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Applying the 'Human Rights Model of Disability' to Informed Consent: Experiences and Reflections from the SHAPES Project

Richard Lombard-Vance [1,2,*], Evelyn Soye [3], Delia Ferri [2,3], Emma McEvoy [2,3], Malcolm MacLachlan [1,2] and Sari Sarlio-Siintola [4]

[1] Department of Psychology, Maynooth University, Maynooth, W23 X04D Co. Kildare, Ireland
[2] Assisting Living and Learning Institute, Maynooth University, Maynooth, W23 X04D Co. Kildare, Ireland
[3] School of Law and Criminology, Maynooth University, Maynooth, W23 X04D Co. Kildare, Ireland
[4] Department of Research and Development, Laurea University of Applied Sciences, 01300 Vantaa, Finland
* Correspondence: richard.lombardvance@mu.ie

Abstract: Understanding the complexity of informed consent processes is critically important to the success of research that requires participants to test, develop, or inform research data and results. This is particularly evident in research involving persons experiencing neurodegenerative diseases (e.g., Alzheimer's disease, dementia) that impair cognitive functioning, who according to national law are considered to have a diminished capacity, or to lack the capacity, to consent to research participation. Those who would potentially benefit most from applied research participation may be excluded from participating and shaping data and outcomes. This article offers insights into challenges faced by the Smart and Healthy Ageing through People Engaging in Supportive Systems (SHAPES) Project in obtaining the consent of older persons, including older persons with disabilities. The promotion of continuing health, active ageing, and independent living is central to SHAPES, requiring project partners to reflect on traditional informed consent approaches to encourage the full, cognisant participation of older persons with disabilities. We examine how this issue may be addressed, with reference to the inclusive approach of SHAPES. In respecting the inalienable legal capacity of all legal persons, SHAPES uses the UN Convention on the Rights of Persons with Disabilities (CRPD) and the human rights model of disability as part of the theoretical framework. A novel, inclusive, representative informed consent framework was designed and is detailed herein. This framework provides significant opportunity to advance the inclusion of persons with disabilities or those experiencing neurodegenerative diseases in innovative research and is readily transferable to other research studies. The SHAPES approach is a substantial contribution to research on informed consent, demonstrating the utility of the human rights model of disability in facilitating the full research participation of target populations.

Keywords: disability; informed consent; ageing; human rights model of disability

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1. Introduction

Demographic changes occurring across the European Union mean that, by 2050, the population aged 65 years or more will increase to almost 130 million [1] (p. 16). By 2070, it is estimated that 30% of the European population will be aged 65 or more, up from approximately 20% currently, while the proportion of the population over 80 years is projected to double [2] (p. 10). In the last 50 years, life expectancy has increased by about 10 years for both men and women [2] (p. 7). However, longer lifespans are associated with a greater prevalence of chronic diseases and physical, sensory, and cognitive impairments, which, in interaction with social and environmental barriers, may give rise to disability [3,4]. Relatedly, according to the European Commission's *Report on the Impact of Demographic Change*, people aged over 65 account for the majority of the 50 million EU citizens who suffer from two or more chronic conditions [2] (p. 18). Therefore, while Europeans are

living longer, the promotion of higher quality of life and more years spent in good health and well-being is crucial.

The SHAPES Project

The promotion of continuing health, active ageing, and independent living is at the core of the Smart and Healthy Ageing through People Engaging in Supportive Systems (SHAPES) Project. SHAPES is a response to the European Commission's funding call, Trusted digital solutions and Cybersecurity in Health and Care (H2020-SC1-FA-DTS-2018–2020). SHAPES is a four-year project (November 2019–October 2023) that endeavours to build, pilot, and deploy a large-scale, pan-European platform and care ecosystem that will provide a range of supports to older persons, including older persons with disabilities, to facilitate healthy and independent living. The SHAPES Platform is designed to be a standardised, interoperable, and scalable platform for the integration of smart technologies. The SHAPES Platform has three core functions: to collect and analyse data relating to individuals' health, environments, and lifestyles; to identify needs on an ongoing basis; and to provide reliable, trustworthy, and affordable recommendations and solutions in return. Individual technological solutions in the SHAPES projects, such as social robots, aim to specifically address users' requirements and expectations regarding supporting and extending older adults' independent living and active and healthy ageing at home. With this shared objective, the project brings together thirty-six partner organisations and research institutions, across fourteen European countries, with expertise in health, social sciences, IT development, robotics, health and social service provision, advocacy, ethics, and law.

The SHAPES Platform will be co-developed based on ethnographic research of older adults' lifeworlds; organisational, structural, and sociotechnical perspectives on integrated care delivery; and a set of technological requirements to accommodate an open and interoperable ecosystem of digital technologies designed to support and extend the independent living of older individuals, including older individuals with disabilities. Subsequently, commencing in the final quarter of 2022, the SHAPES Platform will undergo validation via a multidisciplinary, large-scale piloting campaign. Pilots will involve over 2000 older adults across fifteen pilot sites in ten states (nine EU Member States and Northern Ireland), including six reference sites of the European Innovation Partnership on Active and Healthy Ageing. Pilots will be conducted with multiple technology use-cases across seven themes:

(1) Smart Living Environment for Healthy Ageing at Home;
(2) Improving In-Home and Community-based Care;
(3) Medicine Control and Optimisation;
(4) Psycho-social and Cognitive Stimulation Promoting Well-being;
(5) Caring for Older Individuals with Neurodegenerative Diseases;
(6) Physical Rehabilitation at Home;
(7) Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals.

SHAPES operates within defined ethical and legal frameworks to protect both researchers' and participants' fundamental rights, privacy, and personal data. SHAPES adopts an inclusive and person-centred approach. Furthermore, it is informed by the human rights model of disability, which underpins the United Nations (UN) Convention on the Rights of Persons with Disabilities (CRPD) [5]. The CRPD is the leading international law instrument on the rights of persons with disabilities, affirming that persons with disabilities must enjoy all human rights and fundamental freedoms and recognising their human dignity (Article 1 CRPD). By adopting a social-contextual perspective on disability [6], the CRPD recognises attitudinal and environmental barriers as being the source of disablement. The CRPD places the focus on persons with disabilities as the subjects of rights, rather than being considered as objects of rights, charity, or medical interventions [7] (e.g., p. 316). Central to this is Article 12 CRPD which enshrines the principle that persons with disabilities must be given equal recognition before the law. In particular, States Parties

are obliged to recognise that persons with disabilities "enjoy legal capacity on an equal basis with others in all aspects of life" (Article 12(2)). Article 12 CRPD encompasses both legal personality (i.e., being able to bear rights and duties under law) and the capacity to act. While many national regimes still consider a person not to have legal capacity where a cognitive or psychosocial disability is considered to impair an individual's decision-making or "mental capacity", the Convention differentiates between mental capacity and legal capacity (CRPD Committee, General Comment, para 15). Mental capacity refers to the individual's psychological abilities, whereas legal capacity refers to the legal recognition of the individual and their decisions. Furthermore, and for the purpose of this article, it is worth recalling that Article 25 CRPD, which provides for the equal right to health, states that healthcare providers must not discriminate against persons with disabilities, including on the basis of free and informed consent (CRPD, Article 25(d)).

