ETHICAL CONSIDERATIONS IN OBTAINING INFORMED CONSENT FOR RESEARCH PARTICIPATION: A REVIEW

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Abstract. Informed consent is widely regarded as a foundational ethical requirement in research involving human participants; however, contemporary research practices increasingly expose the limitations of viewing consent as a static, procedural obligation. This paper critically examines informed consent as a dynamic, relational, and context-dependent ethical process shaped by power relations, institutional governance, and participant vulnerability. Drawing on international ethical frameworks and regulatory standards, the analysis demonstrates that meaningful consent extends beyond disclosure and documentation to encompass comprehension, voluntariness, and sustained participant engagement across all research phases. Particular attention is given to systemic challenges, including excessively complex consent materials, unequal researcher–participant relationships, culturally and linguistically mediated misunderstandings, and the ethical tensions surrounding incentives and compensation. The paper further interrogates consent practices involving vulnerable populations, such as children, individuals with diminished capacity, pregnant persons, prisoners, and marginalized communities, arguing that heightened protections must not devolve into paternalistic exclusion from research participation. Emerging issues surrounding broad consent, secondary data use, biobanking, and digital data infrastructures reveal how traditional consent models struggle to accommodate evolving research ecosystems. This analysis advances the argument that ethical informed consent requires a shift from compliance-driven formalism toward reflexive, participant-centred ethical practice. By reconceptualising consent as an ongoing moral negotiation rather than a one-time legal safeguard, the paper underscores the necessity of integrating ethical reflexivity, cultural sensitivity, and accountability into research design and governance. Ultimately, strengthening informed consent practices is essential not only for protecting participant autonomy and dignity, but also for sustaining public trust and the epistemic legitimacy of human subjects research.

Keywords: *informed consent, research ethics, participant autonomy, vulnerability, ethical governance*

Introduction

Obtaining informed consent from research participants is not simply a bureaucratic formality; it is a critical ethical requirement for conducting research with human participants. Because participation in research exposes individuals to a variety of foreseeable risks that are associated with the research, it is vital that prospective participants be permitted to make sufficiently informed evaluations of whether or not to take on those risks. Prospective participants can only undertake this thoughtful evaluation if they are informed about the nature of the research, the risks and anticipated benefits of participation, the limits of privacy and confidentiality protection, and any alternative procedures that may be advantageous to them.

The ethical foundations of informed consent are well established: respect for persons and protection from harm underlie the expectation that researchers will furnish critical information that facilitates the voluntary decision to participate in, or not to participate

in, research. Informed consent should therefore be viewed as an ongoing process rather than a one-time event. Individuals who agree to participate in research retain the right to withdraw from participation at any stage in the process, and researchers must remain continually attentive to maintaining open and honest communication with participants throughout the research. For research that involves prospective review of samples collected prior to participant enrollment into a study or that, in fields such as the social sciences, ensures that all identifying information is permanently stripped prior to analysis so that no de-identified information can be traced back to individuals, some researchers advocate the use of generic information sheets that provide basic information about the research study and indicate that any data provided is treated according to these stringent privacy and confidentiality safeguards (Cini, 2018).

Results and Discussion

Foundations of informed consent

In the pursuit of ethical research and a commitment to balancing societal benefit with respect for individuals and communities, the requirement for informed consent plays a central role. Several widely accepted documents and regulatory frameworks offer legal foundations for the requirement: the Nuremberg Code, the Declaration of Helsinki, the Belmont Report, U.S. federal regulations at 45 CFR 46 and 21 CFR 56, and the Canadian Tri-Council Policy Statement (Xu et al., 2020; Cini, 2018). The overall principle is uniform: respect for persons includes the obligation to provide information and ensure comprehension. Thus, before participating in research, individuals must receive, reflect on, and understand sufficient information to ensure decisions align with their beliefs and values. Such consideration extends to those who might influence a decision, such as community representatives when consent from the larger group is relevant.

An ethical foundation for informed consent emerges from respect for autonomy, nonmaleficence, beneficence, and justice. Respect for autonomy supports the right to self-determination, and people can consider the core ethical principles as they make decisions about participation. Nonmaleficence prohibits causing harm, whether physical, psychological, social, or economic; researchers must strive to maximize benefits while minimizing risk. This involves careful consideration of all foreseeable detriments and the level of exposure acceptable to potential participants. Beneficence mandates efforts to ensure benefits of participation outweigh burdens. Justice concerns the equitable distribution of risk and benefit.

