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1. Introduction

1.1 A little background

Informed consent is a process which allows prospective participants in a research activity to voluntarily decide whether to take part. Typically, prospective participants are provided with information about the research activity and what they will be required to do, and then asked to sign a form to indicate their consent to being involved. In the case of clinical trials, this process is well-established and mandated in law via the Clinical Trials Directive 2001/20/EC (which is due to be repealed in 2019 by the Clinical Trials Regulation 536/2014).

A common complaint is that informed consent forms can be lengthy, complex, and difficult to understand. The impression can easily be given that primary aim of the forms is to limit the legal liability of researchers and sponsors, rather than to protect the rights and interests of participants. Against the backdrop of these and other challenges, there is a need to improve the informed consent process to ensure that it protects and promotes the rights and interests of participants, and that it does not stand as a barrier to – and, if possible, even promotes – the participation in clinical trials of a wider, more representative range of people.

1.2 Introducing the i-Consent project

The i-Consent project starts from here.1 Recognising the challenges, the project aims to develop guidelines that researchers can follow when developing informed consent procedures. The guidelines will support them in ensuring that information is provided clearly, comprehensibly, with sensitivity to differences due to age, gender, cultural background, and other characteristics. The guidelines will also promote the use of technology and social media as, when, and if appropriate in the informed consent process.

This document presents some of the challenges that were identified in the first work package of the i-Consent project. The work package, titled “A multi-layered approach to informed consent”, aimed at identifying: ethical and legal issues concerning informed consent; socio-cultural, psychological and behavioural perspectives on informed consent; gender and age-related issues concerning informed consent; and perspectives from patient groups. The full reports generated in Work Package 1 as deliverables can be found on the project’s website.

1.3 Characterising the informed consent process

It is generally agreed that informed consent is a process whose effectiveness is a factor of a few core criteria. These criteria are typically held to include concepts such as disclosure, understanding, capacity, and voluntariness.2 Though guidelines differ somewhat in details or emphasis (for example the Belmont Report focuses on information, comprehension, and

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1 i-Consent (full title: “Improving the guidelines for Informed Consent, including vulnerable populations, under a gender perspective”) began in May 2017 and will finish in April 2020. See: https://i-consentproject.eu/. This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 741856.

voluntariness), they share a common thought: that through the informed consent process all relevant information about the study should be disclosed to the prospective participant; that the participant should adequately understand the information; and that the participant should have the capacity not only to comprehend the information, but also to knowingly and voluntarily agree to take part in the study, under the conditions disclosed to them.

When we say that informed consent is a process, we mean that it is not a one-off event which “finishes” with the signing of a form; but rather that it is an ongoing engagement between the researcher and the participant, in which the participant’s consent is always a live concern to which both participant and researcher are attentive. What form should that attention take?

At least this: that the participant is aware of their right to withdraw their consent at any time for any (or no) reason; and that the researcher keeps the participant fully informed and up-to-date about any changes in or around the research that might influence the participant’s desire to continue in the study.

Informed consent, though a key tool for ensuring respect for the rights of participants in clinical trials, faces a number of challenges which, if unaddressed, threaten to undermine the value of the process and integrity of the research. In i-Consent Work Package 1 we undertook to identify these challenges, as a preliminary step towards the development of our guidelines.

To help better conceptualise the challenges, one may categorise them in various ways. In Deliverable 1.4 (Ethical issues concerning informed consent in translational/clinical research and vaccination) for instance, challenges were characterised as falling into one of two tracks: patient-centred challenges; and process-centred challenges. In this paper, we adopt a similar approach, focusing on:

1. issues deriving from differences in participants’ backgrounds or statuses which pose challenges to the traditional informed consent process;
2. issues arising from the nature of the traditional informed consent process which challenge its capacity to protect participants’ rights and interests.

Challenges to the informed consent process can also be thought of as deriving from different aspects of the nature of informed consent, as a concept and as a process. It is worthwhile, therefore, to briefly discuss that nature.

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1.4 Foundations of informed consent: autonomy and others

Consent, as a concept in general, but particularly in the context of informed consent, is held to have an “inherent morally transformative” power.\(^4\) i-Consent deliverable D1.1 argues that this morally transformative power is not in fact inherent to consent itself but derives from whatever it is that gives consent its ethical basis. Majority opinion has it that consent’s ethical basis is autonomy. That is, the moral imperative to ensure that participants give informed consent to their participation in clinical research derives from the moral imperative to respect people’s autonomy – their right to self-determination.