Consistent with its purpose and ethos, the project is seeking inclusive participation in the design and development process, in particular in the piloting of the SHAPES Digital Technologies, i.e., the set of technologies, systems, and mobile applications that are part of the SHAPES Platform. The research conducted includes participants living across 10 EU Member States (Czech Republic, Cyprus, Finland, Germany, Greece, Ireland, Italy, Portugal, Spain, Sweden) and the UK, whether in their own homes or in residential care facilities, experiencing permanent or temporary impairments and neurodegenerative diseases impacting on their cognitive functioning, such as Alzheimer's disease or dementia. As well as such specific populations, the SHAPES research cohorts of older adults may conceivably also include individual participants who have a history of acquired brain injury, stroke, transient ischaemic attack, or other health conditions that may have precipitated cognitive impairment, or that may do so in the future. The project seeks to align with the human rights model of disability and to realise a participatory approach that will permeate its various facets including, inter alia, SHAPES governance, research and piloting, and the development and deployment of the Integrated Platform. SHAPES aims to take into consideration the ability of each individual to make decisions concerning their participation, and endeavours to implement the human rights approach and the paradigm shift in legal capacity brought about by the CRPD. This has required us to reflect in particular on our approach to informed consent, in order to ensure full and cognisant participation of older persons with disabilities in the project.

The above-mentioned factors—pan-European research, inclusive ethos, the human rights model of disability, participatory research, inclusion of persons who may have cognitive impairment, and so on—make the experience of constructing the SHAPES Project's informed consent process a valuable one. This article discusses the challenges and the strengths related to the inclusive participation sought in SHAPES, with the involvement of service recipients usually referred to as "vulnerable adults", paying particular attention to informed consent. In that regard, the whole SHAPES Project recognises that the concept of vulnerability is "an open-textured, ambiguous and elusive notion which is used in many different disciplines" [8] (p. 780). If understood as exposure to risk, it is argued that vulnerability is a universal experience [9]. This may be contrasted with the view that certain groups within society are inherently vulnerable by virtue of certain characteristics. However, Herring considers that acknowledging that individuals' experiences of vulnerability are not equal allows us to reconcile these ostensibly competing schools of thought [10]. SHAPES uses the term "individuals experiencing vulnerability", linking the idea of vulnerability to the inherent vulnerabilities of human beings [9], but also to structural inequalities and barriers faced by specific cohorts.

There is a wealth of research on informed consent in social and health science [11–13]. There is also an array of research on informed consent in research taking place in residential care facilities [14]. While building on that research, this article aims to adopt a disability perspective and uses the human rights model of disability and the CRPD as part of the theoretical framework. In light of that connection, this article aligns with CRPD terminology

and prefers the term "persons with disabilities"/"older persons with disabilities", albeit using the term "vulnerable adults" when referring to research on informed consent.

Further to these introductory remarks, Section 2 briefly recalls the human rights model of disability. Section 3 briefly highlights the growing scholarship on participatory research, as well as "patient" and public involvement (PPI) of vulnerable adults in research. Section 4 focuses on informed consent and the participation of persons whose legal capacity is restricted by national law, while Section 5 examines how this issue may be addressed, with reference to the inclusive approach adopted in the SHAPES Project.

2. The Human Rights Model of Disability as a Theoretical Framework

The CRPD is considered a "revolutionary" treaty [15,16], since it "precipitated a dramatic sea change in the relative human rights empowerment of persons with disabilities by recognizing their equal dignity, autonomy, and worth, and by ensuring their equal enjoyment of all human rights and fundamental freedoms" [17] (p. 2). The revolutionary cipher of the CRPD is connected to the "human rights model of disability" embedded in it [18,19]. Without engaging in a discussion of the models of disability [20], or whether the "human rights model of disability" represents a development of the social model [18], or whether the two are complementary models [19], this section recalls the core tenets of the human rights model [18,21–23] and refers to the CRPD Committee [24].

Degener [22] argued that this model "encompasses the values for disability policy that acknowledges the human dignity of disabled persons", and that the human rights model does not focus purely on social and environmental barriers, but values impairments as part of human diversity (p. 47). This entails that the human rights model goes beyond anti-discrimination and "encompasses both sets of human rights, civil and political as well as economic, social and cultural rights" (p. 44). Furthermore, she suggests that the human rights model pays particular attention to intersectional discrimination (p. 49) and "offers room for minority and cultural identification" (p. 9). In fact, the CRPD Committee in its General Comment No. 6 not only recognises that disability is a social construct, but conceives of it as "one of several layers of identity" [25]. Notably, Degener also states that "the human rights model offers a basis for assessment when prevention policy can be claimed as human rights protection for disabled persons" [22].

Accessibility is a general principle of the CRPD and applies across all rights of the CRPD. In its General Comment, the CRPD Committee has defined accessibility as a precondition for the enjoyment of all human rights provided for in the CRPD [25].

Article 25 CRPD frames the right to health of persons with disabilities in a human rights context by demanding equal access to health care services. It also requires that services must be fully accessible to persons with disabilities, community based, and respectful of the dignity of persons with disabilities. Lack of accessibility of healthcare entails discrimination and can amount to a denial of health care. It is important to acknowledge that the experience of disability is not synonymous with health, or a lack of health. While disability is not a "health problem" [26], some people with disability do clearly have health needs that extend beyond their needs for disability services and supports. Given that the human rights model "sets out standards of behaviour expected of States and institutions to ensure basic social justice for disabled people" [19] (p. 368), this should also inform participatory practices in research projects concerned with health and well-being. In this regard, as noted above, Article 25 CRPD also places an emphasis on informed consent.

3. Participation of "Vulnerable Adults" in Research Projects: A Review of the Relevant Literature

The World Health Organization's Declaration of Alma-Ata, which broke new ground as the first international policy instrument on primary health care, provides that "[t]he people have the right and duty to participate individually and collectively in the planning and implementation of their health care" [27]. This reflects the movement of "emancipatory" disability research that began in the UK in the 1970s seeking to redress the imbalance in

the power dynamic between the researcher and the participant and to promote the rights of persons with disabilities [28]. Beresford and Russo make the distinction between this ideology of democratising research and the consumerist or managerialist motivation that they consider as underpinning the mainstreaming of user involvement in health and social care. In this regard, they suggest that "[i]f the first approach is essentially about empowerment, the second is more concerned with extraction" [28] (p. 147). Additionally, the synergy between research evidence and advances in practice and care has been reaffirmed with new strength in recent movements to embed evidence-based practice. Participatory research—particularly in the form of "public and patient involvement" (PPI)—has emerged as a way to both integrate such rights and duties as have variously been expressed in Alma Ata or the CRPD and simultaneously move to improve the rigour, reliability, and applicability of research advancements, thus supporting evidence-based practice.

