4

Social Value

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4.1 INTRODUCTION

This chapter starts from the assumption that science is a matter of co-creation. To open up science to democracy means that we have to think about the social value of research, which in itself we cannot leave to science to evaluate. This raises detailed questions around patient and public involvement (PPI) in deciding which research to perform, and about how to handle conflicts between individual and public interests. These are addressed elsewhere in this volume.[1]

In this chapter we focus on social value in health-related research involving humans, including data driven research. We first describe the background to the concept of social value and its meaning. Then we examine the concept itself and define the social value of an intervention as the value that an intervention could eventually have on the well-being of groups of patients and/or society. We also discuss some of the open issues in the scholarly debate about the concept of social value.

We find that to state a requirement for social value is one thing; to actually evaluate the social value of a research project in a Research Ethics Committee (REC) is another. We therefore elaborate on how the requirement of social value can be applied. We argue, first, that it is important to have this requirement as a separate condition. To increase systematisation, we further discuss how social value can be assessed in the steps that together constitute the risk-benefit task of RECs.

Returning to our opening statement, we argue that the addition of the requirement of social value can be seen as a consequence of a change in the sociology of science. It illustrates the move away from a science–internal understanding of scientific validity into an inclusive understanding of social value. Accepting social value as a requirement for research to be evaluated by a REC means that social value has matured from an attractive but illusive idea into something that has to be assessed, evaluated and optimised and can be used to address some of the justice issues in healthcare.

4.2 SOCIAL VALUE IN THE 2016 CIOMS GUIDELINES

Social value is a key principle in the 2016 version of the International Ethical Guidelines for Health-related Research prepared by the Council for International Organizations of Medical

[1] See Burgess, Chapter 25, and Aitken and Cunningham-Burley, Chapter 11, in this volume.

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Sciences (CIOMS) in collaboration with the World Health Organization (WHO). The account of social value in this chapter has been largely influenced by the wording in the 2016 CIOMS Guidelines. Its very first guideline reads:

> The ethical justification for undertaking health-related research involving humans is its scientific and social value: the prospect of generating the knowledge and the means necessary to protect and promote people's health. Patients, health professionals, researchers, policy-makers, public health officials, pharmaceutical companies and others rely on the results of research for activities and decisions that impact individual and public health, welfare, and the use of limited resources. Therefore, researchers, sponsors, research ethics committees, and health authorities, must ensure that proposed studies are scientifically sound, build on an adequate prior knowledge base, and are likely to generate valuable information.
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> Although scientific and social value are the fundamental justification for undertaking research, researchers, sponsors, research ethics committees and health authorities have a moral obligation to ensure that all research is carried out in ways that uphold human rights, and respect, protect, and are fair to study participants and the communities in which the research is conducted. Scientific and social value cannot legitimate subjecting study participants or host communities to mistreatment, or injustice.[2]

The entry of the requirement of social value in the 2016 CIOMS International Ethical Guidelines for Health-related Research involving humans was certainly not unprecedented. Many scholars trace its origins back to the Nuremberg Code of 1947, which states that 'The experiment should be such as to yield fruitful results for the good of society'.[3] Also, it is commonly understood that the social value of a research project may be part of the evaluation of risks and benefits of such a project.[4] The concept also plays a key role in the Belmont Report, the World Medical Association's Declaration of Helsinki, and the Common Rule. Furthermore, social value is considered to be of relevance when international collaborators are conducting health research in resource-limited settings. The concept also plays a key role in frameworks for research ethics, such as the '7- principle-framework' of Emanuel and colleagues[5] and the component analysis framework of Weijer and Miller.[6]

4.3 SOCIAL VALUE AS INDICATION FOR A CHANGE IN SOCIOLOGY OF SCIENCE

The addition of social value to the 2016 CIOMS International Ethical Guidelines at this point in history can be understood as part of a broader movement within the sociology of science, which describes how people come to accept certain scientific statements. Elements of this movement can also be seen in other guidelines within the 2016 CIOMS Guidelines, such as those on Community Engagement (7) and Public Accountability for Health-related Research (24). A first example of this broader movement within the sociology of science is the current critique of

[2] Council for International Organizations of Medical Sciences, 'International Ethical Guidelines for Health-related Research involving Humans', (CIOMS, 2016), 1.

[3] The Nuremberg Code (1947), (1996) *British Medical Journal*, 313, 1448.

[4] See Coleman, Chapter 13 in this volume.