Autonomy is certainly a key ethical basis of consent. However, a couple of important points should be noted. First, there is no real consensus as to the precise definition or nature of autonomy. Second, it has been argued that there is more to informed consent than just respect for individual autonomy. This view is, in part, motivated by the widely shared observation that the consent relation is inherently communicative and that, therefore, “it takes place against an already present normative backdrop”.\(^5\) It follows from this that there are “a variety of ways in which a consent transaction can fail: any of a number of ethical or epistemic norms can be violated.”\(^6\) If this is correct, then informed consent processes might fail in ways that are only indirectly connected to autonomy.

1.5 The communicative nature of the informed consent process

Building on the idea of informed consent as an inherently communicative process, Manson & O’Neill (2007) identify four key points about the nature of communication and the process of delivering information (informing)\(^7\): that informing is context-dependent; that it is norm-dependent; that it matters how you say something (since what is communicated often goes beyond what is literally said); and that, relatedly, informing is inferentially fertile (i.e. what can be inferred from a statement goes well beyond what is literally said). Awareness of these four points must inform thinking about how best to disclose information to prospective participants.

\(^6\) Ibid. [p. 29]
\(^7\) Ibid. [pp 41-47]
2. Challenges of diversity of backgrounds and statuses

2.1 Respecting diversity of values and backgrounds

Informed consent forms typically do not distinguish for specific characteristics of the prospective participants, for example their age or gender. Moreover and in general, there is a lack of clearly established standards – be they ethical or legal – for determining how specific characteristics of prospective participants should influence the interpretation of the core criteria of informed consent. What bearing, for instance, should age, gender, socio-cultural background (and so on) have on decisions about what information should be disclosed, and how it should be presented? Do such factors require researchers to adopt different practices to assess a prospective participant’s comprehension of the information presented? How can the capacity to consent be accurately judged, for example in cases of minors or adults of reduced mental capacity? On the other hand, one might wonder, should there simply be some set of baseline standards from which we never deviate, regardless of the circumstances or status of the prospective participants?

An important question, therefore, is whether there should be different informed consent procedures for different groups, or, similarly, whether there should be room for variation in certain aspects of the process for different groups. This issue requires careful thought. On the face of it, it would seem, as a matter of fairness, that everybody should get the same information (at least on the paperwork). However, research reviewed in i-Consent Work Package 1 suggests that some groups do benefit from receiving different information – or at least from receiving the same information presented in quite different ways. Children, for instance, may be unable to comprehend information that is readily comprehensible to adults, and therefore benefit from more accessible information delivered via different media. The manner of presentation of information should be allowed to vary, suited to different participants.

This raises many difficult questions about how to decide which participants get which paperwork or undergo which informed consent processes. In Work Package 1 much of the research focused on the challenges of assessing and addressing the needs of minors involved in clinical research, the measures that can be taken to promote the involvement of women in clinical research, and on the recruitment of participants from minority cultural backgrounds. The next sections discuss some of the issues identified.

2.2 Involvement of minors

There is certainly a need to adjust the way in which information is presented to suit the intended audience. Minors especially will need a dedicated approach. However, it is equally important to remember that even within groups there can be significant variation. Information should be tailored to individuals as much as possible. To be a minor is to have a certain legal status: it says nothing of one’s maturity. A typical 16-year-old, for example, has a very different level or maturity and mental, emotional, and psychological development to a typical 12-, 8-, or 4-year-old.
The involvement of minors in clinical trials has been a contested issue. Some studies have suggested that minors should only be included in clinical trials when it would be impossible to include adults instead—a view which seems rooted in the idea that minors are vulnerable and require protection. However, recent opinions from the Nuffield Council on Bioethics have taken a slightly different tone. They challenge the conception of children as a vulnerable group: clinical trials should be carried out with children, not on them; they suggest that we focus on the benefits to children of participation, for instance in promoting progress into the study of conditions specific to children. This ties in with an important methodological point: it is important to include participants from all backgrounds not only as a matter of inclusivity, but as a matter of sound scientific method.