3.1. Participatory Research

Jagosh et al. define participatory research as "the co-construction of research through partnerships between researchers and people affected by and/or responsible for action on the issues under study" [29] (p. 311). Similarly, Cargo and Mercer consider it an umbrella term "for a school of approaches that share a core philosophy of inclusivity and of recognising the value of engaging in the research process (rather than including only as subjects of the research) those who are intended to be the beneficiaries, users and stakeholders of the research" [30] (p. 326). Under this broad understanding, the participation of a wide spectrum of the community with an interest or influence in the area under study may be included: inter alia, patients or service users, community members, health professionals, and representative organisations, as well as decision-makers such as health managers, policymakers, and community leaders [29] (p. 312).

Broadly speaking, participatory research may take numerous forms, including but not limited to PPI and co-research. PPI has been variously defined, a prominent definition being that given by the UK National Institute for Health Research (NIHR): "Involvement is research done with or by patients and the public, not to, about or for them" [31]. This definition has also often been used for co-research [32,33], although Di Lorito and colleagues, for example, situate co-research at the centre of a PPI spectrum that ranges from members of the public providing consultation to them directing the entirety of the research [34]. NIHR further state that PPI "is about working collaboratively with patients and the public and sharing decision-making", which NIHR distinguishes from engagement (raising awareness, dissemination) and participation ("giving formal consent and taking part in a trial or study" as a participant/"subject") [31]. While the stated ethos of PPI is relevant to older people with disabilities, the medical terminology of "patient" may be seen as problematic. Unless people with disabilities have health problems, they are unlikely to consider themselves "patients", while persons with health problems may also not feel represented by the term "patient", preferring terms like "service user", or the preferred term in SHAPES, "care recipient". This issue points toward the critical perspective we must maintain in relation to PPI, or more accurately how PPI and its language are used, interpreted, or even "appropriated" [35] (p. 2). PPI may be seen as a subcategory of the superordinate "engaged research", which encompasses persons and disciplines beyond healthcare.

The increased interest in participatory research, in the last decade in particular, may be generally attributable to the recognition that the meaningful involvement and contribution of those persons to which the research relates has the potential to improve research outcomes for all stakeholders. As Jagosh et al. summarise, PPI offers the potential to "[strengthen] relations between the community and academia; ensures the relevancy of research questions; increases the capacity of data collection, analysis, and interpretation; reduces the 'iatrogenic' effects of research; and enhances program recruitment, sustainability, and extension" [29] (p. 313). Moreover, the integration of researchers' theoretical and methodological knowledge with the real-world knowledge and lived experiences of participants is recognised as the key strength in participatory research [30] (p. 327).

A recent systematic review reported that the participation of older adults as co-researchers in ageing research has manifold benefits, for both the older adults and the academic researchers [36]. Psychosocial benefits reported for co-researcher older adults included the following: increased self-confidence; personal growth; intellectual stimulation; knowledge and skill acquisition; enjoyment; feelings of achievement or satisfaction; being valued; feeling useful; being able to "give something back"; challenging pre-existing assumptions and prejudices; the development of relationships with other co-researchers, academics, and the wider community; and opportunities for activism or career progression. There were also, however, a number of challenges reported. Most germane to considerations of inclusion, human rights, and consent—and contrary to the spirit of PPI—co-researchers also reported a disempowerment engendered by power imbalances between themselves and both the academics and the research funding bodies. Dissatisfaction of co-researchers with their level of involvement was also evident; some desired more involvement in the research process, some desired less, and others were unsure of expectations. Co-researchers often reported challenges related to demanding workloads and difficulties "navigating" relationships with academics and other co-researchers.

Additionally, in the context of ageing research, older adults may have a more positive disposition toward their potential contribution to research via PPI than many academics [37], the latter of whom have cited the following as barriers to PPI: the early stages of research sometimes rendering PPI premature, the specificity of scientific protocols, and the lack of mechanisms to implement PPI. Academics were also less likely to see the benefits of PPI to themselves. It is worth noting the authors' acknowledgment of limitations relating to the exploratory nature of the research. Baldwin and colleagues' systematic review also pointed to power imbalances and the hierarchical relationship between academics and co-researchers being a challenge reported by academics [36].

Realising the full potential of PPI is likely to be at least partly contingent upon the form it takes and the overarching aim of its implementation in particular contexts. The part of the "spectrum" of participation that the research aligns with is likely to be instrumental. How much meaningful involvement do the public, care recipients, or co-researchers have, and what roles do they assume? Involvement may be limited to traditional participation as a subject. Alternatively, they may be included in a manner that aligns with a certain point of the PPI spectrum, whether in a consultation or advisory role, as partners (for example, in joint research design or data analysis), or even as research principals who assume an overall directorial role [38].

Green argued that while the voice or wishes of the public are increasingly infused into applied health research proposals, and subsequently funded research, the ultimate balance of the power to transform and empower oneself, or empower others, remains largely unchanged [39]. Academia or scientific research remains the locus of such power, rather than the public. Beresford and Russo consider that the move toward participatory research must be understood in the context of broader social and political developments [28] (p. 145). Indeed, Madden and Speed propose that the perceived democratic deficit in research reflects the neoliberal policy context of "post-truth" and "dog whistle" politics (2017, p. 1). Given the broad nature of the concept, it is clear that the meanings and motivations behind participatory research are many and may reflect differing values and priorities, as well as political and social changes over time. This undoubtedly presents the potential for negative and harmful consequences where these values and goals are not aligned.

In this regard, Jagosh et al. acknowledge the difficulty in evaluating the benefits of PPI in research given the heterogeneity of participatory research, the variance in extent of collaborative involvement, and the complexity in considering outcomes [29] (p. 311). In their study of a large sample of participatory research projects, Jagosh et al. employed a realist approach based on assessment of synergy in research process and outcomes. Their findings indicate that multi-stakeholder co-governance of research can have both intended and unintended benefits to research contexts, processes, and outcomes, but can also contribute to negative outcomes [29] (p. 333). Compellingly, they found that

unintended outcomes, such as capacity-building, self-empowerment, and infrastructure development, were sometimes described as having a more profound impact on well-being than the intended outcomes of planned interventions [29] (p. 334). Further, it was found that where conflict and negotiation arose, it was not necessarily antithetical to synergy in collaboration and, in fact, often increased understanding and trust, and served to reaffirm stakeholders' commitment to the project [29] (p. 335). However, in this regard, the authors recognised a possible bias, whereby only those studies reporting successful outcomes are published, as a limitation to their findings.

