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ORIGINAL RESEARCH

Third-Party Perspective in Medical Research Ethics: A Case Series of Clinical Trials Involving Individuals with Sexual Interest in Children

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Abstract It is a central principle in modern research ethics that the rights, safety, and well-being of research participants are the most important considerations. This should also apply to third-party individuals, that is, individuals who are not research participants but may be affected by the research. Despite this, international research ethics guidelines give limited attention to protecting third parties. This gap became evident when we were involved in the design and conduct of a series of clinical trials involving individuals with sexual interest in children, where children may constitute an identifiable third-party group at risk of harm. In response, we systematically analysed these ethical challenges and developed preventive strategies to safeguard third parties alongside the protection of research participants. We discuss specific risk mitigation measures implemented in our clinical trials and propose that international guidelines be revised to strengthen the protection of third parties at risk of harm in medical trials.

Keywords Child abuse · Clinical trial · Paedophilia · Randomized controlled trial · Research ethics · Third-party consent

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Introduction

Influential ethical documents on human medical research provide guidelines for designing clinical trials. Historically, the primary aim has been to protect research participants. Less attention has been given to third parties (3P), that is, non-research participants who may be harmed or benefited by particular research studies. Although potential harmful effects on 3Ps in research may often be insignificant, there are certain areas in which risk of harm to 3Ps constitutes a central ethical concern. This includes studies involving participants with infectious diseases (where 3P are people at risk of transmission), participants with genetic diseases (where 3P involve genetic relatives affected by detection of disease traits), participants who are pregnant or breastfeeding (where 3P involves fetuses or nursing infants), caretakers of

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participants, or participants with an increased risk of harming others. The limited attention to 3Ps in research regulations and guidelines leaves researchers without clear ethical guidance as they attempt to reduce harm to people other than the primary research participants.

Major international research ethics guidelines, such as the Declaration of Helsinki (World Medical Association 2013), the Council for International Organizations of Medical Sciences (CIOMS) guidelines (2016), the International Council for Harmonisation Good Clinical Practice guideline (ICH 2025), and the Oviedo Convention (Council of Europe 1997), emphasize that research should benefit society but address harms to 3P either only in general or vague terms or only in relation to specific categories of 3Ps. The Declaration of Helsinki states in paragraph 11 that "medical research should be conducted in a manner that minimises possible harm to the environment." CIOMS generally acknowledges risks to communities and other 3Ps, such as disruption of care or group stigmatization but also specifically addresses pregnant and breastfeeding women and their fetuses or nursing infants (Guideline 19). The Oviedo Convention includes a general statement that rights may be restricted to protect the rights and freedoms of others (Article 26). Importantly, except for the CIOMS provisions concerning fetuses and nursing infants, these guidelines do not specify when particular safeguards such as risk minimization, consent, or exclusion of participants are required in relation to 3P. However, some more specific or national frameworks may include strong protections to individuals indirectly affected by research (Eyal et al. 2019). There have been scholarly discussions about how to address 3Ps, focusing on overarching ethical principles and the role of institutional review boards (Hausman 2007; Kimmelman 2005; Resnik and Sharp 2006; Eyal et al. 2019; Eyal and Holtzman 2020), but these discussions have not yet led to revisions to international policy guidelines.

In this article, we discuss the ethics of 3Ps in relation to four randomized controlled clinical trials of novel interventions for individuals with paedophilic disorder and related conditions: 1) an evaluation of the efficacy of an anti-androgen drug (Landgren et al. 2020); 2) an internet based study on cognitive behavioural therapy with recruitment from perpetrator forums on the darkweb (Lätth et al. 2022); 3) an internet-based study on cognitive behavioural therapy with recruitment from several sources, including the police (Maimone et al. 2025); and 4) a motivational interviewing intervention (Karolinska Institutet 2024). One of the authors (CR) served as Principal Investigator for the first (PRIOTAB) and second (Prevent It 1.0) studies and co led the third (MI BRIDGE) and fourth (PRIORITY) studies together with the investigators acknowledged below. Drawing on prior research and the experiences gained from designing and conducting these studies, we propose ways for research ethics review to more explicitly address the needs and interests of 3Ps.

