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REVIEW ARTICLE

Addressing ethical confusion in deceased donation and transplantation research: the need for dedicated guidance

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SUMMARY

Innovative research in deceased donation and transplantation often presents ethical challenges for researchers and those responsible for ethical governance of research. These challenges have been recognized as potential barriers to the conduct of research. We review the literature to identify and describe ethical considerations that may cause confusion or uncertainty in the context of research involving potential deceased donors or deceased donor transplantation. We normatively examine these considerations and discuss their implications for the ethical conduct of research. In addition to the complexities of research involving critically ill, dying or recently deceased individuals, uncertainty may arise regarding the ethical status of various individuals who may be involved in research aimed at improving availability and outcomes of organ transplantation. Consequently, routine ethical guidelines for clinical research may fail to provide clear guidance with regards to the design, conduct and governance of some deceased donation or transplantation studies. Ethical uncertainty may result in delays or barriers to research, or neglect of important ethical considerations. Specific ethical guidance is needed to support research in deceased donation and transplantation as the ethical considerations that arise in the design and conduct of such research may not be addressed in the existing guidelines for human research.

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Introduction

Innovation and ethical complexity are an integral part of research and clinical practice in organ and tissue donation and transplantation. This is particularly true in the context of deceased organ donation where potential conflicts of interest in clinical decision-making may intersect with scientific and philosophical uncertainties regarding the determination of death [1]. Research relating to deceased donation and transplantation is also ethically complex because it typically involves participation by people who are critically ill, dying or recently deceased (all of whom may be 'potential deceased donors'); reliance on substitute decision-makers at a time of significant personal anxiety and distress (kin of potential donors) and involvement of people for whom participation in research may represent a scarce and potentially life-saving opportunity (potential transplant recipients). New ethical challenges have also arisen with the expansion of organ donation following determination of death using circulatory criteria and the emergence of novel techniques and therapies for use in organ repair and replacement. Several authors have observed that ethical considerations and related logistical and regulatory factors may present potential barriers to clinically oriented, innovative research in donation and transplantation [2–5]. The success of continued work to increase the availability of organs for transplantation and to improve outcomes for transplant recipients depends on the ethical conduct of research in this field and on efforts to address ethical considerations that may pose a barrier to the research itself [6].

In this paper, we explore several ethical considerations that may cause confusion or uncertainty in the context of research involving potential deceased donors or deceased donor transplantation [henceforth, 'research in deceased donation and transplantation' (RDDT)]. As shown in Table 1, there are several interrelated and overlapping types of innovative research that may intersect with donation and transplantation decision-making or activities during the end-of-life period, and which may be associated with specific ethical considerations and complexities. One such consideration is whether the research will actually result in transplant, will relate to future transplant or will use donor tissue for purposes unrelated to transplant. We focus on research of types 2–4, namely donor and ex situ organ intervention studies that aim to improve the viability of organs recovered for transplantation [4,7,8], and studies in which transplant interventions are tested in recently deceased individuals [9,10]. These types of studies explore vital opportunities to expand the number of potential deceased organ donors, to improve outcomes of transplantation and to reduce risks associated with early-stage trials of innovative technologies and new therapeutics for transplantation.

We do not seek to provide practical ethical guidance in this paper but rather to lay the foundations for future development of ethical guidelines specifically for RDDT. In particular, we clarify a fundamental ethical challenge that may be more common in RDDT studies than in other forms of clinical research during the end-of-life period, namely determination of the ethical status of various individuals who may be indirectly or directly involved in the research. Determinations of ethical status in a research protocol have significant implications for ethical governance and conduct of the research; for example, identification of individuals as participants in research may entail specific requirements with regards to consent for their involvement. We also discuss uncertainties that may arise with regards to management of common research ethics considerations in the context of RDDT, specifically concerns regarding consent, proportionality of risks and benefits and equity. In conclusion, we argue that new ethical guidelines are needed to address the exceptional ethical challenges associated with RDDT and ensure public trust in research activities.

Determining the ethical status of individuals who may be involved in research

Broadly speaking, 'human research' encompasses any form of research that is 'conducted with or about people, or their data or tissue', including research in which people are unaware of the use of their data or biological materials [17]. Much of the human research ethics literature is focused on ethical critiques of and guidance for practice in the context of clinical trials involving interventions in healthy volunteers or patients requiring therapy [18]. In this kind of research, these individuals are typically designated as human subjects or participants. These terms broadly refer to individuals from or about whom data are collected or generated for the purpose of research. We employ the term participant in this article, as it is now preferred in many countries [19]. The designation of research participant confers a particular ethical significance or status in the context of research activities (see Box 1); participants are usually the primary focus of ethical consideration, and their protection from exploitation and undue harm is a core ethical goal. Ethical consideration may also be given to

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Table 1. Types of research of relevance to donation and transplantation during the end-of-life period.