Legal and regulatory foundations

Obtaining informed consent is a fundamental ethical and regulatory requirement for research involving human subjects (Cini, 2018). Ethical guidelines generally define informed consent as a universal prerequisite for ethical scientific research that involves human participants. Researchers must be aware of all regulations and guidelines pertinent to research involving human subjects. In many jurisdictions, regulatory requirements define human subjects and provide limited discretion for researchers. When a research activity meets the relevant regulatory definition of human subjects research, the legal requirements that govern the conduct of that research become critical.

This section reviews the legal and regulatory foundations framing human subjects research and the provision of informed consent.

Core ethical principles

The principles of respect for persons, beneficence, and justice, outlined in the Belmont Report (Cini, 2018) , highlight ethical obligations intrinsic to the conduct of research with human participants. Respect for persons incorporates recognition of personal autonomy and protection of those who cannot make informed decisions. Upholding this principle necessitates obtaining voluntary and informed consent prior to research participation, throughout the entire duration of the study. Participants grant permission for their engagement based on the understanding that their decision rests not on coercion or undue influence, but on their assessment of the potential risks, benefits, and drawbacks emerging from the study (Xu et al., 2020). In protecting individuals with diminished capacity to provide fully informed consent, such as children, individuals with impairment, and other vulnerable populations, regulations permit researchers to consider the interests of potential participants. Nevertheless, whenever possible, procedures should accommodate informed consent aligned with participants' individual beliefs, values, and preferences. Beneficence obliges researchers to maximise potential benefits and minimise risks. Informed consent, as a prerequisite for initiating research involving human participants, operates as an essential safeguard for both beneficence and a participant's ability to withdraw from a study at any time. Finally, the principle of justice pertains to the equitable selection of individuals for research. The National Statement, for instance, advocates an equitable selection process for biobanking within the Australian Red Cross Blood Service; it encourages ethical consideration of the social situation, broader health system, or the uncertainties of untested substances and techniques concerning transfusion.

Information disclosure and comprehension

Participants' comprehension of the research being undertaken is critical for enabling informed consent. Ensuring that participants comprehend the research allows them to attend to both elements of informed consent—information disclosure and voluntariness (Kadam, 2017). Regulations regarding informed consent specify the initiating information to be provided to potential participants prior to consent, the nature of explanatory information, and the continuing obligation to provide further information and seek additional consent throughout the research process when unexplained risks emerge, or unexpected events occur (Cifelli, 2008). The expectations concerning what must be included in the consent process can lead to the generation of lengthy and often poorly comprehended consent forms that may undermine verification of the true informed nature of the proposed agreement. Many mainstream consent forms are drafted in complex sentences reflecting high reading levels, often at least one standard deviation above readily grasped levels for the intended audience, which, together with extensive pages of content, ill-adapts even the best-designed consent materials to the needs of the likely readership, risking the consensus behalf of all parties that participants truly grasp the study to which they are agreeing (Isles, 2013).

Appropriate content of information

Informed consent is an ethical prerequisite for human participant research, requiring that prospective participants voluntarily decide whether or not to participate (Orzechowski et al., 2021). Regulatory bodies expect researchers to disclose sufficient information for prospective participants to understand the nature, purpose, and risks of the study before deciding to continue. The specific information necessary or appropriate for participants' understanding has been widely debated, and regulations and guidelines differ between countries. The potential harms, risks, benefits, and discomforts involved constitute the most significant research information to disclose; comprehension of the possible adverse consequences allows participants to gauge whether or not to take part. Researchers also need to describe the methods that will be used if the study includes a data collection process such as answering questionnaires, undergoing tests or interviews, or providing biological materials. When habits, behaviors, or attitudes are being investigated, openness about the questions posed can help participants assess the implications of participation. Because research often relates to personal, sensitive, or even stigmatized topics, prospective participants might hesitate to participate if they only discern through indirect reasoning what the study truly involves.