The Studies: Identifying Risks to 3Ps

The four studies were conducted to address evidence gaps in treatment for paedophilic disorder and related conditions. The overarching goal was to develop interventions that are safe, effective, and tolerable, and that can be adapted to different stages of prevention. These stages include early intervention to prevent first offenses, harm-reduction approaches in situations of ongoing risk, and relapse prevention among individuals with a history of sexual offending. Alongside these preventive goals, the studies also aimed to reduce psychological suffering among individuals distressed by their condition.

Clinical guidelines for individuals with sexual interest in children typically recommend cognitive behavioural therapy, with the possible addition of pharmacological treatment for those assessed as high risk (Thibaut et al. 2020). Yet these recommendations largely rest on expert consensus rather than high-quality empirical evidence. There is also a clear need to develop new treatment and outreach models that lower barriers to help-seeking. Many individuals with sexual interest in children report willingness to engage in treatment if it is offered in formats perceived as acceptable, confidential, and accessible. This is particularly relevant for individuals who avoid care due to stigma, fear of disclosure, or legal concerns.

When designing the studies, risk assessments were extended beyond research participants to include 3Ps, in this case, children at risk of sexual abuse or exploitation in offline or online contexts. To strengthen consideration of the interests of 3Ps, patient and public

involvement (PPI) (Stewart et al. 2011) was applied throughout the research process in the first two trials: PRIOTAB and Prevent It 1.0. PPI was used to ensure that the research addressed questions also relevant to 3Ps and was feasible and acceptable to affected groups. PPI also helped identify potential risks, strengthen trust, and increase the likelihood that findings would be meaningful and implemented in practice. Practically, this involved establishing an advisory board including representatives from the police, prison and probation services, child rights organizations active in child sexual abuse prevention, and individuals with lived experience of sexual interest in children. Researchers also worked with the university's legal department to develop internal procedures for close dialogue on complex legal cases. Ethical approval was first obtained in Sweden and subsequently in the other countries where study sites were located.

Some risks to 3P existed independently of the research, whereas others were potentially triggered or amplified by the research, as shown in Table 1. Pre-existing risks included the possibility that children could be abused or exploited by individuals who enrolled in the studies. Research-related risks across studies included the fact that the experimental interventions had not previously been systematically evaluated in individuals with paedophilic disorder or related conditions. Consequently, there was a risk that certain study conditions could inadvertently increase the risk of sexual offending, not only in placebo or waitlist conditions but also, in theory, in active intervention arms, despite clinical experience and theoretical work suggesting the opposite.

Additional concerns included the risk that participants might interpret research framings in ways that rationalized harmful behaviour, for example by externalizing responsibility to a medical diagnosis or that individuals with psychopathic traits might exploit participation to deflect responsibility for offending. The risk that research could inadvertently medicalize a problem better addressed through other safeguarding strategies was also recognized. By signalling that a condition is treatable and potentially reversible, research participation could lead family members or institutions to delay protective actions, such as separation, workplace reassignment, or reporting, thereby increasing risk to 3Ps. Furthermore, there was a risk that interventions perceived as ineffective could discourage future

Table 1 Risks potentially amplified or triggered by the research. *3P*—Third parties