	Type	Examples of research	Examples of potential ethical concerns about the research
1	Social sciences research relating to decision-making about deceased donation or transplantation of deceased donor organs and tissues	Qualitative studies exploring factors influencing decisions to authorize deceased donation on behalf of a relative; interventions to improve quality of communication with donation decision-makers [11]	Potential exacerbation of family distress when approaching family to discuss sensitive issues at a time of emotional upheaval
2	Clinical research involving potential and actual deceased donors		
2a	• Donor (ante mortem) intervention studies	Trial of anticoagulants ante mortem in potential donors;	Potential impact of experimental interventions on end-of-life care of the potential donor;
2b	• Donor (post mortem) intervention studies	Trial of steroids in potential donors following neurological determination of death [12];	Unsuccessful trials may jeopardize the quality of organs that would otherwise be suitable for transplantation [2].
2c	• Donor observation studies	Thanatological studies investigating the determination of death and phenomena such as autoresuscitation [13–15]	Potential impact of research on end-of-life care, and the experience of donor families [13]
3	Clinical research with the recently deceased(10) (16)	Trial of bio-synthetic organs or xenografts [8,9], or of novel transplant surgical techniques in the body of a person following neurological determination of death (NDD)	Potentially disrespectful treatment of the dead – changes to physical appearance or delay of laying to rest – which may exacerbate trauma or grief on the part of the deceased's family [16].
4	Clinical research involving organs or tissues donated after death		
4a	• Ex situ organ intervention studies	Trials of machine perfusion	Unsuccessful trials may jeopardize the quality of organs that would otherwise be suitable for transplantation [2].
4b	• Post-transplant studies in recipients of deceased donor organs or tissues obtained via other research described in this table	Trials of immunosuppressants; studies evaluating quality of life post-transplantation.	Recipients may have foregone standard-of-care transplant for research transplant of uncertain benefit.
5	Basic scientific research using organs or tissues donated after death	Investigation of organ physiology	Donated organs may be used in for-profit research; disposed of without according due respect for values or cultural beliefs of donors or donor families; or inappropriately taken from the pool of organs viable for transplant

other individuals or groups who may be involved in other ways or affected indirectly by the research.

In the context of RDDT, determining the ethical status of individuals who may be involved in the research is often complicated. For example, the status of some individuals may change throughout the course of a study – for example, when an individual dies – which may create confusion regarding ethical obligations towards that individual over time. In addition, many individuals may be involved in the research in ways that are not typical of clinical research participation, making it difficult to determine when an individual should be considered a participant as such. Individuals who may play vital roles in decision-making and be profoundly impacted by the research may not be considered participants as such, including the family of deceased donors. Research ethics guidelines may, thus, appear to provide little guidance with respect to the treatment of individuals who are usually a focus of ethical concern in routine donation and transplantation practice.

Other forms of ethical guidance and governance exist for research that takes place outside clinical trials. For

Box 1. Ethical status in research versus moral status
We use the term 'ethical status' here to refer to the ethical significance of individuals, which is defined with respect to the nature of their involvement in research in a particular context. Ethical status will be relative in a particular context.

In contrast, the term 'moral status' is typically used in ethics and philosophy to refer to the *intrinsic value* accorded to particular entities by virtue of inherent properties such as species membership, vital status or cognitive capabilities. A clear distinction is made between the moral status of living persons and deceased individuals.

For example, the ethical status of living, human individuals involved in various ways in a research study may differ, with the highest ethical status usually accorded to those deemed to be participants in a study. In contrast, all living human beings would be equally accorded the highest moral status irrespective of their roles in the research.

example, ethical guidelines have been developed for biobanking and for biospecimens research [10,20]. However, these may also fail to address some of the unique aspects of RDDT, given that much of RDDT involves elements of clinical trials research that are not typical of biobanking research. Ethical governance of biobanks has also been critiqued as failing to adequately consider the interests of donors to biobanks as research participants [21]. This highlights the need for nuanced accounts of research participation or involvement that can engage fully with the potential implications of ethically significant involvement in specific kinds of research. We focus here on individuals or groups whose role in research activities is personal rather than professional; for example, we exclude consideration of researchers themselves and other stakeholders such as research funders and organizations.