When children are included in a clinical trial, it is essential that there be a favourable ratio of benefits to risks, that the children give their assent (assuming they are of an age and maturity to so do), and that their objections to participating (if they have them) are wholly respected. Parental authority of course emerges as an issue. In a clinical—as opposed to therapeutic—setting, parental authority should not override the objections of a child who does not wish to participate. This injunction is clearly reflected in the evolution from the Clinical Trials Directive (2001/20/EC) to the Clinical Trials Regulation (536/2014), due to come into effect in 2019. The Regulation insists that children’s objections be “respected”, as opposed to merely “considered” (as in the Directive).

Naturally, the ideal is that the parent(s) permit(s) the child’s participation and that the child gives their assent. But of course, further difficulties are easily imagined. For instance, what to do when parents disagree as to permission? And what are the most effective ways of judging whether a child gives, or is genuinely capable of giving, their assent? Guidelines do not give a single answer as to the age at which a child can provide valid assent, and insofar as the issue is addressed in law, it varies across Member States.

2.3 A gender perspective

Despite a growing weight of suggestions that the role of gender should be more closely considered when preparing informed consent processes, coverage of gender issues is somewhat lacking in existing guidelines and other soft law resources—and there is no coverage at all of gender issues specific to informed consent in clinical trials in hard law.

i-Consent researchers (especially in deliverable D1.3: Ethical and legal review of gender and age-related issues associated with the acquisition of informed consent) found that while soft law resources often recommend and promote women’s participation in clinical trials—as participants, as researchers, as representatives of patient associations, and as members of ethics committees—specific strategies to achieve this are not provided. Such coverage, as is found, tends to focus on woman-specific situations or conditions, such as those concerning pregnancy, breastfeeding, and diseases specific to or with higher instances among women.

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Issues that arise in discussions of gender and informed consent often focus on (potential) clashes of rights and interests, for instance between those of a mother and unborn child or foetus, or between a pregnant woman and the father of the unborn child or foetus. There is some variation among ethical assessments concerning the status of the foetus; there is also some variation among ethical assessments concerning the rights of fathers of unborn children. But there is nonetheless consensus that while in some contexts it is advisable for a pregnant woman to consult the father, in no cases is it permissible for the father’s consent to replace that of the woman herself.

2.4 Diversity of cultural backgrounds

Variations in the way that participants assess the informed consent process are to be expected when we consider the diversity of cultural backgrounds. Many cultures approach the concept of autonomy differently to the most commonly approaches in European Union Member States (which is not to discount diversity of opinion within and between Member States). In some so-called “non-Western” cultures, community leaders and/or family members can have a significant influence in determining whether a participant takes part in biomedical research. This is just one indication of the ways in which it can be challenging for researchers to identify culturally appropriate and respectful means to request informed consent. What works in one cultural setting cannot be uncritically assumed to work in another.

If the informed consent process is largely based, from an ethical perspective, on the concept of respect for individual autonomy, how then should we adapt it to better cater to people of these kinds of cultures? The CIOMS Guidelines provide recommendations for cross-cultural cases. They recommend that local “institutional procedures or cultural customs should be respected” when, for example, identifying or approaching prospective participants. However, the guidelines emphasise that permission granted by anyone other than the participants themselves – be they community leaders, a council of elders, or anyone else – may “in no case […] substitute for individual informed consent”.

Further difficulties abound. How, for example, should we identify or delimit cultural groups, especially when they are subgroups of wider communities or societies which broadly adopt the attitudes to autonomy that underwrite the traditional informed consent process? And how should we address these groups? If a different approach is adopted on cultural grounds, how

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11 Ibid.
does that sit with broader societal questions of inclusion and integration? Might it increase feelings of being an “outsider” for members of such communities? And how should we know whether a given individual is a member of such a group? Maybe they are members of many different groups with many different attitudes towards autonomy (the medical profession, researchers, and so on). This mightily difficult area was addressed in i-Consent deliverable D1.7, which discusses socio-cultural, psychological, and behavioural aspects of the informed consent process.

The need to translate informed consent forms and other paperwork into participants’ languages is commonly cited as a problematic area. Effective translation requires cultural competence and thus it should not be assumed that a simple word-for-word translation will suffice. As mentioned above, the process of delivering information is context-dependent, norm-dependent, and it really matters how you say something. Translations that are not sensitive to background cultural contexts and norms are liable to misfire.