Risks for 3P	Mitigation strategies
Increased background risk: Risk that participats sexually abuse or exploit 3P	• Close monitoring of risk development and proactive follow up of any known 3Ps at riskq • Have procedures in place for participants who report increased urges to act out or who report having acted out • Have procedures in place for any information about identified 3Ps who are at risk or who have been harmed
Unspecific risks to 3P introduced by research: Risk that unspecific factors in the research contributes to harm to 3P, such as: – Participants perceive that we diminish their responsibility for acting out toward 3P through medicalization or therapeutic framing – Participants are scared off from future treatment by negative experiences in trials – 3Ps perceive the researchers' approach as excusing offending or being passive toward it	• Include 3P representatives in the Advisory Board and Steering Committee to ensure that all aspects of the study design and clinical conduct have a child rights perspective, so that 3P do not become a silent stakeholder • Ensure clear communications about the project, including that an important aim is to prevent harm to 3P • Maintain mandatory reporting obligations
Risks of research to 3P specifically pertaining to the interventions: Risks that the active arm or control arm interventions unintentionally contribute to increased risks for 3P See Table 2 for details about specific interventions	• Consider establishing effects on proxy measures before moving to hard outcome measures such as actual acting out • Use outcome measures that also capture effects on 3P • Use sample sizes no larger than needed to answer the research questions

help-seeking if participants perceived treatment as futile.

Furthermore, there were risks specific to different phases of the trial process. In early phase studies, including feasibility trials, key considerations for 3P involve selecting outcome measures that capture meaningful pre to post treatment changes, including outcomes relevant from a 3P perspective, and defining inclusion and exclusion criteria that recruit participants at sufficient risk while ensuring they can understand and adhere to study procedures, such as reaching out for help if the urges grow stronger to harm a 3P. During the RCT phase, randomization procedures must avoid exposing 3P to unnecessary risk. In the adaptation phase, when interventions are translated into other languages and implemented at sites in new countries, attention shifts to ensuring that safety procedures remain effective across different legal jurisdictions, healthcare systems, and academic cultures. Finally, during scaling and implementation, challenges include maintaining safety standards across heterogeneous clinical settings and managing the reduced capacity of research teams to oversee day-to-day interactions with participants.

Special attention was also given to challenges associated with confidential outreach. Three of the studies (PREVENT IT, PRIORITY, and MI BRIDGE) were delivered with a high degree of anonymity (researchers did not collect any personally identifiable information such as IP number, name, address, or social security number) and online, with the therapy platform adapted to allow participation via privacy-preserving technologies such as the Tor browser. This design aimed to lower barriers to help-seeking among individuals deterred by stigma, fear of disclosure, or legal concerns, to facilitate honest reporting of highly taboo thoughts and behaviours, and to enable wide international outreach. At the same time, anonymity complicated mandatory reporting to police or social services when crimes were disclosed or children were believed to be at imminent risk of harm.

Finally, a number of risks specific to the interventions and control conditions were identified, see Table 2. In PRIOTAB, the pharmacological compound degarelix, a testosterone-lowering medication sometimes referred to as "chemical castration" posed theoretical risks of paradoxical effects due to its libido-reducing effect, including increased risk-taking or compensatory behaviours such as increased

Table 2 Key features of the clinical trials discussed in this paper and some study-specific 3P risks connected to the interventions in each trial. *GnRH*—Gonadotropin Releasing Hormone; *RCT*—Randomized clinical trial; *3P*—Third parties

Study	Main recruitment	Main inclusion criterion	Active intervention	Study design	Primary outcome measure	Study specific 3P risks
PRIOTAB	Telephone helpline, Sweden	Adult men with pedophilic disorder	GnRH-antagonist, a testosterone-lowering medication	Double masked, placebo controlled RCT	Composite risk measure for offending	Sexually harmful side effects
PREVENT IT 1.0	Darkweb perpetrator forums, globally	Adults who use child sexual abuse material	Internet-based cognitive behavioral therapy	Single masked, placebo controlled RCT	Hours spent on child sexual abuse material per week	Reduced motivation in placebo arm for behavioural change
PRIORITY	Police referrals, Sweden, Portugal, Germany	Adults with sexual urges involving children	Internet-based cognitive behavioural therapy	RCT, cross-over waitlist control	Severity of sexual urges involving children	Acting out abusive fantasies during waitlist
MI BRIDGE	Darkweb search engine, globally	Adults who use child sexual abuse material	Text-based Motivational Interviewing (8 languages)	Feasibility trial followed by RCT with cross-over waitlist control	Motivation to seek care	Treatment goals incompatible with risk reduction