Potential donors prior to their death

The involvement of potential deceased donors in research is likely to be considered during their end-of-life care, and often prior to their death. At the time of decision-making about deceased donation, those who are authorized to make or confirm a decision about donation may also be asked to consider opportunities for involvement of the potential donor in research. For example, the person's organs or tissues might be donated for use in research if they are deemed unsuitable for transplantation.

Where an intervention is proposed to occur prior to the person's death in the context of a research study, the person (potential donor) is likely to be considered a participant. However, where permission is sought simply for use of deceased donor organs or tissues in research, in some jurisdictions the potential donor may not be considered a participant in the research as such, or not recognized as a participant in the sense of being accorded significant ethical status in the context of the research. This may be because the potential donor is considered through the ethical lens of organ and tissue donation frameworks rather than that of research, or because the donation for research is treated as akin to biobank donation with only limited consideration of the donor as participant [21].

The recently deceased

The ethical status of individuals whose involvement in RDDT commences following death is uncertain. In some countries, only living persons are considered potential research participants, for example, in the USA [22]. While there is often an implicit or explicit assumption in donor intervention studies, for example, that formal human research ethics committee (HREC) review is not needed for the deceased, other studies recognize the need for HREC review and designate deceased donors as participants [5,23].

Ethical concern for the treatment of bodies after death, and for the potential posthumous interests of the deceased is a matter of philosophical debate, for example, with respect to the question of whether a deceased person can suffer harm [22,24]. While most agree that there are important ethical considerations with regards to the treatment of the deceased, there is also consensus that the living are necessarily of greater ethical concern. Accordingly, ethical constraints on the treatment of the deceased are often strongest when framed in the context of their potential impact on the living. In RDDT, the involvement of the deceased usually occurs at or immediately after their death. This may heighten ethical concerns for researchers and for the family of the deceased, as the recently deceased often have special significance for the living [16], in particular those determined to be dead by neurological criteria but who continue to receive organ preservation support – 'the heart beating recently deceased' [25].

Clinician researchers involved in donation and transplantation may be accustomed to managing a shift in the ethical status of patients who die and become donors. After death is declared, for example, the

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procurement of organs and tissues becomes ethically permissible despite being prohibited only moments before. However, many of the clinical ethical standards applied to the critically ill and dying person have parallels in the treatment of the recently deceased. For example, the deceased's family may be consulted regarding decisions about the care of the deceased, most notably with regards to decisions about donation that are made after NDD. Significant care is taken not only to ensure that the body of the deceased is treated respectfully but that the wishes of the deceased – when these are known or may be estimated – are considered in making posthumous decisions on their behalf.

When responding to a case presented in a survey by Rodrigue *et al*., a majority (71%) of American transplant surgeon participants indicated that a deceased donor would face at least a minimal risk of harm in a hypothetical donor intervention study [26]. Rodrigue *et al*. suggest these responses may reflect concerns about the impact of study involvement on the donors' interests in successfully donating organs for transplantation, or on donor privacy [16]. The finding is consistent with other studies and commentaries that indicate a belief that the recently deceased are capable of being harmed, or at least wrongfully treated in ways that are ethically important [16,27]. (See Table 3) Individuals who believe that death does not truly occur until after permanent cessation of circulation or who lack confidence in the NDD may raise concerns about research involving the heart beating recently deceased, even if they are supportive of heart beating donation. Concerns may relate to potential conflicts of interest in the determination of death, or risks of harm to these research participants.

No authoritative national or international ethical guidelines for human research provide advice specifically with regards to the involvement of the recently deceased, leaving only the general recommendations of the North American multidisciplinary Consensus Panel on Research with the Recently Dead convened in 2005 [16]. Even where general research ethics guidance can effectively support decision-making, expert legal analysis of interrelated regulations may also be needed to navigate gaps or conflicts in legislation that may be applicable to research involving the recently deceased [28]. The involvement of the deceased in particular kinds of research may be limited, for example, by lack of clarity or inconsistencies in legislation governing the recovery of tissues or organs from deceased donors [4,29], or the treatment or storage of deceased bodies. Furthermore, legislation that permits surrogate decision-makers to provide consent for the recovery and use of organs and tissues after death in research may not clearly encompass the possibility of donor bodies being sustained through artificial ventilation for use in research.