The inclusion in clinical research of people of all ages, genders, and backgrounds is extremely important. In order to successfully address the challenges to informed consent posed by promoting such inclusion, it is important to strive, as far as possible, to adopt individualised approaches, i.e. to focus on the particular circumstances and characteristics of individual prospective participants, rather than adopting standardised approaches or group-based approaches. Nobody is vulnerable tout court and everyone’s identity is multi-faceted. Respecting people for who they are – respecting their dignity and autonomy – involves a step away from blanket categorisations, however nuanced, and towards a more personalised approach. This is perhaps a council of perfection, but much of our research in Work Package 1 suggests this line of thought.

2.5 Vulnerability

All guidelines advert to the need to identify and respond to vulnerability in prospective research participants. CIOMS Guideline 15, for example, states that:

“When vulnerable individuals and groups are considered for recruitment in research, researchers and research ethics committees must ensure that specific protections are in place to safeguard the rights and welfare of these individuals and groups in the conduct of the research.”

The Declaration of Helsinki (WMA, 2013), specifies that groups or individuals are considered vulnerable when they “have an increased likelihood of being wronged or of incurring additional harm”\(^\text{12}\); the Commentary on CIOMS Guideline 15 states that “persons are vulnerable because they are relatively (or absolutely) incapable of protecting their own interests”.

The question of vulnerability is a difficult one. People’s identities and circumstances are always multifaceted. As we have said, nobody is vulnerable tout court. On the contrary, any person can reveal vulnerabilities based on contextual parameters, situational factors and

variables associated with procedural aspects of the research study. The National Bioethics Advisory Commission (NBAC) writes that “vulnerability is sensitive to context and individuals may be vulnerable in one situation but not in another.”¹³ The CIOMS Guidelines concur (Commentary on Guideline 15), noting that it is important to “avoid considering members of entire classes of individuals as vulnerable”¹⁴.

Characteristics that may lead to vulnerability in some respect include (these are all taken from CIOMS Commentary on Guideline 15):

- **limited capacity to consent** (e.g. children, adults unable to consent, e.g. dementia sufferers);
- **individuals in hierarchical relationships** (e.g. students, members of armed forces);
- **institutionalised persons** (e.g. people in nursing homes, prisons);
- **women** – women are not vulnerable in general, but in certain circumstances they may be relatively vulnerable (e.g. studies about sexual violence, with asylum seekers, studies of abortion in jurisdictions in which it is illegal);
- **many other characteristics and factors, depending on circumstances**, including: “people receiving welfare; benefits or social assistance and other poor people and the unemployed; people who perceive participation as the only means of accessing medical care; some ethnic and racial minorities; homeless persons, nomads, refugees or displaced persons; people living with disabilities; people with incurable or stigmatized conditions or diseases; people faced with physical frailty, for example because of age and co-morbidities, individuals who are politically powerless; and members of communities unfamiliar with modern medical concepts. Furthermore, in some contexts vulnerability might be related to gender, sexuality and age”.

It is important that researchers are alert to these kinds of factors, but also that they do not exclude individuals based on assumptions about vulnerabilities due to membership of a group or community.

2.6 Bias, optimism, and therapeutic misconception

Research in i-Consent deliverable D1.4 suggests that, in addressing the challenges to informed consent, it is important to be aware of the role that biases – whether from psychological or cultural origins – play in influencing both participants and researchers. One manifestation of this can be bias in selection of participants by researchers who unintentionally favour prospective participants they find it easier to communicate with (e.g. those from similar cultural backgrounds) and whom they perceive as less likely to object to taking part.

Here we see a tension between, on the one hand, the importance of fostering trusting relationships between researchers and participants and, on the other hand, the importance


of including less-well represented groups (e.g. from minority backgrounds) in studies. Groups that are less-well represented are, to a relatively greater extent, those more likely to be adversely affected by the abovementioned bias. There is potential here for a downward spiral: the researcher aims to build trusting relationships with participants and so is drawn, by unintentional biases, to prospective participants with whom they already have a basis of trust and communication, leading to the further exclusion of those with whom the researcher has relatively more difficulties in establishing a trusting relationship. That this can all happen unintentionally, at an individual level, suggests that building trust between researchers and prospective participants is a challenge that is in some ways better addressed on a societal level. But that being said, individual researchers need to be realistic and show self-awareness about their own cultural background, the cultural background in the place where they work, and their understanding of the cultural background of the different prospective participants they interact with.