internal pressure to search for extreme sexual material or illicit substance use. In PREVENT IT 1.0, the use of a psychological placebo designed to resemble active therapy risked confusion and reduced motivation for behavioural change. In PRIORITY, assignment to a two-month waitlist risked increased frustration and risk escalation before access to treatment. In MI BRIDGE, the use of motivational interviewing, in which patients are involved in goal setting, raised concerns that participants might set treatment goals that are incompatible with risk reduction.

How Should 3Ps' Interests be Handled?

One option is to ignore the risk of harm to 3Ps entirely. However, this seems unreasonable and would be inconsistent with the underlying principles of the Declaration of Helsinki and other major research ethics guidelines. Importantly, 3Ps are equally persons and no less worthy of regard than research participants. Accordingly, the risk of harm to 3Ps cannot in itself be of less concern than the risk of harm to research participants. This moral claim rests on the formal principle of justice: equal cases should be treated equally. The point of departure should be that researchers take the interests of both research participants and 3Ps into account when the research affects both groups. As stated in paragraph 17 of the Declaration of Helsinki:

> All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved, compared with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation. (World Medical Association 2013, §17).

Researchers' obligations to protect 3Ps are particularly compelling in the types of studies under discussion. This is not only because the 3Ps are children, a vulnerable group who have limited capacity to protect their own interests, but also because participants experience sexual attraction to children and therefore may pose a risk to them. Consequently, researchers cannot assume that participants will reliably safeguard the interests of these 3Ps.

The case of a research participant who sexually abuses a child may seem to differ from many discussions of 3P risks because the risks arise through participant misconduct rather than through the research procedures themselves. This has been discussed in relation to HIV prevention studies, where risks to 3Ps may result from participants' unprotected and undisclosed sexual activity or partial adherence to treatment (Eyal et al. 2018; Bärnighausen 2019). However, the moral status of the actions leading to 3P-risks does not remove researchers' obligations to consider and take measures to reduce such risks when designing a study. Although researchers cannot control participants' actions, foreseeable risks arising from participant conduct are not, in themselves, ethically less important than other risks to 3Ps. Hence, neither the fact that 3Ps are not formally research participants nor that the risks result from participant misconduct is a reason to disregard the interests of 3Ps.

Accordingly, it may be argued that researchers should obtain informed consent from affected 3Ps, just as from research participants. This would seem to express equal concern for both groups. However, any requirement to identify and contact 3Ps must be carefully balanced against the need to preserve trust in the researcher–participant relationship and to protect participants' privacy and confidentiality. Informing 3Ps that an individual within their vicinity qualifies for participation in a particular study, and that the 3Ps may be at risk of harm or otherwise negatively affected by that individual or the research, risks revealing sensitive information about the participant, undermining confidentiality, and compromising the feasibility of conducting research at all. These concerns are particularly acute in research involving sensitive topics such as paedophilic disorder and child sexual abuse.

In addition, the practical details of the research in question may be morally relevant. Unlike research participants, who are in direct contact with the researchers, potential 3Ps are often unknown and inaccessible. In our cases, researchers lacked the practical capacity to know who the 3Ps are unless the study participants inform them. 3Ps may, in many cases, be unrelated individuals with whom the participant is in contact only online. To identify, locate, and notify all 3P individuals may be difficult or even impossible (Hausman 2007). Moral obligations are constrained by what agents can do. Hence, researchers may have more limited obligations toward 3Ps than toward research participants, even though

both groups have equal moral worth. In most cases, it is therefore not reasonable to require researchers to obtain informed consent from 3Ps. However, in exceptional cases, when specific 3Ps at imminent risk of being harmed become identifiable, the moral responsibilities of researchers increase. As Kimmelman (2007) notes, identifiability is a key determinant of what protective actions researchers can and should take. The notion that researchers may sometimes have such obligations toward identifiable 3Ps is reflected in legal and professional duties to warn or protect potential victims (Appelbaum and Rosenbaum 1989; Resnik and Sharp 2006).[1]