Transplant recipients

Several authors have discussed the ethical status of transplant recipients who receive organs recovered as part of a donor intervention study [4,23,26,28]. In the US context, Heffernan and Glazier observe that recipients may be considered research subjects if 'the transplant is itself an "experimental" intervention about which data will be systematically collected', if 'research-driven interventions [involve] the recipient (other than the transplant itself)' or if 'identifiable information about the recipient [is collected] for research purposes' [23]. They point out that from a legal perspective in the USA, merely receiving an organ that was procured from a donor who was part of a donor intervention study does not constitute involvement in research as a subject. In contrast to other jurisdictions (e.g. Australia), the US permits the use of nonidentifiable transplant recipient outcome data as part of the donor intervention studies without entailing recognition of recipients as research subjects [23].

Some have discussed whether recipients of 'bystander organs' should be considered research participants [3,30]. Bystander organs are those that were not the target in a particular donor intervention study, but were nevertheless obtained from a donor in whom an intervention was performed. If recipients of non-target organs are not followed up from a research perspective, then they may not qualify as participants given that information about them is not collected for the purpose of research. However, bystander recipients are likely to share many of the concerns that those involved in research may have with regards to receiving information about the donor intervention and how this may influence the potential risks and benefits of the organs they receive [31]. The design of a study may impact bystander recipients and others in ethically important ways, requiring careful oversight irrespective of whether individuals are participants in the research [30]. Transplant recipients may also become retrospective participants in other kinds of research, for example, if there is a retrospective analysis of transplant outcomes in recipients of organs from donors who were part of intensive care research prior to death, where this research was not

aimed at improving donation or transplantation outcomes [32].

Deceased donor organs

Donated organs are usually recognized as ethically significant; the World Health Organization, for example, describes them as having an 'exceptional nature' distinct from medical products of nonhuman origin [33]. However, their ethical or moral status derives from their relationship to the donor, or following transplantation from their relationship to the recipient. For example, if an organ is removed via standard procedures during the course of a routine deceased donation procedure and then used in an experimental machine perfusion study and transplanted, it is likely the recipient of the organ will be considered a participant in the study.

If organs were instead removed from a living person for use in research, the donor would be recognized as a human participant in the research in many countries. If an experimental intervention occurred with the organs in situ in the deceased donor, then the study would fall within the scope of research involving the recently deceased. While the research itself is likely to be considered human research given the involvement of the transplant recipients, the role of the donor and the potential interests of the donor or their family in the study may be overlooked in the absence of due recognition for the ethical significance of the organs.

Arguably, donation of organs for transplantation implies a willingness to contribute to research or other activities such as clinical training which may benefit others, and that donation should be an unconditional gift. However, the unconditional gift of donation for transplantation should be distinguished from donation for research purposes, in which living donors are typically given the opportunity to make informed decisions about how donations may be used in research. In the UK, for example, consent for donation is distinguished from consent for use of organs or tissues from deceased donors in research [34].

Donor families

Donor families are frequently closely involved and impacted by RDDT, given their potential role in decision-making about donation, end-of-life care and inclusion of potential donors in research. Although donor families are not usually participants in RDDT in the sense that data are not collected about them – except if they participate in Type 1 research – they are often tasked with providing surrogate consent to research involving potential donors. Families also have ethical significance and must be considered when evaluating the potential benefits and risks of research given that the treatment of the potential donors during research may significantly impact their families from an emotional perspective. Some kinds of research may also materially impact families, for example, when information collected about donors is also information about families.

Ethical considerations in deceased donation and transplantation research

Requirements for consent

For many researchers, the ethical status of individuals involved in RDDT, and in particular, their designation as research participants, is primarily of interest because of its implications for consent requirements. The requirement to obtain consent for participation in research (including consent by surrogate decision-makers on behalf of potential participants who lack decision-making capacity) is considered an ethical priority because it serves to promote the autonomy of individuals who may contribute to research as participants, and to protect people who may be most at risk of harm from research. It is, therefore, essential for maintaining public trust in research activities, in particular by assuring individuals and communities that they have control over their involvement in research. However, even when stakeholders are recognized as participants, consent in some studies may be waived [35,36]. Furthermore, when consent is required, there may be considerable variation in the specific requirements.