3.2. Participation of "Vulnerable Adults" in Research Projects

As already noted, the movement for PPI in research has its origins in the disability rights movements of the 1970s [28] (p. 146). Traditionally, bioethics, which emerged in the wake of human experimentation atrocities of WWII, sought to safeguard from exploitation persons with disabilities and persons who were considered vulnerable [40] (p. 371) [41] (p. 289). However, too often this results in their exclusion from having input and from contributing to the research that affects them and is of most concern to them. The movement of emancipatory disability research, along with greater understanding of the social model of disability in recent years, have challenged paternalistic attitudes. Moreover, the significance of participation in research is increasingly recognised in bridging health disparities, addressing social justice issues, and facilitating self-determination both in richer countries [30] (p. 326) and among people with disabilities in poorer countries [42].

This is equally true of vulnerable adults who may lack the capacity to make decisions unassisted. Dalpé et al. cite, in particular, the involvement of such participants as critical to the effective research of neurological and neurodegenerative diseases [41] (p. 4). At the same time, there is a notable research gap in the health conditions affecting vulnerable groups, with the result that there is insufficient knowledge of effective treatment or interactions with other medications [43] (pp. 662–663) or other forms of therapeutic interventions. Similar exclusion, at times related to implicit ageism or to concerns about capacity to consent, has been noted in digital health and the use of technology in care [44]. Alzheimer Europe has set out a position and framework for the meaningful and active involvement of people with dementia throughout the research lifecycle, which strengthens the transparency and validity of the research and confers a range of benefits on the community of persons with dementia [45]. Therein, co-production is seen not only as participation, but also as a valuable form of empowerment.

Littlechild et al. observe that while there has been an increase in the uptake of co-research with older people generally, this has been slower amongst certain groups, such as older persons with dementia and those from black or minority ethnicity communities [46] (p. 18). In their nuanced assessment of PPI with older persons, they conclude that co-research with older persons offers the potential for change at both individual and social levels; in particular, they cite benefits such as "sustaining a sense of self, building confidence and skills, promoting affirmative social relationships and opportunities and challenging negative social attitudes" (p. 33). This is echoed in qualitative research findings about the experiences of persons with dementia, researchers, and "gate-keepers" in co-research endeavours [47]. In particular, co-researchers with dementia expressed a sense of satisfaction at being able to contribute in a manner that was valued. Waite et al. emphasise the importance of flexibility and tailoring the approach to the individual participant. Reflecting on the participation of persons with dementia, Morbey et al. conclude that training, development, and support for researchers is essential to developing meaningful working relationships with the organisations and individuals involved [48] (p. 9).

In addition, it is noted that participants can sometimes benefit directly from involvement in research through access to health care treatment and monitoring which may not otherwise be available to them [49] (p. 3). However, given these potential incentives, the critical importance of research ethics and the notion of informed consent to participation is clear [40]. In a vein similar to how the NIHR distinguishes different aspects of involvement

and participation as outlined above [31], participatory research designs must be complemented with a consideration of inclusive participation as a research participant, which requires facilitation by a clear and inclusive consent procedure.

4. Conceptual, Legal, and Procedural Challenges: The Winding Road toward Enacting Participatory Research in line with the Human Rights Model

The traditional view in research ethics was that the interests of vulnerable individuals were best protected through safeguarding from participation in clinical trials. However, this has resulted in the neglect of vulnerable groups in biomedical research [41]. The emergence of PPI, the social model of disability, the approval of the CRPD, and the rise of the human rights model of disability have challenged paternalistic attitudes and brought greater recognition to the rights of persons with disabilities. Furthermore, the importance of the participation of target populations in scientific research is increasingly recognised, including those traditionally excluded as lacking the capacity to give informed consent. Indeed, the new EU Regulation on Clinical Trials of Medicinal Products (Regulation 536/2014), which entered into force on 31 January 2022, states that, unless otherwise justified, the participants in trials should represent the target population group.

However, the increasing emphasis on the participation of persons with disabilities, including older persons with disabilities, in mainstream research practices has also brought new challenges to the fore, particularly where the issue of consent is concerned [41]. This section explores those challenges from conceptual, legal, and procedural (and practical) points of view.

4.1. Conceptual Challenges

The preceding sections have introduced the concept of PPI in research, noting that it can represent diverse principles and ideologies. Beresford and Russo identify service users and representative organisations on the one hand, and policy makers on the other, as being at least two proponents of PPI whose interests and aims have differed with political and social shifts over the years [28] (pp. 145–146). They express the view that it is impossible to approach PPI in research with an entirely neutral perspective, and that the development and implementation of PPI is undermined by these interests (p. 146). While originating as a movement to empower persons with disabilities to meaningfully contribute to the research that concerns them, PPI in healthcare policy is principally motivated by optimising efficiency, with the objective of increasing benefits to the end consumer. Beresford and Russo observe that "confusingly, both approaches use the same language, the same terminology, the same rhetoric" (p. 147). Knaapen and Lehoux identify a further "lay expertise" model based on furthering the recognition of experiential knowledge in research [50]. The lack of any genuine, common understanding of PPI is recognised as problematic. Per Madden and Speed, it amounts to a "poorly monitored, complex field of activity, variously framed by the expectations of policy makers, funders, host organizations, researchers, health professionals, individual recruits, volunteers, activists, and third sector organizations" [51] (p. 1). This mismatch leaves open the potential for unfulfilled expectations or feelings of being tokenised among research participants [28] (pp. 147–148). Indeed, in their study of PPI in research projects, Jagosh et al. observe that instances of unresolved conflict or disagreement in coalition lead to disaffection and loss of trust amongst the stakeholders [29] (p. 335).

Participatory research continues to be perceived as having lower value than traditional methods, which tend to attribute quality based on neutrality, expert oversight, and scientific methods [28]. This is exacerbated by the traditional criteria by which research impact is assessed, which focusses on output, ignoring whether the research approach itself may provide a valuable contribution to knowledge. Furthermore, assessment of participatory research remains dominated by academics and researchers, with little or no input from the actual participants [28] (p. 160). It is clear that the benchmarks by which research is assessed are prejudicial to PPI and to the introduction of experiential knowledge in

research. This has further detrimental consequences when it comes to funding applications and dissemination of findings [28] (p. 155).

