
Passive consent for passive participation?

PERSPECTIVES

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***Passive consent* meets important ethical concerns and ought to be more applied in certain types of medical and health-related research.**

The purpose of the Health Research Act is to promote good and ethically sound research [\(1\)](#). A key approach to this effect is to instruct the researchers to obtain consent from the participants. One challenge, however, is that the Act stipulates only two categories – either *active* consent or *exemption* from consent. We believe that there are good ethical reasons to commend *passive* consent and give it a clearer role to play.

The main rule is active consent

The main rule in all health research is to require informed, voluntary and explicit consent, cf. Section 13 of the Health Research Act. Informed consent means that potential participants must be informed about risks and possible advantages and disadvantages, as well as rights and practical issues associated with their participation. This information must be understandable and truthful, not too sparse and not too comprehensive. Voluntary consent means that nobody should feel pressured into participating or be lured into something against their will. This is of special relevance in research on persons who are in a situation of dependence. Explicit or active consent implies that participation comes from an active declaration of intention – you must actively accept. If you do nothing, you are not included.

The justification for consent

Today, there is widespread consensus that the requirement for active, informed consent in medical and health research is ethically correct and important. This consensus is so strong that we may sometimes forget the justification. We share the views of the ethicists James Wilson and David Hunter, who argue that the best justification for strict regulation of research is primarily associated with *risk* (2). Medical and health research can expose the participants to risk and inconvenience, even though it may not have as its primary objective to achieve therapeutic gain for the individuals concerned. It is essential to inform potential participants about this, so that they can make an informed and active choice of whether or not to expose themselves to this eventuality.

Risk is mainly associated with physical harm, but mental strain may also be relevant. In turn, physical and psychological risk associated with participation in research is linked to projects that imply an intervention or interaction, so-called *primary research*.

Secondary research refers to studies of previously collected data that may include anything from health information in patient records to central health registries. In this article we will not discuss registry-based research which must comply with other types of regulations. Secondary research is characterised by an absence of physical risk, and in this respect, a fundamental distinction can be drawn between primary and secondary research. Reference to risk may indeed be relevant also when it comes to secondary research, for example in the form of violations of privacy or integrity. We therefore do not claim that secondary research is invariably risk-free or ethically unproblematic, nor that primary research always implies risk. We nevertheless believe that the fundamental position that active consent has held in medical research ethics since the Nuremberg Code and the Declaration of Helsinki must be understood

on the basis of primary research. Interaction – and the risk associated with it – represents the paradigmatic justification for strict research regulations and the requirement for active and informed consent.

If active and informed consent is considered to be of crucial importance also in secondary research, a justification other than risk is needed. Such a justification could be respect for autonomy as such. An *autonomy-based justification* for consent does not require that the research involves risk or inconvenience; the belief that each individual has the right to decide over his or her own data is sufficient. Hence one may believe it is important to be asked, even though there may be little to ask for. In addition, we associate consent with such basic principles as respect, good manners and courtesy – we ask before borrowing something (3).

Exemptions from the requirement for consent

The Health Research Act includes an exemption clause, according to which the Regional Committees for Medical and Health Research Ethics (REK) may waive the requirement for consent when researchers wish to use health information collected by the health services. It is reasonable to interpret this exemption clause as an admission that there is not much at stake for individual participants in secondary research. The precondition for granting exemption is that the welfare and integrity of the participants are safeguarded and that the social benefit is assumed to be considerable. Here we might think that the problem of rigid requirements for consent is solved, but it is worth noting that this is formulated as an exemption clause. In addition, the preparatory work of the Act states that exemptions can only be granted if it is impracticable to obtain consent (4). We know that researchers generally find that obtaining consent is time-consuming and difficult. However, the National Committee for Medical and Health Research Ethics (NEM) and REK have interpreted this criterion of impracticability more strictly than as being merely a matter of inconvenience. This follows from the preparatory works of the Act, where the Ministry of Health and Care Services underscores that 'in order to waive the main rule for obtaining consent, the considerations must include more than mere expediency' ((4), p. 127). Obtaining an exemption from the requirement for consent is thus no easy matter.

Passive consent in practice

It is important to be aware, however, that when REK grants exemption from the requirement for consent, the researchers are usually made subject to a disclosure requirement pursuant to the Personal Data Act, cf. Article 13 of the Personal Data Regulations. The disclosure requirement means that the participants must be informed that their health data will be used for a specific research project. The participants must also be informed of their right to decline such participation. This approach respects the participants' autonomy, and provisions are made for them to exercise their rights according to the

Health Research Act and the Personal Data Regulations. If someone included in the sample has any real objections to participating, they can thus decline to be included.

«When a research project is granted exemption from the requirement for consent, the participants can still decide whether they want to participate or not»

In practice, this means that when a research project is granted exemption from the requirement for consent, the participants can still decide whether they want to participate or not. A popular term used for this information and reservation procedure is 'passive consent' or 'opt-out'.

Is passive consent to be regarded as an *exemption* from consent?

The fact that the Health Research Act fails to include even a single reference to passive consent reflects the widespread opinion in research ethics that a consent is valid only if it is provided actively. The apparent problem with passive consent is that it appears to guide people into participation in research without them having made a deliberate and informed choice to do so. In the preparatory works of the Biobank Act, there was explicit concern that passive consent could 'gradually come to replace informed, active consent' ((5), p. 79).