Table 2 outlines some of the general points of ethical uncertainty with regards to consent requirements in the context of RDDT. Similar considerations have been raised in the context of clinical consent for ante mortem interventions in potential donors and protocols for DCD [37], and consent for transplantation using extended criteria donor (ECD) organs in the absence of research activity, highlighting the need for research ethics frameworks to engage with clinical ethics work on decision-making in these contexts.

Risks and potential benefits of involvement in research

The ethical status of individuals involved in research also often corresponds to the nature of their

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Table 2. Ethical uncertainty regarding requirements for consent to participation in research.

Areas of ethical uncertainty	Possible influential factors
Authority for decision-making on behalf of potential deceased donors	• Potential donors usually lack capacity to provide consent at the time of potential participation in research. • Different legislation may determine authority for decision-making about end-of-life care, deceased donation, use of donated organs in research or involvement of potential donors in research prior to death [4,29]. • In some jurisdictions, recognition as a research subject entails an obligation to obtain participant consent, which may be logistically burdensome or unfeasible in some contexts [38].
Information requirements	• Decision-makers may vary in their preferences regarding level of detail of information. • Regulatory requirements for consent in research may require review of extensive or generic information which may conflict with decision-maker's needs and preferences regarding information. • Potentially significant burdens of decision-making and barriers to timely consent for research associated with
Voluntariness of consent	• Potential conflicts of interest on the part of surrogate decision-makers or those supporting their decision-making, as is the case when surrogates provide consent for deceased donation per se [1,39,40]. • Pressures on potential transplant recipients to agree to participate in research if participation is likely to increase their chance of receiving a life-saving transplant.
Capacity for decision-making	• Decision-making about research is likely to occur under significant time pressures and in addition to burdensome decision-making about other matters [31,38,41]. • Burdens of decision-making may impact capacity of decision-makers to receive, process and apply information effectively in decision-making.
Limitations on individual choice within research protocols/Extent of choices/ Determining which decisions are pertinent to specific research participants	• Specific study protocols influence the range of choices available to individuals or surrogate decision-makers with regards to interventions in potential donors, or to transplant offers. • Despite recognition of an individual as a participant in, or authorizer of, research, it may be difficult to determine which steps in the research protocol are specifically relevant to that individual and, hence, require specific disclosure and consent, for example decisions about particular methods of organ preservation that involve reperfusion.

involvement and associated risks and potential benefits, examples of which are summarized in Table 3. These are general examples; some risks may be modifiable or absent in some studies. The probability and magnitude of risks and potential benefits will vary according to individual studies and participants. For example, the risks and benefits of participation in research by transplant candidates will be heavily influenced by the potential impact of the research on their opportunities for transplantation, which will require evaluation in the context of individual circumstances when a transplant offer is made.

Equity in research

Equity in access to the benefits of research and in distribution of the burdens of research participation is an important goal in research ethics. In the context of RDDT, equity considerations may intersect with broader concerns about equity in donation and transplantation. For example, selection of transplant candidates as participants in research requires consideration of equity in allocation of organs for transplantation. Care must be taken to ensure that research interests do not disrupt organ allocation systems in ways that create or exacerbate inequities in access to transplantation, for example, if donors or organs are diverted to transplant centres involved in research [30]. Care must also be taken to ensure that deceased donors involved in research are not disproportionately recruited from marginalized or vulnerable populations, especially via potentially coercive incentives [9].

While research may expand the supply of organs suitable for transplantation, some research may result in loss of organs at least in the short term, for example, if interventions have a negative impact on organ viability, or if organ offers are declined as a result of concerns about the quality of organs that are recovered as part of a research trial. In some contexts, research activities may also raise concerns about exacerbating inequities in healthcare more broadly, for example, if resources used to conduct research such as intensive care services are consequently not available for use in other patients.

Table 3. Examples of potential benefits and risks associated with involvement in deceased donation and transplantation research.