One way of reducing these risks is to ensure the involvement of researchers from diverse backgrounds. In this way, the scope of the communities that are “easy to communicate with” could be widened. It should not be imagined, however, that this is a silver bullet. The barriers to optimal communication are not solely due to cultural background, at least not in any simplistic sense.

A further form of bias is optimism bias. This, as with other forms of bias, can manifest in various ways affecting both participants and researchers. As regards researchers, they may have a tendency to overemphasise the positive aspects (potential benefits, for example) of the proposed study; while participants may be subject to therapeutic misconception. Therapeutic misconception – the false supposition by a participant that their involvement in a trial is likely to have a positive therapeutic benefit – is a key concern that came up throughout all the research in Work Package 1, including the consultations with patient groups (carried out within the scope of i-Consent task 1.6).

Research in Work Package 1 also suggested that it may be effective to promote interaction between prospective participants and people who are already enrolled in the trial, or who have experience of other trials. This may be effective in introducing a greater sense of realism, limiting expectations, and minimising therapeutic misconceptions.

When the risk of biases is revealed it can and should be consciously addressed. It is important to be aware of the stressors that can trigger biases. Chief among these, perhaps, is information overload, which, as we have seen, is a significant risk in the informed consent process, as the attempt to ensure maximum transparency and openness about the nature of a study leads to a lengthier and more complex paperwork. When presented with volumes of information, the natural reaction is to revert to the heuristics that one has developed to cope with such overloads. But these heuristics are liable to harbour inbuilt biases of the kind mentioned. Thus the trouble with lengthy and complex informed consent forms is not only that they are difficult to understand, it is also that the most natural ways of attempting to understand them are likely to introduce or embed biases in participants’ decision making processes.
2.7 Ensuring and assessing comprehension

Recognising that participants have a right to be fully informed about the research in which they might participate, researchers have sought to be as transparent and open as possible when preparing informed consent forms and information sheets. This has tended to add significantly to length and complexity of the paperwork and, in turn, has had a negative effect on comprehension.

According to the Belmont Report, the concept of a “reasonable volunteer” should be taken as standard when assessing the comprehensibility of informed consent paperwork. But this is not necessarily feasible in all cases, and possibly not even optimal. The patient groups consulted in Work Package 1 indicated a concern that information should be presented in ways that are accessible, clear, and tailored to different groups. However, they also acknowledged that there is a risk inherent in generalising about groups (for example on the basis of gender or on assumptions about what is “reasonable”), and instead favoured a more individualised approach.

Several barriers to comprehension should be considered. These include:

- level of education;
- presentation of content;
- nature of information;
- age;
- literacy skills;
- cultural differences in attitudes to and understanding of risk.

How best to adapt informed consent forms in response to these barriers is likely to vary from case to case, possibly from individual to individual. It is consequently extremely important to find a way of accurately evaluating participants' level of comprehension.

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3. Challenges of procedural protections of rights and interests

3.1 Reimbursement

The issue of reimbursement is a difficult one, which comes up often in discussions of informed consent (including in the consultations with patient groups carried out i-Consent Work Package 1). There is consensus that participation should not be paid, but that reimbursement of expenses is acceptable.

In some cases, it should be considered whether even a small reimbursement might constitute a form of undue inducement to participate. This could be the case for children, for example. The issue of reimbursement ties in with issues of vulnerability with respect to socio-economic status.

3.2 Privacy, confidentiality, and incidental findings

Confidentiality is an important factor for any participant in any clinical trial. The protection of participants’ personal data is paramount. This is particularly so given the sensitive nature of health-related personal data, and the special provisions for such “special categories” of personal data in the EU General Data Protection Regulation (2016/679). Confidentiality can be especially important with relation to vulnerable people. With respect to minors, there is often a possibility for a clash of rights and interests, say between the child’s right to privacy and their parents’ understandable interest in the health of their child.

A further important issue concerns incidental findings. Where these have an impact on a participant’s health, they should be informed. But again, the issue intersects with others, for instance the rights of other people who may be directly or indirectly affected.