Assessing participant understanding

Understanding clearly the implications of research participation is essential to maintaining respect for persons and protecting the autonomy of participants. Ethical guidelines that seek to promote informed consent typically invoke as a moral imperative the need to ensure comprehension by research participants; however, the guidelines seldom define what constitutes adequate participant understanding. Researchers with first-hand experience of the informed-consent process may themselves doubt that true understanding is attainable when research prospects and goals are still unknown. Dissatisfaction exists with the places designated in current frameworks for participant understanding of information, leading to the view that it ought, in fact, to be a central focus (Walker et al., 2018). Extensive research suggests that simply conveying information does not ensure comprehension. The findings from a quasi-experimental field study of comprehension in groups of adults and children that found participants subject to varying levels of information tailoring subsequently demonstrated differential levels of understanding, even one week later. Participants exposed to only the standard-information presentation did not manifest any comprehension improvement. The ability of information to produce understanding is evidently subject to various influences; adequate communication of information is therefore not synonymous with participants understanding the content of the information conveyed.

Increasing disclosure of information is not, in itself, sufficient for ensuring adequate understanding by potential research participants. Several approaches can be employed to enhance participants' comprehension with respect to a broad array relevant characteristics for the specific research.The traditional method of simply reading the consent form aloud is often largely ineffective in improving patients' understanding; they remain unable to give any coherent and meaningful account of the proposed research after such reading (Dekking et al., 2014). Neither is it sufficient to present only a reasonably well-prepared document to subjects for their reading alone. The comprehension of research protocols presents generally a specific critical situation with an appropriate level of risk, general public awareness, and understanding of basic issues and preconditions of participation that can be assessed. Solution criteria applied to gauge other areas nevertheless seem still relevant. Difficulty in understanding complex

information, for example, represents an intrinsic challenge for human communication. General lack of empathy on the part of researchers also precludes ready comprehension of what it is like to "sit on the other side of the table" and to be helplessly confronted with a potentially frightening position (McGregor et al., 2016).

Presentation of the information may be organized in a layered fashion, allowing participants to be first acquainted with a respectful and general description of the research, gaining access to second-level, middle-detail particulars, and retaining the possibility of pausing there—to dive further or to drop out at any moment. Low-anxiety and early-staged enter-stage techniques involve comic figures or cartoons, for instance, to smooth admiration and impression, provide focused control of attention, and inhibit pre-programmed, evade-defensive reactions-stage responses. Comprehension may be assessed both during the information session and at its end, gauging how much understanding and how many relevant points have really been captured. The "teach-back" technique, enjoined with dumping a short set of core subjects, attains these goals, asking patients to repeat essential details in their own words; moreover, in a touch-and-go, mid-term check, the most important items can be gathered with no risk of fixated counter-transfer.

Voluntariness, coercion, and compensation

Informed consent depends on the voluntary nature of participation: participants should be free to choose without external manipulation or control. The U.S. federal regulations describe voluntary participation as "the free choice" of a subject who has "the capacity to make that choice" and has made that choice "without undue influence or coercion." Although all definitions of coercion and undue influence are still debated, coercive recruitment involves the use of force or threats that compel research participation against a person's will. Undue influence refers to the offers of excessive or inappropriate incentives that might alter an individual's risk–benefit calculus or interfere with an individual's ability to make a voluntary and considered choice.

Offering incentives is common in research to facilitate recruitment or retention. Ethical questions arise about whether certain recruitment incentives interfere with voluntariness and, if so, what amount and type of compensation constitute undue influence in the context of research participation. Compensation for time, effort, and inconvenience is often offered in research studies, including low-risk research involving healthy volunteers. Financial incentives to participate constitute a form of compensation. Research participants encounter risks that may involve time commitment, exposure to discomfort, or inconvenience. At the same time, some authors have argued that any financial offer carries the risk of sustaining an undue-influence concern, such as research participation involving significant physical risks or that the research improves a subject's future health (Aguila et al., 2016).

Defining voluntary participation

The revised 7th chapter helps researchers to get a clear understanding of whether the participation in a research project is voluntary or not. The content presented encompasses the different ways of measuring and gauging voluntariness, coercion and undue influence, and the role of incentives. Participation is defined as voluntary when it is free from coercion and undue influence. Coercion occurs when a person acts against his or her will, under threat or punishment (Xu et al., 2020). Similarly, to be undue,

influence must engender substantial pressure units, leading people away from a voluntary choice. Researchers should determine the influence of the relationship between the subject or subject group and the researcher on the decision whether to take part in the research. Research participation in particular circumstances should comply with the principles of Minimal risk and Equitable selection. The relatively low level of risk may render a substantial incentive for a lower class employee toward participation. Decision-analysis and social-exchange research can reveal ways of modelling this process and testing the effect of various rewards on participation. Long viaducts, such as Scott and Becker 1989 contribute understanding of level of consciousness volition as intrinsic part of vast body of knowledge expanding on benefits and risks of such incentives for research participation.