PPI offers a more inclusive and progressive approach to research, particularly in addressing the power imbalance between researcher and participant. However, it has proven controversial. Scholarship points to PPI's potential to serve both progressive and regressive roles in health care research [28] (p. 148). Criticism is directed at the inherent vagueness of this broad concept "that can mean anything (and nothing) and serve a variety of purposes" [51] (p. 3). In this regard, the International Collaboration for Participatory Health Research considers participatory research a "research paradigm rather than a research method." [52] (p. 4). Beresford and Russo propose the steps to be taken to improve the sustainability and credibility of PPI as a research approach including, inter alia, strengthening its theoretical basis, fostering education and training on participatory research, equalising access to funding, and ensuring equitable recognition within research structures [28] (pp. 165–166).

4.2. Legal Challenges

An individual's understanding or expectations of PPI may be a significant factor informing their consent to participation in research. In that regard, free and informed consent may easily be undermined where expectations are not met, or confidence is broken. This may be all the more complex in the case of persons with disabilities who are either partially or entirely deprived of legal capacity under national laws that do not align with the CRPD. In this context, legal challenges also play a role, as participation may not be possible without certain national legal requirements being respected and the support of caregivers being secured.

Legal capacity may be described as the legal construct which is generally recognised in persons of majority age, enabling them to have and exercise rights and obligations [53] (p. 7). The right to equal recognition before the law, under Article 12 CRPD, implies that legal capacity is "a universal attribute inherent in all persons by virtue of their humanity" (CRPD Committee, para 8). No person can be deprived of legal capacity. The CRPD Committee General Comment on Article 12 notes that legal capacity acquires a particular significance for persons with disabilities when it comes to the exercise of their rights and making fundamental decisions regarding their health, education, and work (para 8). As noted above, as a legal concept, capacity may be understood as comprising two strands: legal standing to hold rights and to be recognised as a legal person before the law, and legal agency to act upon these rights and to have those actions recognised by law. Both strands must be recognised for the right to legal capacity to be fulfilled (CRPD Committee, para 14). Under Article 12 CRPD, where assistance is required in the exercise of legal capacity, States Parties must take measures to ensure that appropriate support is available, while safeguards must be in place to prevent the abuse of any such measures (Article 12(3) and (4)). Further, safeguards must ensure that any measures in relation to exercising legal capacity are proportionate and tailored to the individual's circumstances, and apply for the shortest time possible and are subject to review by an independent and impartial authority. They must also ensure that the rights, will, and preferences of the person are respected, and are free from conflicts of interest or undue influence. Notably, where the will and preferences of an individual cannot be determined "after significant efforts", supported decision-making must be in line with the "best interpretation of will and preferences" (CRPD Committee, para 20). Determinations of "best interests" are not considered compatible with Article 12 (para 20).

In spite of the CRPD being a global normative standard, the approach to legal capacity varies in regional contexts (such as in the ECHR [54]), and national laws differ greatly on this. Moreover, the implementation of Article 12 CRPD has been complex and contested. In the European Union (EU) in particular, national legislation on legal capacity is varied [55] (p. 9). Even though the CRPD was ratified by the EU alongside its Member States, in areas outside of EU competence, Member States have to implement the CRPD independently.

Article 12 is one such area outside of the scope of EU law and therefore competence remains with the Member States. Due to this complex division of competences, there has been no attempt at the EU level to harmonise the substantive or procedural rules as regards the protection of vulnerable adults [55] (p. 9). Primarily governed by the domestic laws of the EU Member States, the legal protections with respect to vulnerable adults may range from regimes with no alternative to full guardianship and denial of any legal capacity, to less restrictive regimes that recognise functional capacity complemented by assisted or supported decision-making [56]. A report by the Mental Disability Advocacy Centre notes that the traditional approach to mental disability in some European countries is institutionalisation, while plenary and partial guardianship under various regimes grant extensive powers of fully substituted decision-making [57]. The CRPD Committee expressed concerns in its observations on the implementation of the Convention that a number of EU State Parties, despite making efforts at reform, maintain forms of guardianship and substituted decision-making [24,58,59]. For example, the regimes in place in Bulgaria, Croatia, Hungary, and Romania allow for guardianship and full denial of legal capacity [60].

Such a fragmented legal context may prevent participation of individuals with disabilities, and it may be a significant hurdle for researchers seeking to align with the human rights model of disability. In fact, full denial of legal capacity denies an individual the ability to consent, thereby potentially preventing their participation in research. However, reforms across many Member States in recent decades demonstrate a move toward supported decision-making, with any loss of legal capacity only as a last resort [61] (p. 121). In this regard, many jurisdictions now provide for advance directives whereby individuals may make their will and preferences known in such a way that is legally binding in the event that they cannot communicate their wishes in the future. Indeed, the CRPD General Comment endorses advance planning for persons with disabilities on an equal basis with others (CRPD Committee, para 17). Although legal and ethical questions arise as to the degree to which the will and preferences, or advance directives, envisage an individual's participation, or on-going relationship, with a project, researchers need to be mindful of those when seeking involvement of older people with disabilities.

4.3. Procedural and Practical Challenges

Scholarship makes the distinction between vulnerable individuals whose decision-making abilities have diminished with old age or disease progression, and children as a group considered inherently vulnerable by virtue of immaturity and therefore not legally capable of giving informed consent [41,43]. In this respect, they recognise profound differences: older persons and people with neurodegenerative diseases have lived entire lives during which they have expressed their ideals and preferences. Therefore, it is important to respect that, in such cases, dependence on others is a loss [43] (p. 662). Without this recognition, trust and confidence may be undermined and provoke dissatisfaction among participants. Per Madden and Speed, "[p]articipation without redistribution of power is an empty and frustrating process" [51] (p. 4).

The recognition of the will and preferences in assisted decision-making reflects the provisions of the CRPD, but also recognises that, in some jurisdictions, individuals may make their wishes known in advance of the loss of capacity by way of an advance directive. Although not generally addressed in research norms, some suggest that the known wishes of vulnerable adults in such cases should be given greater consideration in determinations of capacity to consent [41]. Concerning the risk-benefit assessment that underpins research ethics, Dalpé et al. suggest that while older persons and those with degenerative health conditions are unlikely to directly benefit from their participation in research, they may receive personal benefits from the experience of involvement, such as sharing their stories, social activity, and the sense that they are making a valued contribution [41] (p. 4). This is supported by the findings of Littlechild et al. (2015) and Waite et al. (2019), as we have seen in Section 2 [46,47]. Furthermore, it must be recognised that vulnerability in adults is

not necessarily a permanent state, and that the capacity of a participant to make decisions may fluctuate, diminish, or be regained over the course of a research project [41] (p. 5).