[5] E. J. Emanuel et al., 'What Makes Clinical Research Ethical?', (2000) *JAMA*, 283(20), 2701–2711.

[6] C. Weijer, 'When Are Research Risks Reasonable in Relation to Anticipated Benefits?', (2004) *Nature Medicine*, 10(6), 570–573; A. Binik and S. P. Hey, 'A Framework for Assessing Scientific Merit in Ethical Review of Clinical Research', (2019) *Ethics & Human Research*, 41(2), 2–13.

science and scientific knowledge.[7] Part of the critique concerns the replicability of research results, which in some areas is disturbingly low. Another part concerns the way in which scientists are evaluated: in many areas of science this is done, at least until recently, by looking at the number of articles produced and/or the number of times an article is cited – e.g. combined into the Hirsch-index – creating an incentive to produce enormous quantities of papers. But the most important critique – also implied in the former point – is that science appears to be concerned more with producing science as such, than with furthering socially valuable goals through research. The term 'research waste' was coined to describe the result of this way of doing research.

In response, we currently see programmes such as the EU programme on Responsible Research and Innovation, movements such as that for Open Science – which is certainly about more than just open access publishing – and Science in Transition.[8] These programmes try to reinvent the sociology of science in order to enable it to perform the tasks society has entrusted to scientists. They also encourage the involvement of all stakeholders in the production of science, including patients and publics, in order to increase the relevance of research results. Present-day problems in society are simply too complex to think we can solve them without cooperating across borders. Science cannot continue to take its own interests as primary, instead of living up to its societal task. Science needs to earn and deserve a so-called social licence for research.[9] PPI in research is an essential means to mitigate concerns on research waste.

There are a number of reasons why we need PPI in research – as addressed in more detail elsewhere in this volume.[10] First, this is because research is about all of us! And nothing should be done 'about us, without us'. We therefore need a model in which patients consider themselves as partners in a trustworthy system, not just passive sources of information. Second, the purpose of patient involvement is ultimately to improve our health. By this we do not mean through individual healthcare. Rather, we suggest that this can come about by ensuring that those who conduct research projects ask the right questions, use the right endpoints, make the right choices and effectively implement their findings. This illustrates the efficiency argument as applied to input from patients – and wider publics – who are similarly motivated to find answers to health and disease-related questions. It is believed that this will help science to become more socially valuable and thus to reduce research waste.

These developments also point to important questions in the area of the philosophy of science. It is common to think that science produces facts that are independent of public preferences. Shouldn't science inform democratic decision-making rather than being influenced by it? What is left of scientific independence if we allow PPI in research? It is generally understood why democracies need science, but why would science need democracy?[11]

To answer these questions we turn to Science and Technology Studies (STS) where several schools of thought can be discerned. The first (1900–1960) was a positivistic one: it was believed that science was a way of knowledge-making and that its knowledge was absolute and universalistic.[12] The correctness of scientific research needed no social explanation, it was simply

[7] D. Moher et al., 'Increasing Value and Reducing Waste in Biomedical Research: Who's Listening?', (2016) *Lancet*, 387(10027), 1573–1586.
[8] F. Miedema, *Science 3.0* (Amsterdam University Press, 2010).
[9] P. Carter et al., 'The Social Licence for Research: Why care.data Ran into Trouble', (2015) *Journal of Medical Ethics*, 40(5), 404–409.
[10] See Burgess, Chapter 25, and Aitken and Cunningham-Burley, Chapter 11, in this volume.
[11] H. Collins et al., *Why Democracies Need Science* (Cambridge: Polity, 2017).
[12] Ibid.

true. What needed explanation was how false beliefs were mistakenly taken to be correct, typically by pointing at prejudice, bias and so on. This is what Nowotny calls Mode 1 research.[13] Although this view is no longer supported by social science, it remains the common-sense view of many scientists and the public. One needs only to watch an episode of *CSI* to see how a forensic scientist reveals 'the truth' about the case.

The second school of thought (1960–2000) started when others took the work of Kuhn and other researchers to show that scientific truth is best seen as an outcome of negotiation and agreement located within social groups. Science is a human activity subject to all the strengths and flaws of humans. Nowotny speaks about Mode 2 research in which interaction between science and society is taken as a starting point and science has become a matter of co-creation.[14] Science needed to be democratised. This second school illuminated the constructivist side of science, in order to deconstruct science, but did less to provide an alternative.[15] A risk of this type of thinking is that this may produce the kind of relativism in which scientific claims have become 'just another opinion' and alternative facts are as good as any other account.