In the studies described above, such considerations were reinforced by Swedish law, which requires healthcare workers to immediately report any suspicion that a child may be at risk of harm to social services (Social Services Act 2001). The participants in the clinical trials were informed about this as part of the informed consent process. During participation in the studies, they were repeatedly asked whether they knew of any child at risk of harm and were informed that the more precisely they described the child and the risk, the greater the likelihood that protective action could be taken. As a result, some participants disclosed information that enabled the identification of specific children or provided information about online locations where identifiable children appeared to be subjected to abuse. Such information could then be forwarded to the relevant authorities. This occurred more frequently in the projects where participants were fully anonymous to the researchers (PREVENT IT, PRIORITY, and MI BRIDGE) than in the project where participants were not (PRIOTAB). Although legal requirements vary across jurisdictions, the existence of duties to report illustrates a broader societal recognition that the interests of vulnerable 3Ps may sometimes justify limitations on confidentiality. The combination of vulnerability and identifiability provides particularly strong reasons for protective intervention. The question, therefore, becomes how such considerations should be incorporated into research ethics review more generally.

First, if the risks to 3Ps are so great that the research would not be allowed if imposed on research participants, then the research should not be allowed. In other words, there is a threshold for permissible risk, which should not be lower for 3Ps. This follows from basic considerations of consistency and justice. Second, when risks fall below this threshold, they should be mitigated as far as reasonably possible and weighted against the potential benefits of the research. Medical research involving humans typically involves some degree of risk to participants and is generally considered justifiable if the value of the research is proportionate to these risks. In the studies described here, the ultimate aim of the research is to prevent child abuse, meaning that the vulnerable population exposed to potential 3Ps risks may also stand to benefit from the knowledge generated.

Applied Risk Mitigation Measures

In the absence of established ethical guidelines for the field of clinical child sexual abuse perpetration prevention research, the studies implemented a set of preventive and risk-mitigation strategies tailored to the risks identified above (Table 1). These strategies were integrated into study design, participant monitoring, and clinical governance.

To address pre-existing risks, procedures were implemented to manage situations in which participants reported increased risk of acting on sexual urges towards a child, and for handling information about identifiable children at risk of harm. Risk levels were repeatedly assessed throughout participation, which included questions to participants about access to children and current risk situations. The procedures also included adherence to mandatory reporting requirements. In three of the studies, PREVENT IT 1.0, PRIORITY and MI BRIDGE, acute crisis management chats for those with increased risk of offending was offered.

To mitigate nonspecific research-related risks common across the studies, several strategies were implemented. Besides implementing the PPI strategy with an Advisory Board as described above, participant information about study design and potential risks was provided. Individuals who could not understand or adhere to study requirements were excluded. Researchers also aimed for a consistent approach for communication with research participants that emphasized the individual's responsibility

[1] We would like to thank an anonymous reviewer for bringing this to our attention.

for preventing harm, while framing the role of healthcare as supporting those seeking to avoid offending.

External communication explicitly avoided reducing child sexual offending to a purely individual or medical problem, highlighting group-, organizational-, and system-level dimensions of risk and prevention, in line with a public health model for prevention of violence (World Health Organization 2002).

Finally, study-specific risk mitigation strategies were developed. Outcome measures and questionnaires that capture the effects on 3Ps as well as on participants were chosen and sample sizes were limited to the minimum required to answer the research questions, as determined by a statistical power analysis. In PRIOTAB and PREVENT IT 1.0, qualitative interviews with open questions exploring both positive and negative effects of active and placebo conditions in the studies were conducted. This enabled the detection of unintended or unexpected effects on 3Ps that were not captured by structured questionnaires. The interviews were later reported in the supplementary material of the study publications. In MI BRIDGE, where motivational interviewing was used, a detailed therapy manual was developed specifying that counsellors should actively guide participants toward goals compatible with help-seeking and risk reduction. Weekly supervision sessions with experienced MI supervisors provided a forum to identify and manage ethical or clinical concerns related to individual participants.