Addressing coercion and undue influence

Voluntary participation in research is a fundamental ethical mandate. The commonly cited Belmont Report definition indicates that "an action is voluntary if it is taken without justifiable external coercion and undue influence" (Dekking et al., 2014). Both coercion and undue influence compromise freedom of choice. Coercion involves the threat of harm to another person or a desired object, with a particular emphasis on conditions of low freedom. Undue influence arises in dependent relationships, where an individual holds a position of power over another and uses their authority to sway a choice. A typical view of coercion thus draws a line between physical constraint and an array of dependent relationships that do not represent coercion yet may still disrupt a free choice. Participants who have a pre-existing relationship with the investigator still retain the freedom to choose, yet the influence of that relationship may be considerable. A new framework for research consent considers the motivation behind participation, the consequences of withdrawing from participation, and the nature of the relationship between investigator and participant. When those dimensions are altered during the research process, coercive or undue influence is present. Investigators already aware of and controlling those factors may offer consent for methods and procedural safeguards designed to monitor and prevent such influences.

Use of incentives and compensation

Research protocols often include financial compensation or incentives for participation, which can create ethics concerns. Because many people willing to participate in research for altruistic reasons are also financially disadvantaged, determining appropriate compensation for participation is often difficult. Payment levels that are too low can inappropriately restrict participation and reduce diversity. At the same time, excessive payment could unduly influence individuals' decisions to enroll and thereby compromise compliance with the ethical principles outlined in the Belmont Report. Individuals with greater financial resources are more likely to accept challenges perceived as risky, even if the compensation does not fully cover potential inconvenience or loss. Undue influence, therefore, can arise not only from excessive payments but also from insufficient payment in certain circumstances. The Ethics Working Group of a National Institute of Health-sponsored collaborative study noted that early regulations governing human-subject research addressed compensation and incentives only indirectly. The group acknowledged that remuneration beyond reimbursement of out-of-pocket costs accompanying participation ought to be evaluated

case by case, in light of social and cultural norms. The lack of explicit guidance and dependence on locally defined standards led to the need for a more comprehensive analysis of the ethical considerations involved, particularly in jurisdictions where attention to this aspect of ethics remains limited.

Special populations and vulnerabilities

Individuals belonging to special populations may face vulnerabilities that can significantly impede their ability to provide unbiased voluntary informed consent. Such special populations typically include children, adolescents, and individuals with legal incapacity to consent due to mental disorders or related reasons. These individuals may also collectively fall within the category of inapplicable populations because the law precludes them from giving informed consent. Although children and minors cannot independently provide informed consent, ethical norms permit engaging them in research subject to compliance with statutory provisions and appropriately safeguarding their legitimate interests. Adolescents and certain minors may also be eligible to participate. Other vulnerable groups requiring additional protections encompass pregnant individuals, prisoners, and those at heightened risk of medical and psychological harm due to societal typecasting, extreme prejudice based on age, ethnic background, economic circumstances, mental disability, or other factors. Lower levels of comprehension that impede full understanding for breadth of comprehension, rather than low levels of understanding regarding a specific decision, are also possible.