With these considerations in mind, it is clear that informed consent with respect to persons with disabilities and older persons with disabilities is a complex and nuanced issue. Dalpé et al. note the practical challenges that arise from these considerations, particularly given the data-intensive nature of health research [41]. They note, for example, "broad consent", which arises when the exact use of the data or sample cannot be determined, the question of privacy in data sharing, the return of data to participants, and incidental findings. As noted above, it may be difficult to ascertain the precise extent to which an advance directive or estimation of will and preferences permit an individual's participation in research. In relation to data processing, the General Data Protection Regulation (GDPR) makes particular reference to the protection of the fundamental rights and freedoms of children as data subjects (Regulation 2016/679, article 6(1)(f)). Arguably, vulnerable adults should be considered similarly. On the other hand, it is observed that the data of under-represented groups is particularly valuable and that, by sharing, it reduces unnecessary repetition of research on vulnerable groups [41] (p. 8).

With respect to incidental findings and the return of data, the most prevalent approach in research ethics is that data should be communicated to the participant, in accordance with their preferences, where it is analytically valid, clinically significant, and actionable [62] (p. 556). While family members may in general be best placed to assist in decision-making and in determinations of will and preferences, where findings concern genetic data, this may be considered problematic. For example, findings pertaining to genetic data may potentially create a conflict of interest in light of its relevance to a biological relation who assists or represents the participant in their decision-making [41] (p. 9). Interestingly, Shepherd remarks on the lack of research in the area of assisting and proxy decision-makers in general, especially given evidence of the emotional and decisional burden they may experience [49] (p. 5). In this regard, she proposes that a formal process documenting an individual's preferences in relation to research participation would assist proxy decision-makers in best reflecting the wills and preferences of the participant, such as that provided by advance directives.

Separately, Tozzi and Cinelli warn of emerging ethical implications for vulnerable adults associated with the use of artificial intelligence (AI) solutions in research studies. In light of the recent acceleration of the application of digital tools and AI in clinical trials, the authors observe that specific ethical challenges arising from the use of the AI should be reflected in the informed consent process [63]. Such challenges relate to the difficulties in explaining the mechanisms used by AI algorithms and the reliability of technologies used. However, as has been pointed out, as new challenges emerge, guidelines must be adapted to prevent the exclusion of key individuals from the research process [64]. Individual precautions and measures to mitigate risk should be inserted into the informed consent process. A commitment to outlining any risks and uncertainties in the process may prevent the potential onset of challenges arising from the use of AI solutions [65]. Indeed, digital solutions may be utilised to enhance communication and knowledge transfer during the informed consent procedures [63]. As the SHAPES Project intends to build, pilot, and deploy a large-scale, EU-standardised open platform, significant time has been spent in assessing the ethical challenges relating to the integration of a broad range of technological, organisational, clinical, educational, and societal solutions.

5. How to Address Those Challenges? The Approach Enshrined in SHAPES

Having explored the challenges that arise in relation to informed consent when it comes to the participation of vulnerable adults in research projects, this concluding section examines how they have been addressed through the approach adopted within the SHAPES Project.

The participation and meaningful contribution of SHAPES Platform users is essential to the SHAPES ethos of inclusivity. In ensuring a person-centred approach throughout, it is

vital that the voices of older persons are heard in the research, development, and piloting of the SHAPES Innovations and Platform. Moreover, we recognise the importance of the contribution of the diversity of SHAPES Platform users, including vulnerable adults who are often excluded form research due to their presumed inability to give informed consent. Exclusion would limit the findings of the research and further marginalise those who could conceivably derive considerable benefit from it. In line with the provisions of Article 12 and Article 25 CRPD, SHAPES respects the inherent legal capacity of all persons to give their free consent to participation. Commenting on Article 3 CRPD (Equality of Opportunity), with a human rights–based and social model perspective, Browne and Dorris have recently affirmed that involvement in research should be "open, enabling, and inclusive" [66] (p. 4).

SHAPES secures consent from participants for several purposes, as part of its research and dissemination activities and end-users' engagement with the SHAPES Platform. Research for which consent is collected includes ethnography, focus groups, interviews, piloting the use of SHAPES technologies, questionnaires, and the analysis of data with artificial intelligence. With respect to dissemination activities, consent is sought where personal data is collected and processed, including email newsletters and photography.

The SHAPES Ethical Framework [67,68] sets out relevant ethical requirements for SHAPES endeavours:

- Providing the legal basis for consent: ensuring that there are sufficient capabilities for asking consent as part of the service and that the consent is documented properly (obligatory), and building up a repository where consents can be collected centrally (optional, contingent upon value to the SHAPES project).
- Providing a process for the implementation of services for single end-users (older persons) and for the assessment of the suitability of the services from time to time (including a process to assess the digital literacy of the end-user and adapt the services according to end-user needs and capabilities). The process should include more time to discuss choices or have an advocate regarding important appointments in order to make notes and help the person understand or remember choices.
- Providing a detailed process, taking into consideration national laws, to determine if the older person is able to decide on accessing the services and, secondly, if they are able to give informed consent and re-consent for the collection of the information.
- Providing understandable and plain-language materials, instructions, and information in visual form (including information on each service and how it operates and what data it collects) and providing video-based instructions for the end-user (older persons).

The SHAPES consent document, in addition to the physical consent form, also comprises an information sheet containing a clear statement of all aspects relevant to their decision of whether or not to participate. Participation Information Leaflets (PIL) contain information regarding the research which is provided in language that is understandable and accessible to the participant. PILs were developed with the input of accessibility experts from the World Federation of the Deafblind and the European Union of the Deaf, both of whom are accessibility-focused partners on the SHAPES Project. Furthermore, SHAPES includes AGE Platform Europe as part of the consortium which provides feedback where needed. Notably, AGE Platform Europe is a European network of non-profit organisations of and for older people and includes a range of national organisations representing people with Alzheimer's disease or degenerative diseases.

While PILs take into account specific national requirements and the nature of the pilot, and are laid out in the language of the country in which the pilot is conducted, the PILs address the following questions and issues:

1. An explanation of why the research is being conducted.
2. Who is organising and funding the research?
3. Why am I being asked to take part?
4. How will the research be conducted?
5. What will happen if I agree to take part?
6. What are the benefits/What are the risks?

7. Is the research confidential?
8. Information on data protection (specifically GDPR regulations).
9. Where can I get further information?
10. How do I withdraw consent?

Appropriate efforts are made to ensure understanding of the implications of the decision to participate, including the nature and consequences of this decision in the context of the available choices. All participants are given adequate time to consider the materials and to ask any relevant questions. Having done so, if the prospective participant is happy to proceed, the consent form can be signed. Importantly, the decision to decline participation will always be respected.

With participants across 10 EU Member States and the UK, the variance in approach to and recognition of legal capacity across the national jurisdictions is certainly a complicating factor in SHAPES. For the purposes of the SHAPES Ecosystem, it is necessary to establish, firstly, whether an individual needs support in making decisions pertaining to their informed participation in the SHAPES pilots. This is determined locally by the researchers. Secondly, it must be ascertained, with respect to an adult who may be considered as vulnerable, whether protective measures have been imposed under national laws, and the implications of any such protections on the legal recognition of their decisions.