To counter this, the third school (after 2000) emphasises that we do not need to end up in relativism, and that there are more arguments in favour of some claims about states of the world than there are for others. Textbook science is not perfect, and remains open to revision, but is more reliable than primary research, because we have more reasons to accept the claims in a textbook than in primary research. In ethics, the Rawlsian understanding of ethical claims as provisional fixed points captures the same idea: claims are always open to revision (hence 'provisional') but we have good reasons to accept them (hence 'fixed'). It is important to note that the last school of thought accepts the rationale established by the former, but tries to make the next, constructive step.

We think that the addition of the requirement of social value into the CIOMS Guidelines can be seen as a consequence of this change in the sociology of science. It clearly illustrates the move away from a science–internal understanding of scientific validity into an inclusive understanding of social value. It sends the message that science needs to be cognisant of its societal role and should explain how it aims to fulfil that role. That message is reinforced by guidelines on community consultation and public accountability. Placing social value as a requirement in a list of conditions to be evaluated by a REC means that social value has matured from an attractive but illusive idea into something that has to be assessed, evaluated and optimised. In other words: social value has gained 'teeth'.

4.4 MEANING OF SOCIAL VALUE

We will now zoom in on the meaning of the concept 'social value' itself. According to Wendler and Rid, the standard view on social value is that 'it is an ethical requirement for the vast majority of clinical studies'.[16] They also argue that there is 'strong support' that social value of research is important 'for protecting participants who cannot consent, preventing inappropriate research that poses high net risks, and promoting appropriate investigator behaviour'[17] (see also below).

[13] H. Nowotny et al., *Rethinking Science* (Cambridge: Polity, 2001).
[14] Ibid.
[15] Collins et al., *Why Democracies Need Science*.
[16] D. Wendler and A. Rid, 'In Defense of a Social Value Requirement for Clinical Research', (2017) *Bioethics*, 31(2), 77–86, 77.
[17] Ibid., 86.

Here is the description of the meaning of the term social value according to the 2016 CIOMS Guidelines:

> Social value refers to the importance of the information that a study is likely to produce. Information can be important because of its direct relevance for understanding or intervening on a significant health problem or because of its expected contribution to research likely to promote individual or public health. The importance of such information can vary depending on the significance of the health need, the novelty and expected merits of the approach, the merits of alternative means of addressing the problem, and other considerations.[18]

We next examine separately the concepts of value and social value. We understand value to mean the potential of a study to improve health, broadly construed as biological, psychological or social well-being.[19] Health value can be categorised along two dimensions: immediate versus future health value, and the population that receives this value.[20] It is also important to note that social value is attributed both to information that has direct relevance in promoting health, and to the contribution this information may have for subsequent valuable research.

The concept 'value' has been scrutinised in many different research fields such as sociology and philosophy. However, little agreement exists on how 'value' should be defined. Consensus does exist on the fact that values arise out of human experience. Whereas the term 'benefit' refers to an advantage or profit gained from something, the concept of value refers to the regard that something is held to deserve. The latter is thus a relational concept; both the object to be valued, and an evaluator are necessary preconditions for value to exist.[21]

Turning next to 'social value', this functions in two main ways in our everyday use. First, social value can be seen as values shared by a community of individuals; they are values held by society and are contrasted with individual (non-shared) values. By social value, we refer to socially collective beliefs and systems of beliefs that operate as guiding principles in life. Second, besides values *of* society, the concept can also be used to refer to values *for* society. Here, social value is an assigned predicate or property of an object, and, in our case, of health-related research.[22] This implies that we have to assess the importance of the information in terms of the nature and magnitude of the expected improvement an intervention – as assessed in the study – is expected to have on society. Note that benefit for the individual research participant would be called a direct benefit. Social value is not about rewarding careers for scientists, employment for citizens or a sense of fulfilment for participants.[23]

We conclude that the social value of an intervention encompasses the value that an intervention could eventually have on the well-being of groups of patients and/or society. In case of early phase trials, this value may lie in the distant future; in those cases, RECs may also assess the ability of trials to promote progression to later stages of research in which successful clinical translation becomes more likely.

It is important to note that the CIOMS guideline on social value also explicitly talks about what social value cannot do, as follows:

[18] CIOMS, 'International Ethical Guidelines', 1.