Informed consent for research involving such individuals remains absolutely indispensable for ensuring that ethically acceptable research practices are upheld, the appropriate management of potential risks is effectively conducted, and the continuous maintenance of the essential trust of the public is meticulously observed and carefully protected. It is significantly important to highlight that while human subjects research is not legally forbidden with these specific populations, it is, nevertheless, vitally crucial that the entire informed consent process proceeds under conditions that engage qualified individuals and systematically implement robust safeguards to effectively protect the legitimate interests of those involved in this particularly sensitive research. Moreover, understanding and addressing the unique vulnerabilities present in these populations is paramount to maintaining the ethical integrity of the research process. The informed consent process must take into account these additional risks and therefore must meet a much heightened regulatory standard to ensure that thorough protections are firmly established, diligently maintained, and irrevocably in place, thus upholding the rights and dignity of every participant involved. Ethical principles, therefore, assertively advocate for the possibility of potential participation only upon strict compliance with all legal and formal requirements that have been thoroughly established for such specialized and sensitive research. Indeed, every single aspect of biomedical research continues to entail a committed and dedicated interest in conducting the proposed research with integrity, while clearly elucidating that—in the absence of ethical oversight and if the research remains outside the enforceable boundaries of law—other viable, ancillary pathways should either be pursued or rigorously investigated in conjunction with diligently seeking out willing and able candidates for participation in the study. This comprehensive and multifaceted approach emphasizes the utmost necessity of a transparent and ethical framework that not only prioritizes the well-being and safety of participants but also actively strengthens the inherent integrity and credibility of the research process itself. Additionally, it goes further to establish a

mutual understanding and rapport between researchers and participants, effectively fostering an environment of respect, accountability, and ethical responsibility that fundamentally underpins and supports good research practices while navigating the complexities inherent in such sensitive inquiries and rigorous studies. Through this conscientious engagement and awareness, researchers can better address any potential misunderstandings and foster an atmosphere of trust, ensuring that participants feel valued and their contributions recognized.

Children and inapplicable populations

Prospective research participants who are not legally competent to provide informed consent, such as children, individuals with cognitive impairments, or other inapplicable populations, pose special challenges for clinical investigators. Ethical guidelines view respect for autonomy, the key principle underlying informed consent, as applying only to those capable of understanding the relevant information and making an independent choice; hence, a supportive decision-making framework is required for those who lack autonomy. Because such individuals have reduced self-protective ability, they are viewed as requiring additional safeguards, even if they possess some decision-making capacity but are unable to consent fully.

In pediatric research, for example, both parents and children capable of understanding must exercise voluntary choice concerning participation. Informed consent has limited application, because only those with relevant capacity and legal authority can provide it; typically, parents or surrogates grant permission, with child assent obtained when appropriate, both are necessary for research enrollment unless waivers are granted. Parents must receive detailed information about the research, risks, benefits, and alternatives. When children are capable of understanding, they should affirmatively agree, with the level of understanding varying by age and maturity. Many adolescents grasp key informational elements similarly to adults, whereas younger children may need only to express simple preferences. Assumptions about a lack of capacity in very young children risk disregarding their wishes. More research is needed on the voluntariness of permission and assent, including the relationship between decision-making autonomy and understanding, and factors influencing perceived voluntariness among children and vulnerable groups.

Pregnant individuals, prisoners, and others at risk

Research on pregnant individuals is essential for reducing pregnancy-associated morbidity and mortality and improving maternal and fetal outcomes. Despite this need, they are often excluded from clinical trials that are likely to benefit them. This is perpetuated by fears of harming the fetus or preterm delivery, complicated by sociocultural factors, differences in risk perception, and lack of policy guidance. Moreover, notifying regulatory authorities about pregnancy or contraception is often thought to confer protection against liability. Thus, the predominant paternalistic attitude discourages trial recruitment. Yet, national and international policy documents indicate that pregnant women should be allowed to participate in research that satisfies certain ethical criteria. These include providing at least potential direct maternal benefit, avoiding exposure to risks greater than those incurred in standard medical care, and ensuring that research is not conducted entirely for the benefit of the fetus. Consideration of ethical principles indicates that safeguarding childbearing women

should not diminish their right to participate in research. Regulatory guidance, supported by ethical frameworks, calls for work on pregnant subjects wherever necessary preclinical studies, particularly on pregnant animals—have been performed and irrespective of whether any direct maternal benefits is anticipated.

