<td>Each individual who took part in the questionnaire survey was given a €5 (US$6) shopping voucher and each family that took part in an interview was given a €30 (US$38) shopping voucher.</td>
<td>Each individual who took part in the questionnaire survey was given the equivalent of a €11 (US$14) shopping voucher and each family that took part in an interview was given the equivalent of €29 (US$36) shopping voucher.</td>
<td>Compensation was not given to any individual taking part in the research.</td>
<td>Each individual who took part in the questionnaire survey and each individual who took part in an interview was given a €7 (US$9) cinema ticket.</td>
</tr>
<tr>
<td>Sensitive third party information</td>
<td>Non-imprisoned parents were asked about the imprisonment record of the imprisoned parents.</td>
<td>Non-imprisoned parents were asked about the imprisonment record of the imprisoned parents.</td>
<td>Non-imprisoned parents were asked about the imprisonment record of the imprisoned parents.</td>
<td>Non-imprisoned parents were not asked about the imprisonment record of the imprisoned parents.</td>
</tr>
<tr>
<td>Ethnicity information</td>
<td>Researchers asked each participant about his or her ethnicity without prior specific consent and recorded ethnicity on the basis of the participant’s</td>
<td>Researchers asked each participant about his or her ethnicity without prior specific consent and recorded ethnicity on the basis of the participant’s</td>
<td>Researchers obtained specific consent from a participant in order to ask him or her about his or her ethnicity and recorded</td>
<td>Researchers did not ask respondents specifically about their ethnicity. Ethnicity data were collected in the form of child</td>
</tr>
<tr>
<td>Facial features</td>
<td>Requests were made of the police to ascertain whether they had any information in which there were indications that it would be inappropriate for a researcher to have contact with a child (a person under the age of 18 years). The main concern would have been that the researcher would have harmed a child previously. These checks were carried out by the National Central Registration Registry.</td>
<td>Requests were made of the police to ascertain whether they had any information in which there were indications that it would be inappropriate for a researcher to have contact with a child (a person under the age of 18 years). The main concern would have been that the researcher would have harmed a child previously. These checks were carried out by the Criminal Records Bureau, which is an agency of the national government (in England and Wales).</td>
<td>Police checks were not carried out.</td>
<td>Requests were made of the police to ascertain whether any information was available indicating that it would be inappropriate for a researcher to have contact with a child (a person under the age of 18 years). The main concern was identifying prior criminal activity related to harming a child. These checks were carried out by the National Police Board.</td>
</tr>
</tbody>
</table>