Individuals involved	Potential risks of involvement in research	Potential benefits of involvement in research
Potential deceased donors (ante mortem)	Potential negative impact on aspects of end-of-life care, for example, increased number or prolongation of invasive clinical interventions.	Hawthorne effect (e.g. more attentive care or intensive follow up);[42] fulfilment of altruistic goals including donation-related goals
Recently deceased (assuming that posthumous harms and benefits are considered possible)	Concerns have been expressed regarding the potential for 'disrespectful treatment' of the recently deceased, with examples cited such as overly long duration of use of the deceased body for research purposes; inappropriate disposal of the body or remains following research; unnecessarily invasive research; use in research that would be inconsistent with the deceased's own preferences or values or use that otherwise may cause distress or inconvenience to the family of the deceased [10,16].	Fulfilment of altruistic goals including donation-related goals.
Families of potential donors	Families may experience burdens of additional decision-making, potential psychosocial burdens or harms associated with changes in end-of-life care of the potential donor as a consequence of research requirements, for example, delayed funerals and distress associated with particular uses of the deceased in research. Particularly innovative studies may also threaten the privacy of donors and their families, for example, when rare transplants are performed using vascular composite allografts.	Psychosocial benefits including satisfaction in helping to achieve relative's donation or research-related goals, and finding comfort or solace in their grief as a result of the deceased's successful donation or contribution to knowledge that could eventually improve the field of organ donation and transplantation.
Transplant recipients	Potential additional burdens associated with research participation such as additional invasive tests or interviews for data collection; risks of unexpected harms resulting from experimental interventions.	Therapeutic benefits of any immediate transplant opportunity; potential future benefits from application of research knowledge in future transplant opportunities; psychosocial benefits of achieved altruism, contributing to transplant community.

Ethical guidance is needed to address barriers to RDTT

Several commentators note ethical considerations or uncertainty represents a significant barrier to innovative research in donation and transplantation [2,43]. While this may be true of much research, RDTT faces additional barriers caused by the inherent complexity of studies that involve multiple stakeholders, some of whom may be expected to change ethical status during the study (donors die), the presence of pre-existing conflicts of interest and challenges in decision-making (i.e. for donation and transplant offer acceptance), the time critical nature of much decision-making and the involvement of some clinical practices that remain (at least in some jurisdictions) ethically if not clinically contentious (e.g. donation after euthanasia). This means that those responsible for reviewing or guiding ethical conduct of the research must first grapple with the ethical complexities of deceased donation and transplantation before contending with additional considerations of the research.

HRECs may struggle to assess and provide advice on proposed research in more specialized fields owing to lack of familiarity with technical or scientific aspects. In the case of RDTT, these challenges may be exacerbated by lack of familiarity with some of the unique ethical aspects of donation and transplantation. Despite clinical experience with these ethical aspects, researchers may also have difficulty engaging with them from the research perspective. Confusion regarding the ethical considerations of RDDT is evident in the uncertainty

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demonstrated by HRECs and researchers regarding the ethical status of individuals involved in research [5,26]. Such confusion risks undermining public confidence and trust not only in the research but also in donation and transplantation activities more broadly.

Training and guidance are needed to support researchers and HRECs in designing, evaluating and conducting RDDT. Furthermore, variations to existing protocols and novel procedures may not always be recognized as constituting research as such, or may initially require ethical governance under the clinical innovation framework [44–47]. Dedicated HRECs at the regional or national level may be helpful in ensuring sufficiency of expertise to provide oversight of studies that are likely to be relatively rare in the experience of most HRECS, and help to address issues that may arise when multiple HRECS are involved in review of studies with differing levels of expertise. In the UK, for example, the recently established Research Innovation and Novel Technologies Advisory Group (RINTAG) provides guidance and helps to facilitate RDDT [48]. RINTAG supports HRECs in ensuring that RDDT meets relevant legal and ethical standards for donation and transplantation [48]. In the case of research involving the recently deceased, we suggest that in the absence of specialist review boards for such research as proposed by Parent *et al* [49] all studies should be subject to review by HRECs, who should consult existing guidelines for research in the recently deceased [16], and expert bodies such as RINTAG.

Existing ethical guidelines for RDDT from the USA and the UK provide a helpful starting point for guideline development in other countries [3,48], although these may not address all the ethical considerations that may arise in the context of research types outlined in Table 1. Each of the ethical considerations briefly outlined in this article and many more require careful explication in order to formulate specific principles to guide evaluation and management of concerns in the context of new research protocols. The context in which research is conducted, with regards to the clinical, economic and sociocultural environment as well as the relevant jurisdiction, may require more nuanced ethical guidance. Nevertheless, international collaboration on guideline development will be helpful in supporting consistency of ethical practice around the world, addressing potential ethical barriers to international collaboration on research, and ensuring that public trust in deceased donation and transplantation extends to research in this field.

Authorship

DM wrote the initial manuscript, led manuscript editing and wrote the final manuscript. AJC, ADA, FVH, JEL, EM and GCO contributed to critical revision of the manuscript. BP contributed to critical revision of the initial and subsequent manuscripts. All authors approved the final version of the manuscript.

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