Cultural and linguistic considerations

Participation of non-English-speaking individuals in health research embodies a significant moral dilemma given the broader challenge of involving cultural and linguistic minorities in scientific inquiry. Efforts to improve research on health disparities for selected ethnic groups have escalated, prompting scrutiny of the specific ethical concerns associated with recruiting and retaining diverse populations. Obtaining informed consent from such groups emerges as a prominent ethical issue. Interventions to enhance clinical trial participation in culturally and linguistically diverse (CALD) communities include the development of culturally targeted strategies to strengthen links between researchers and CALD populations and the investigation of approaches to recruit and retain older ethnic minority populations. Literature investigating the recruitment and retention of culturally and linguistically diverse (CALD) populations in research highlights perceived barriers and potential solutions. Culturally targeted strategies consist of establishing connections with community stakeholders and creating oversight structures that involve CALD input. These strategies address the need for ethical and effective participation of CALD populations in health research and consider the provision of verbal and written information in appropriate languages. Southern Ontario, Canada, has been identified as a region where participation of CALD groups in health research remains insufficient. Research involving vulnerable groups such as older persons, immigrants, and refugees may raise ethical concerns that addressing recruitment and retention challenges assists in alleviating. Culturally adapted recruitment materials accompanied by culturally relevant information sessions and community-based partnerships to establish connections of trust have been undertaken to support efforts.

Informed consent represents an ethical principle designed to protect the dignity and welfare of research participants, ensuring the freedom to make voluntary, informed decisions. Once protected by elaborate forms complete with fine print, informed consent increasingly invites consideration of broader cultural contexts. Diverse, non-electronic, accessible formats, oral presentations of materials by familiar and trusted individuals, and community-based efforts to ensure development of customized material conducive to explicit informed consent that responds to the specific needs of particular groups comprise the most promising strategies. Ensuring the rights, integrity, and well-being of participants remains paramount universally, regardless of the linguistic facilitator employed or the strategies adopted to enhance understanding.

Informed Consent Across Research Phases

Obtaining informed consent is not a one-time event but an ongoing process that must address ethical, legal, and regulatory requirements at every stage of research. Ethical considerations must be reviewed each time a new phase is entered. Often, separate approvals from research ethics committees (RECs) will be required for the transition from one stage to the next. The initial approval should describe the entire research project, including all relevant and potential phases, data types, sample storage options,

participant selection criteria, and future plans for new research projects based on the collected data. Whenever unanticipated phases are introduced, their ethical implications also must be addressed (Cini, 2018). The need for consent for research often arises in the periods preceding data collection. Regardless of whether the study is classified as surveillance, observational, or experimental, research teams must specify the intended purpose and method of data collection and analysis, along with any subsequent sharing of research materials, even before initiation. All these considerations remain relevant even when the data is public or uploaded to an open-access repository, as there remains a need to explain reasons behind such data and any data restrictions. Wide-ranging definitions apply to both research data and biological samples. Data selection and collection are intertwined with specific ethical inquiries, such as data rights regarding repository sharing, biobanking, secondary use, and other similar issues.

Recruitment and screening

Recruitment procedures can influence initial contact and obtain, or not, the consent or willingness to participate. Specific strategies may infringe on the autonomy and privacy of prospective participants or lead to under-representation of certain population groups. Specifically, recruitment that seeks to minimize privacy risk may limit engagement with marginalized individuals with complex health problems who could benefit from research participation and whose experiences may inform population health solutions. The ethical obligation to facilitate equitable access to clinical research for patients with the highest unmet health needs and the most complex health disparities must therefore be weighed against this ethical imperative to protect privacy. Research recruitment remains ethically complex, and scholars have debated methods that exert gatekeeping control by clinicians. Whereas clinicians typically maintain autonomy to refuse permission requests, this sense of ownership over patients raises questions about the justification for continuing gatekeeping control after the research team is in contact. Gatekeeping also raises questions about the willingness of patients entering a clinical research phase in which obtaining the clinician's permission is not expected. Although clinicians advocate for maintaining oversight authority, their perceptions do not always align with patient approaches toward research.

Consent for data collection and biobanking

Informed consent is critical for the protection of public trust in research, especially regarding the use of data and biological materials (biobanking). Current trends toward large-scale data sharing and the development of ever more complex and interdisciplinary research types raise the question of whether broad consent or umbrella consent procedures for future studies can meet ethical review and approval standards. Broad consent typically entails an open-ended consent mechanism permitting multiple, unspecified uses of information, biological materials, and/or health data. Umbrella consent procedures provide the consent necessary to share information and materials in accordance with the evolving research agenda specified in an umbrella application, but at the time research for which they were initially collected concludes, broad consent remains necessary. The principles of autonomy and respect for persons underpin arguments supporting broad or umbrella consent. Similarly, the complex networks of knowledge and the drive towards systems biology, structured data collections, and an increasing body of ethically and legally regulated data described elsewhere in this text

imply that umbrella consent structures are essential. For both types of consent, the ongoing legitimacy, acceptability, and ethical justification of the umbrella framework must be assured and clearly articulated to participants ahead of time.