Together, these measures were intended to reduce the likelihood that participation in research would increase risks to 3Ps while preserving the scientific integrity and preventive purpose of the studies. These risk mitigation strategies proved valuable throughout the research process. They were judged adequate by ethics review boards and regulatory authorities, facilitated communication, including with the university legal department, were helpful for staff training, and were regarded as appropriate by peer reviewers of the resulting publications.

As reported in the primary study papers, most participants entered the studies with an elevated risk of sexually offending against children, and some disclosed ongoing abusive behaviours, most commonly the use of child sexual abuse material. Across all study arms, both risk indicators and self-reported offending behaviours decreased over time, with larger reductions generally observed in the active intervention conditions. Nevertheless, several participants in the anonymous online studies reported acute increases in risk or recent sexual offending against a child. In these situations, the predefined standard operating procedures proved useful, including crisis management chats, child protection notifications to social services, and, when necessary, reports to law enforcement authorities, but not exclusion from study participation.

Not all ethical challenges were anticipated by the mitigation framework. One unforeseen challenge concerned the termination of therapeutic contact at the end of the study period when researchers remained concerned about a participant's ongoing risk to children, yet ethical approvals did not permit continued contact beyond the research protocol. Additional efforts were made to refer these individuals to outpatient services for continued treatment, but this was successful for only some participants. Another category of cases involved exceptional situations in which the interests of research participants and potentially affected children could not be simultaneously accommodated, and legal frameworks provided limited guidance. When such conflicts arose, decisions were informed by structured ethical deliberation within the research team. A guiding principle that helped resolve many of these challenges was to prioritize the protection of children, although these situations also left the team with the impression that existing procedures could have been more purposefully designed to address such dilemmas. These examples illustrate some of the limitations of even comprehensive safeguarding frameworks and highlight the need for ongoing ethical reflection in research involving risks to vulnerable 3P.

Conclusions

In this article, we have explored the ethics of a 3P perspective in medical research, drawing on experiences from a series of clinical trials involving individuals with paedophilic disorder and related conditions. We describe the trials and risk mitigation measures that were implemented.

We argue that considerations relating to 3Ps are insufficiently addressed in research ethics guidelines and should be incorporated more systematically into research ethics review and ethics frameworks. Risks to 3Ps should not be regarded as ethically less important than risks to research participants. There should be upper limits to permissible risks imposed on 3Ps,

and below this threshold, risks should be evaluated using standards similar to those applied to research participants, including requirements for risk minimization and proportionality. Particular attention should be given to identifiable and vulnerable 3Ps, especially children. However, there are practical constraints on the measures researchers can take to protect 3Ps, meaning that, in most cases, requiring informed consent from 3Ps is not reasonable.

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Data Availability Not applicable. This study is theoretical and does not involve data or material gathered from persons or animals. Hence there is no dataset to be made available. Any questions about the study can be directed to manne.sjostrand@ki.se.

Declarations

Conflict of interest The World Childhood Foundation Sweden contributed to initial discussions regarding inclusion criteria for the Prevent It 1.0 study. Beyond that, neither of the funders had any role in the design, collection, analysis, or interpretation of data, or in the writing of the manuscripts for any of the described studies. The content of this publication reflects the views of the authors only and does not necessarily represent those of the funding organizations. In particular, the European Commission does not accept any responsibility for any use that may be made of the information contained herein.

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Ethics Approval Not applicable. This study is theoretical and does not involve sensitive personal information or material gathered from persons or animals. Hence it does not fall under the Ethical review act in Sweden and does not need ethical approval.

Consent Not applicable. This study is theoretical and does not involve data or material gathered from persons or animals.

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