[19] D. J. Casarett and J. D. Moreno, 'A Taxonomy of Value in Clinical Research', (2002) *IRB: Ethics & Human Research*, 24(6), 1–6; C. Grady, 'Thinking Further about Value: Commentary on "A Taxonomy of Value in Clinical Research"', (2002) *IRB: Ethics & Human Research*, 24(6), 7–8.

[20] Casarett and Moreno, 'A Taxonomy of Value'.

[21] M. Habets et al., 'The Social Value of Clinical Research', (2014) *BMC Medical Ethics*, 15, 66.

[22] Ibid.

[23] Wendler and Rid, 'In Defense of a Social Value Requirement'.

> Although scientific and social value are the fundamental justification for undertaking research, researchers, sponsors, research ethics committees and health authorities have a moral obligation to ensure that all research is carried out in ways that uphold human rights, and respect, protect, and are fair to study participants and the communities in which the research is conducted. Scientific and social value cannot legitimate subjecting study participants or host communities to mistreatment, or injustice.[24]

This provision is a reformulation in human rights language of the so-called primacy principle. This is the ethical principle stating that the individual shall have priority over science, found, for instance, in guideline 8 of the 2013 Declaration of Helsinki: 'While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects'.[25] There is an ongoing debate about the tenability of this primacy principle[26] which deserves a separate discussion.

4.5 SOCIAL VALUE IN SCHOLARLY DEBATE

Whereas the merits of the social value requirement have been largely uncontested, over the past few years the concept of social value has received increasing scholarly attention. Among others, the journal *Bioethics* launched a Special Issue (2017, 31(2)) on social value. Also Danielle Wenner's[27] analysis of social value in the Hastings Center Report led to several responses.[28] The attention has not only led to improved understanding of the meaning and scope of social value but also to more critique. Next, we will consider some of the key points from this ongoing debate.

Traditionally, social value has been located in the context of clinical research, but more recently the concept has also been introduced in health systems research and into the global health ethics debate.[29] Whereas the concept, as discussed above, in clinical research focuses on the knowledge to be gained for society in general, in public and global health ethics the requirement seems to have a different role. For instance, according to Nicola Barsdorf and Joseph Millum, social value should be seen as 'a function of expected benefits of the research and the priorities that beneficiaries deserve'.[30] Social value then also becomes a means to address questions of priority setting,[31] promotion of health equity and addressing health inequality.[32]

[24] CIOMS, 'International Ethical Guidelines', 1.

[25] World Medical Association, 'Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects', (WMA, 2013).

[26] G. Helgesson and S. Eriksson, 'The Moral Primacy of the Human Being: A Reply to Parker', (2011) *Journal of Medical Ethics*, 37(1), 56–57.

[27] D. M. Wenner, 'The Social Value Requirement in Research: From the Transactional to the Basic Structure Model of Stakeholder Obligations', (2018) *The Hastings Center Report*, 48(6), 25–32.

[28] D. Wendler, 'Locating the Source(s) of the Social Value Requirement(s)', (2018) *The Hastings Center Report*, 48(6), 33–35; D. B. Resnik, 'Difficulties with Applying a Strong Social Value Requirement to Clinical Research', (2018) *The Hastings Center Report*, 48(6), 35–37; F. S. Holzer, 'Rawls and Social Value in Research', (2019) *The Hastings Center Report*, 49(2), 47.

[29] A. Rid and S. K. Shah, 'Substantiating the Social Value Requirement for Research: An Introduction', (2017) *Bioethics*, 31(2), 72–76; Wenner, 'The Social Value Requirement'.

[30] N. Barsdorf and J. Millum, 'The Social Value of Health Research and the Worst Off', (2017) *Bioethics*, 31(2), 105–115, 105.

[31] Rid and Shah, 'Substantiating the Social Value Requirement'.

[32] D. Wassenaar and A. Rattani, 'What Makes Health Systems Research in Developing Countries Ethical? Application of the Emanuel Framework for Clinical Research to Health Systems Research', (2016) *Developing World Bioethics*, 16(3), 133–139.