The SHAPES pilots commit to upholding ethical research standards, including the European Code of Conduct for Research Integrity [69]. Each research partner is responsible for obtaining the free and informed consent of participants with respect to their research and/or piloting activities, as well as obtaining institutional ethical approval. It is recognised that supported decision-making may take a variety of different forms, including both formal and informal arrangements, regularly or on a one-off basis, whether provided by an individual or a broader support network [70] (p. 3). In the case of vulnerable participants, the SHAPES researchers estimate what intensity of support may be required and what measures are the most appropriate to assist them in expressing their wills and preferences. In respecting the inalienable legal capacity of all legal persons, and in upholding the second paragraph of article 12 of the CRPD, SHAPES does not establish thresholds to assess legal capacity (par. 25). Therefore, informed consent must be considered on an individual basis [71]. By adopting the human rights model of disability as a theoretical framework, the project asserts that persons with disabilities unable to provide written consent will be accommodated by other appropriate means.

Shaping the environment around the person may enable functioning and is consistent with the social model of disability. Per Arstein-Kerslake, it should be assumed that all participants have the potential to make decisions; however, tools should be available to assist in the exercise of decision-making skills and methods [70] (p. 3). In this regard, even where persons are deemed to have legal capacity under national laws, the SHAPES researchers make support available to participants for their decisions regarding consent and re-consent. If needed and requested by the person, the researcher may involve a support person in important appointments to make notes and to assist the person to understand or remember choices. Such persons may include caregivers, trustees, advocates, communications assistants, interpreters, or guides. Support persons have a role in providing relevant information about a potential or actual participant's will and preferences at various stages of research participation, from pre-participation to initiation, to ongoing participation, or withdrawal. Supporters have a role in supporting persons not only to understand and make decisions, but to remember their choices, to express and give voice to their opinions and decisions, and to action or implement their decisions. Alongside a supported decision-making process that supports the individual in the decision as to whether to participate in the research, SHAPES researchers have also adopted a range of accessibility measures as appropriate. Examples of the latter include using plain-language and easy-to-read materials, providing information in visual form, and allowing more time for discussion. Dynamic consent, which is the use of a personalised digital interface to facilitate ongoing, two-way communication regarding consent [72], has been referred to

and may be employed in SHAPES pilots. The SHAPES Platform itself will also include a method to withdraw consent and all personal data from the system.

Where a person is deemed not to have legal capacity under national laws, SHAPES researchers establish what requirements must be met to permit them to give consent in a manner that is legally recognised. While this must be fulfilled to ensure legal compliance, SHAPES researchers ensure that a supported decision-making process is de facto in place. This means that while regard is paid as to whether a trusteeship or guardianship is in place, SHAPES researchers ensure that the person is placed in a position so as to give fully informed consent through a supported decision-making process. Indeed, it is recognised that the involvement of a trustee or caregiver may be helpful in understanding what specific adaptations can be made to facilitate communication in a manner that is understandable to the participant, and which allows them to convey their wishes [41,70].

To secure full inclusion and to guarantee high ethical standards, the project has outlined the following guidelines for an appropriate consenting process. The purpose of designing these guidelines is twofold: firstly, the project ethics document acts as a harmonised guideline for each of the consortium partners; and secondly, it is hoped that the principles will act as general framework for future research projects. The following guidelines (illustrated in Figure 1) can be used to endorse a supported decision-making process centred around the person. In particular, these guidelines may help to ensure that those who are deemed not legally capable, under national law, of providing valid consent may still be involved and potentially benefit from the results of research projects.

5.1. Guidelines for Informed Consent Processes

5.1.1. Rights-Based Approach

SHAPES is built on the principles of respecting human dignity and the intrinsic value of all persons. To this end, SHAPES assumes that all persons have the potential to make decisions regarding consent and takes into consideration the ability of each individual to make decisions concerning their participation, in order to ensure full and cognisant participation of older persons with disabilities in the project. In the first instance, individuals are asked to provide written consent to participate in the project. In all cases, consent shall be presented in a manner clearly distinguishable from other matters and in an intelligible and easily accessible form, using clear and plain language. Regardless of whether a person is deemed to have legal capacity under national laws, additional decision-making support is offered—only when needed—to assist individuals in the exercise of their legal capacity in making a decision concerning their participation.

The SHAPES team must consider (1) whether the person needs support in order to make a decision related to the project activities, and (2) if their decision is legally valid under national law and what would be required under national law to facilitate decision-making or consent. Project partners, upon obtaining permission from their individual ethics governing bodies, should undertake either of the following two options.

5.1.2. Accessibility Measures

In circumstances where individuals require accessibility measures or specific reasonable accommodations to be put in place to make decisions regarding their consent to participate in the project, a variety of flexible options will be made available. Researchers can resort to various types of accessibility measures such as using plain-language materials, information in visual form, or specific reasonable accommodations tailored to the needs of the person, such as more time to discuss choices.