Secondary use of data and future research

Obtaining informed consent for secondary use of data collected in previous research is essential and can be accomplished in a range of ways. Although re-approaching subjects remains the standard procedure, some data types are personally non-identifying and stepwise processes allow concern over understanding to be less of an issue when the intended sample or intended research remain the same. Consent for future genetic research therefore takes various forms, from broad to explicit, with operative threshold necessitating consideration of research ethics board (REB) requirements and anticipated alterations to protocols. When designing an ACME or any other similar system, regarding the feasibility of a reconsent option, it can be important to grasp the broad categories of consent. Regulations differ between Canada and the European Union. The Committee on Bioethics of the Council of Europe's Convention on Human Rights and Biomedicine defines broad consent as "an agreement, in advance of research on specific projects or use of specific data collected for a different purpose, to the processing of relevant data for research." The European General Data Protection Regulation supports such conditions under non-identifiable and minimal-risk requirements.

Documentation and record-keeping

Documentation of the informed consent process aims to provide evidence that consent was obtained appropriately and ethically for a scientific study. Although the specific documentation procedure varies according to the applicable legal framework, some common principles still apply. Some countries require that potential participants sign a declaration confirming that they consent to participate in the study once they have been comprehensively informed and their questions satisfactorily answered. Other countries require written consent to be documented in a manner that is more comprehensive and formally prepared than a simple signature. Regulatory authorities accept a variety of approaches, as long as they fit within the legal requirements and ethical regulations in place.Video recording of the consent process provides an additional and unique level of protection for research subjects in studies involving special considerations, such as greater than minimal risk or other factors identified by the research ethics committee. Video recording provides direct evidence of the information provided, the process used to assess understanding, and any additional interactions between the investigator and the participant. The logging of such material enhances compliance with applicable probity and assists in eventual investigations, should they arise. Subject to adequate safeguards on access and use, video recording of the consent process represents a positive contribution to the improvement of research practice while ensuring ongoing protection.

Conclusion

Oversight, accountability, and responsibilities

Scholars have recognized the significance of obtaining informed consent from participants in research involving human subjects to the ethical conduct of such studies

(Xu et al., 2020). Institutional Review Boards (IRBs) and other review bodies primarily protect participant welfare through adherence to ethical guidelines and governmental regulations. However, participants also have their own responsibilities to be well-informed and active agents in the consent process. Decisions should be voluntary and autonomous, presenting a choice among alternatives. Participants should be free to ask questions regarding the study's nature and incentives to take part, and researchers should provide responses before they made any commitments. Consent should also be regarded as a continuous process; the originally granted consent remains valid for prospective use of the data in future research, provided variables specific to the new study do not alter fundamental characteristics of the earlier research (Cini, 2018).

Challenges, controversies, and emerging trends

Obtaining informed consent for participation in research is a fundamental ethical obligation for investigators. It signals respect for research participants and, alongside encouragement to ask questions, constitutes the first and essential step toward building a trusting researcher-participant relationship. The ethical practice of obtaining informed consent has become a contentious issue in biomedical research as new forms of experimentation continually introduce the need to address the adequacy, relevance, and comprehensibility of information; to determine the appropriateness of potential incentives and their framing; to incorporate consent for future studies involving already collected data; to evolve fresh measures to scuttle outdated practices; and to heed cultural and interpersonal considerations that can cloud understanding. Moreover, the birth of retransmission studies explodes traditional assumptions regarding the duration of consent and thus requires serious reconsideration of prevailing regulations.

Thorough and extensive final conclusion accompanied by essential key insights derived from this comprehensive analysis

Research ethics and investigator responsibilities evolve over the course of human research studies. Informed consent is one of the most consistent and widely recognized ethical requirements from before the commencement of a study until data analysis and even biobanking of residual samples. The arrival of novel sources and forms of data and new uses for data from prior studies have led to increased citations in the literature and altered guidance at the governmental (U.S. Department of Health and Human Services) and institutional (U.S. National Institutes of Health) levels. These changes call for renewed examination of the expectations and obligations regarding informed consent and revision of guidance documents.

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Conflict of interest

The authors confirm that there is no conflict of interest involve with any parties in this research study.

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