Confidentiality and data protection are not only live issues during a trial. The use of previously collected personal data or biological samples can often be scientifically valuable. Research in Work Package 1 showed that such uses can be approved by a research ethics committee (REC) or institutional review board (IRB), even in the absence of the data subject’s consent, after a process of assessing the risks and benefits.

3.3 Communication of Risk

One of the key factors in the success of an informed consent process is the effectiveness with which the researchers can communicate the risks of participation to the participants. This kind of communication involves effectively addressing several aspects, including:

- communication of potential harms and risks;
- communication of uncertainty as to the likelihood and severity of risks involved;
• communication of uncertainty as to the outcomes of the research;
• stressing the importance of two-way communication, i.e. of active participation in the informed consent process by the prospective participant.

One of the main findings to come out of the focus group consultations with patient groups in Work Package 1 was that there is a need to find ways of properly motivating participation in clinical trials. There should be an emphasis on the positive reasons for participation and not only on the ways in which the potential risks will be mitigated or removed. These findings revealed the importance of trust and effective communication. Risks must be communicated in a way that does not make it seem like the goal is just to limit the sponsor’s legal liability.

The importance of effective risk communication is multiplied in the case of translational research, where the connection between scientific research and therapy or treatment may not be clear, and where changes in the research (e.g. acceleration of the process) are more likely.
4. Tools, techniques, technologies

4.1 Technologies, techniques, and methodologies

How might technology assist in ensuring that prospective participants in clinical trials are appropriately informed about the nature of their participation? While it seems obvious that certain innovations and digital technologies would be helpful, overall the reviews conducted in i-Consent Work Package 1 suggest that the evidence is mixed. Some groups, evidence suggests, do benefit from use of IT tools in the informed consent process. These groups include people from minority background and children.17 In i-Consent, researchers in Work Package 2 (Innovation in informed consent) are currently investigating the possibilities.

The consultations with patient groups carried out in Work Package 1 indicated that simple presentational innovations are effective, such as the use of short summaries, flow-charts, or other visual aids. The UK Health Research Authority, for instance, recommends the use of a layered informed consent form to enhance comprehension (i.e. where key information is briefly presented first, and more detailed information later, at a "lower layer"). Other research showed success for methodologies such as cognitive interviewing techniques and teach-back and teach-to-goal techniques as means of assessing comprehension in prospective participants.

4.2 Dynamic consent

Several studies in Work Package 1 showed that dynamic consent provides a powerful tool to assist in the informed consent process.18 This allows participants to update their consent preferences in real time as research progresses or as their personal data or biological samples are requested for use in additional trials.

The virtues of dynamic consent come to the fore when we consider that, in some cases, understanding of the research undertaken in a clinical trial – or particularly in translational research – can evolve as the research progresses. Researchers in i-Consent task 1.4 identified four cases in which participants should be informed of changes and may wish to adjust their consent status:

1) When there emerges any information that would influence the decision or opinion of the research ethics committee (REC) or institutional review board (IRB). In most cases where it would be necessary to inform the REC or IRB of a change, it would also be necessary to inform the participants.


2) When there emerges any information suggesting a decrease in the likelihood of benefits accruing from the research, or when the value of the likely benefits accruing from the research is likely to be less than previously indicated.

3) When there emerges any information suggesting an increase in the risks involved in participation (in terms of likelihood or severity).

4) When any changes to the research methodology are to be implemented.

The principle underlying dynamic consent – that participants can have an ongoing, active relationship with their data and their consent preferences – is one which offers several advantages, and which would appear to be increasingly feasible and simple to implement with digital technologies.
5. Conclusion

This summary document shows that there are many challenges to the traditional informed consent process. Can we identify any common theme among them?

Arguably we can. In the majority of cases, in order to properly ensure respect for a participant’s fundamental rights and interests, it is necessary to treat them as a unique individual, with a specific background and set of characteristics which make for an idiosyncratic array of vulnerabilities. Group level approaches are useful in devising strategies for handling common kinds of challenges (e.g. how to judge when a person is capable of providing consent, or when a person requires some special protections). But the application of any kind of strategy should not be based on group-level generalisations and assumptions about individuals.

The use of digital technologies in the informed consent process seems to hold a lot of promise, even if the evidence of its effectiveness is currently somewhat mixed. The potential uses of these technologies is currently being researched in i-Consent Work Package 2.