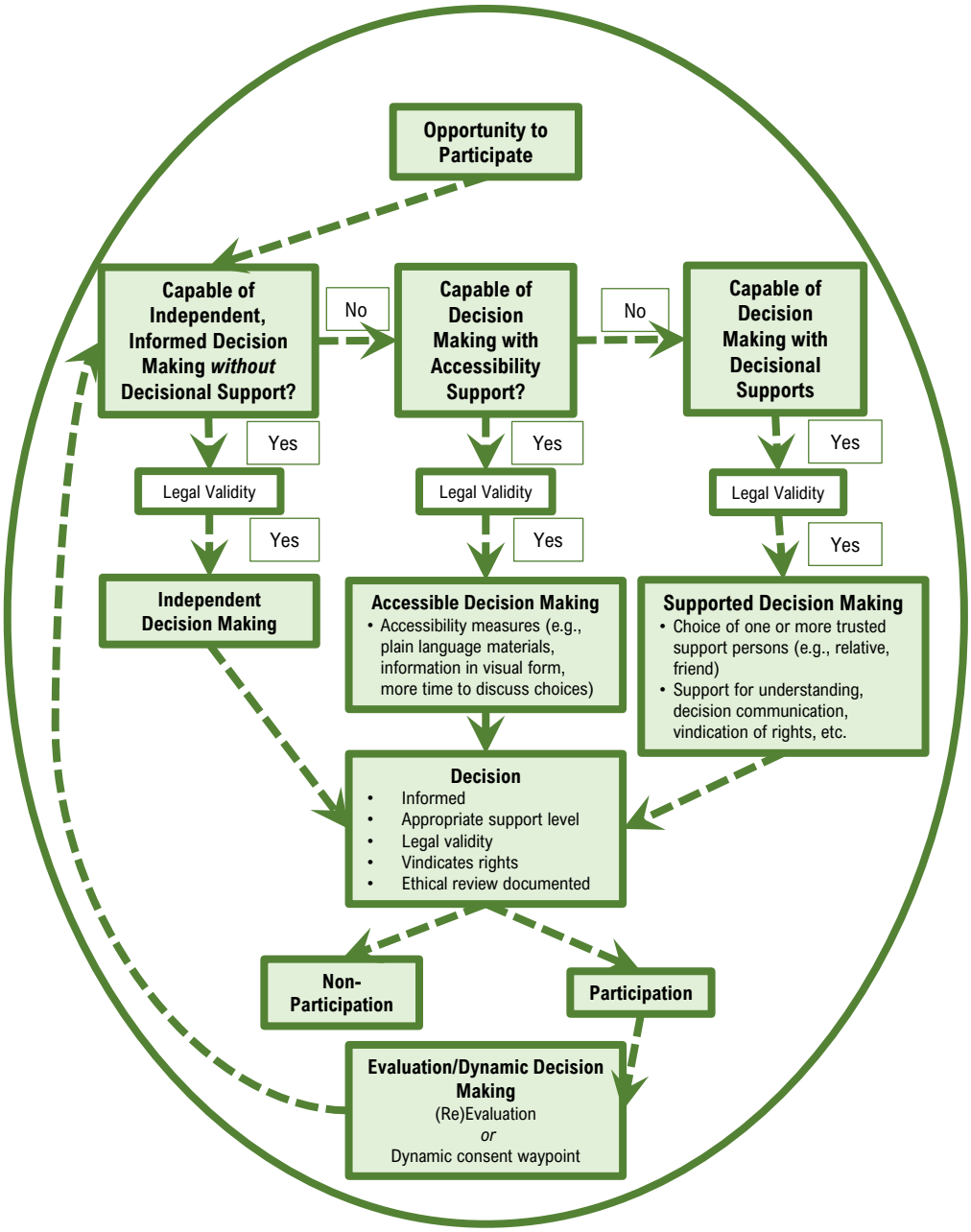

Figure 1. SHAPES human rights–based informed consent framework.

5.1.3. Allow for Decision-Making Supports

Separately, and if required, individuals should be afforded the opportunity to have another person explain the information provided by the project and to communicate the person's preference in relation to the decision. The individual requiring support may choose one or more trusted support persons to assist them in exercising their legal capacity. The involvement of a trustee or caregiver can be helpful in identifying concrete solutions and in explaining necessary information. Trustees or caregivers could make sure that information is provided in a way that is understandable to the person with a disability and could provide the researchers with relevant information about the will and preferences of the individual.

It will be necessary to ascertain whether the research participant is supported by a trustee or caregiver or if a guardianship regime is in place. If a research participant is not deemed legally capable under national law, it is important to verify what requirements

need to be respected in order for the consent to participate in the project to be valid under that national law.

Project partners must at all times be mindful that Article 12(4) CRPD requires that States Parties must ensure that all measures relating to the exercise of legal capacity provide for appropriate and effective safeguards to prevent abuse. In this context, it is important to note that all research carried out on individuals will first seek ethical approval from their local competent authorities (IRBs and/or Ethics Committees). In the event that participants with limited legal capacity under national laws are eligible to participate in SHAPES activities, provided ethics approval has been received, the consent process will also be reviewed by the SHAPES Ethical Advisory Board.

The methods and tools to be used will be chosen carefully by considering their capability to function, so that there will be no burden for, e.g., vulnerable participants, or any risk of stigmatisation. All direct costs for participants will be covered by the project.

5.1.4. Decision-Making as a Cyclical Process and (Re) Evaluation

Consent and decisions regarding consent are continuous, cyclical processes rather than terminal states. Whether decision-making occurs independently or with support, the right to evaluate or re-evaluate one's decisions, consent, or participation remains present. For such evaluation or reconsideration to adhere to a rights-based approach, it must again be assumed that participants have the capacity to decide, and researchers must again estimate and facilitate the appropriate level of support. A participant's decisional support requirements may fluctuate over time, either increasing or decreasing. This includes persons with neurodegenerative diseases, whose cognitive function may fluctuate in line with, for example, the course of disease, treatment, or rehabilitation. Additionally, some decisions relating to elements of research or the research as a whole may also have a higher or lower decisional burden, requiring more or less support. Evaluation of decisions may be facilitated with digitally enabled dynamic consent waypoints, but this is not necessary; research participants always have the right to change their mind or withdraw consent.

These guidelines require the project partners to reflect on traditional approaches to informed consent in order to encourage the full and cognisant participation of older persons with disabilities. It is hoped that this guidance tool will form the basis for future informed consent processes on funded research projects. By ensuring that appropriate safeguards are in place, SHAPES includes the participation of persons experiencing neurodegenerative diseases, who according to national law are considered to have diminished capacity or lack capacity to provide consent to participate in research activities. This novel framework utilised by the project is readily transferrable to other research projects, thus promoting an inclusive, ethical, and practical approach to the governance of informed consent.

Regarding limitations, our approach remains a discursive overview of our thought and experience to date in the design of the above procedure. The procedure has yet to be implemented in full in an empirical setting. However, in implementing a human rights–based framework for informed consent, we do not anticipate any specific risks to either research participants or research practices. On the contrary, we expect fuller, rights-based expressions of the wishes and preferences of participants.

6. Conclusions

In seeking to develop and deploy the SHAPES integrated care platform, essential to the project's ethos of inclusivity is the involvement of persons with disabilities. SHAPES adopts the human rights model of disability that recognises the equal rights of persons with disabilities, in line with the provisions of the CRPD. Moreover, per Article 12 CRPD, SHAPES not only respects the inalienable legal capacity of all persons, but also seeks to enable the exercise of such capacity.

However, in seeking to promote inclusion and participation of persons with neurodegenerative diseases such as Alzheimer's disease or dementia, certain challenges arise where such individuals experience difficulty or lack the capacity to make decisions unassisted.

Specifically, obtaining informed consent—and therefore working toward inclusion and participation more broadly—in the case of persons who are unable to provide such consent unassisted presented as an issue. This paper presented the main challenges to obtaining the consent of vulnerable adults where participation in research is concerned.

Careful consideration was given to these issues in developing the SHAPES approach, particularly in the case of those who are unable to express their decisional preferences or consent independently. We illustrated in Section 5 an informed consent framework and multi-step procedure to facilitate decision-making with respect to consent. In doing so, we have offered schema for independent and supported decision-making, and transitions between each of these, with clear opportunity for communicating decisional changes or withdrawal of consent (whether facilitated by technology or not). The SHAPES approach to informed consent reflects the input of the multidisciplinary expertise which contributes to implementing the project's commitment to respecting the inherent dignity of all members of the SHAPES Ecosystem of participants and platform users.

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