In our opinion, it is worth discussing whether passive consent is perhaps not as bad as it is made out to be. When little or nothing is at stake for the individuals concerned, while considerable benefit can be obtained for patient groups and the health services in general, it is reasonable to assume that most people would be agreeable to such research for the benefit of the community.

Therefore, the fact that the model seems to suggest that participating in research is the norm need not be ethically problematic. When each individual is also being personally informed about the research and given the opportunity to opt out, individual autonomy has been respected to a high degree.

The philosopher Ben Saunders has outlined two further preconditions for passive consent to be considered valid. First, it must have been communicated clearly and unambiguously to each participant that silence will be interpreted as consent. Second, opting out must be easy (6). With the templates that REK has prepared for information and reservation, we claim that the Norwegian procedure in such cases fulfils both criteria (7).

«Passive rather than active consent simply makes for better research»

During the preparatory work on the Act, the practice involving a disclosure requirement and an opportunity for participants to decline participation was not on the agenda. A granted exemption was to be understood as a complete exemption, whereby the participants would not be informed about their

inclusion and unable to opt out if they wanted to. Today, however, NEM and REK rarely grant such a *complete* exemption as authorised by the Act. Therefore, it will be misleading to refer to the practice of passive consent as an *exemption* from the requirement for consent. In our opinion, passive consent represents an ethically sound middle ground between active consent and research without consent, and ought to be far more widely applied than it is today.

The price of active consent

Imposition of a requirement for active consent for secondary research entails the risk that many potential participants do not answer the request. Few – if any – studies have been undertaken of people's grounds for not participating in research when asked. Our colleagues' experience with recruitment to projects indicates, however, that the grounds need not necessarily include any reasoned opposition to participate. Convenience can be the main concern, for example not having to go to the nearest mailbox to post the response slip. Low response rates are a major problem for the validity of studies, and hence for their scientific usefulness. Passive rather than active consent simply makes for better research (8).

If the cause of the low response rate were people's unwillingness to participate in the study, the ethical issues would be quite different. Individual autonomy should trump social utility – this is an ethical cost that we need and ought to pay. On the other hand, when the low response rate is caused by practicalities that 'prevent' people from doing something that they themselves consider desirable, an ethical problem arises. Important research that could benefit us all is delayed or hindered. Correspondingly, strict requirements for consent become an ethical problem (9).

The road ahead

To promote high-quality and ethically defensible research, a balance must be struck between various concerns. We argue that some nuances should be introduced into the requirements for consent stipulated by the Health Research Act. Active consent should remain the norm in primary research. Passive consent ought to be regarded as the norm for *passive research* or secondary research in which there is little at stake for the participants. This is not a matter of sacrificing the interests of the individual at the altar of the common good. It is about finding an optimal ethical solution for both concerns.

The current legal framework does not completely preclude a more prominent role for passive consent, but nor does it promote it, given the formulations about the main rule and an exemption clause. We suspect that the rules for consent are out of step with the opinions of participants, researchers and ethics committees regarding what should be an appropriate balance between concerns

for the participants' integrity and welfare on the one hand and for promotion of socially useful research on the other. Passive consent for passive participation in research could be good research ethics.

The authors wish it to be noted that this article is not written on behalf of the system of national and regional research ethics committees. The viewpoints reflected herein must be read as the authors' own and are intended as an invitation to a debate on the regulation of Norwegian health research.

LITERATURE

1. LOV-2008-06-20-44. Lov om medisinsk og helsefaglig forskning (helseforskningsloven). <https://lovdata.no/dokument/NL/lov/2008-06-20-44?q=helseforskningsloven> Accessed 8.9.2020.
2. Wilson J, Hunter D. Research exceptionalism. *Am J Bioeth* 2010; 10: 45–54. [PubMed][CrossRef]
3. Solberg B, Ursin L. Being polite: Why biobank consent comprehension is neither a requirement nor an aspiration. *Am J Bioeth* 2019; 19: 31–3. [PubMed][CrossRef]
4. Ot.prp. nr. 74 (2006–2007). Om lov om medisinsk og helsefaglig forskning (helseforskningsloven). <https://www.regjeringen.no/no/dokumenter/otprp-nr-74-2006-2007-/id474780/> Accessed 17.8.2020.
5. Norges offentlige utredninger. Biobanker – Innhenting, oppbevaring, bruk og destruksjon av humant biologisk materiale. NOU 2001:19. <https://www.regjeringen.no/no/dokumenter/nou-2001-19/id143909/> Accessed 17.8.2020.
6. Saunders B. Opt-out organ donation without presumptions. *J Med Ethics* 2012; 38: 69–72. [PubMed][CrossRef]
7. Regionale komiteer for medisinsk og helsefaglig forskningsetikk. Informasjon om reservasjonsrett ved bruk av helseopplysninger. <https://rekportalen.no/internal/rest/public/attachmentsByPub/38193428.png> Accessed 17.8.2020.
8. Junghans C, Feder G, Hemingway H et al. Recruiting patients to medical research: double blind randomised trial of "opt-in" versus "opt-out" strategies. *BMJ* 2005; 331: 940. [PubMed][CrossRef]
9. Ebbing C, Brekke M. Pasientsamtykke i pandemiforskningen. *Tidsskr Nor Legeforen* 2020; 140. doi: 10.4045/tidsskr.20.0245. [PubMed][CrossRef]

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