At the same time, in the context of health systems research, some argue that its social value can also be justified 'in pragmatic systems rather than linked only to priority setting'.[33]

Further discussion centres on whether the concept of social value should be located in the traditional account of research ethics that has a focus on clinical trials and observational research. According to Wendler and Rid, there are eight reasons that 'taken together provide strong support' that social value must be obtained in the context of clinical research: (1) to protect participants who cannot consent; (2) to ensure the acceptability of high-risk research with competent adults; (3) to maintain researcher integrity; (4) to avoid participant deception; (5) to safeguard against exploitation; (6) to exercise stewardship of public resources; (7) to promote public trust; and (8) support for clinical research.[34] Others, like Wenner,[35] Wertheimer[36] and Resnik,[37] ground the social value requirement in other principles and outside of the traditional scope of research ethics. According to Wenner, the current view on research ethics is primarily about protection. Instead, she believes it should be grounded in justice-based considerations. She argues that certain developments in research, such as the inclusion of pregnant women, cannot be understood only from a protectionist view towards research subjects but has to be explained from underlying issues of justice.[38]

Whereas some, like Wertheimer and Resnik, argue that studies must have 'significant' social value, Wendler and Rid[39] argue that studies should have 'sufficient' social value. The first group of authors expresses concern that without the qualification of significance, the concept becomes too weak, whereas Wendler and Rid argue that their understanding is also able to distinguish between studies with and without social value. Whether a study has sufficient social value should always be determined in relation to the risks of research. In some cases participants may face significant risks. However, if there is no social value to be gained, they argue that the study should not be approved even if participants consent to participation. At the same time, if the social value is limited but the risks are minimal as well, they argue it is not unethical to offer participation.

4.6 APPLICATION

In the preceding analysis we have considered both what the term social value means and the discussions that it has sparked. As such, we can now go on to look at its role in the set of requirements for acceptance of a research protocol. First, we would like to point to the importance of having this as a separate requirement. It could be argued that the social value of a research project is already being taken into account in the classical requirement in research ethics to have a favourable balance of benefits over risks and burdens. The 2013 version of the Declaration of Helsinki for instance reads: 'Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects'.[40] One could conclude from this that it would not be necessary to have a separate guideline on social value. However, the problem with including social value in this

[33] Wassenaar and Rattani, 'What Makes Health Systems Research in Developing Countries Ethical?', 136.
[34] Wendler and Rid, 'In Defense of a Social Value Requirement'.
[35] Wenner, 'The Social Value Requirement'.
[36] A. Wertheimer, 'The Social Value Requirement Reconsidered. The Social Value Requirement Reconsidered', (2015), *Bioethics*, 29(5), 301–308.
[37] Resnik, 'Difficulties with Applying a Strong Social Value Requirement'.
[38] Wenner, 'The Social Value Requirement'.
[39] Wendler and Rid, 'In Defense of a Social Value Requirement'.
[40] The Declaration of Helsinki (2013).

so-called risk/benefit ratio is that in research projects without risks or burdens, a lack of anticipated benefit would not be sufficient grounds for a REC to deny approval of the project. If one thinks that the main aim of research ethics guidelines is to protect the individual, then one might be satisfied. If one takes a broader view and includes justice among the ethical principles that are relevant to such a deliberation, then allowing a project without benefit is unacceptable from a societal perspective. Projects still use time, money and energy in addition to contributing to more research waste. Therefore we argue that it is necessary to have social value as a separate requirement.

Some might object on the basis that social value cannot be a necessary requirement for research to be ethical since certain medical discoveries have been made by coincidence, and that requiring social value may limit medical advancement. However, accidental findings cannot be planned, nor does requiring social value mean that we will no longer find accidental findings by restricting clinical research to interventions with expected social value.

Having made the preceding claim, we now turn to the role of RECs, which are currently tasked with judging whether a favourable risk-benefit balance is achieved to ultimately decide whether a research project can proceed. This judgement has to be systematic, transparent and grounded in evidence. Evaluating the social value of a particular research project can be seen as part of this task. To increase systematisation we draw upon insights from decision-theory and propose that the risk-benefit tasks are divided into the following steps: (1) analysis; (2) evaluation; (3) treatment; and (4) decision-making.[41]

4.6.1 *Benefit Analysis*

It is the primary responsibility and expertise of investigators to map and characterise benefits, including the social value of research. However, evaluators should be able to judge whether they agree with the reasoning that supports the presented characterisation of benefits.[42] To map benefits, we divide these into direct, collateral and aspirational benefits.[43] Social value can be regarded as one of the aspirational benefits. We further divide social value into: (1) the direct social value of the intervention; (2) the progressive value; and (3) the translational value of a trial.

In characterising the social value of an intervention we draw upon the proposal by Habets and colleagues.[44] They argue that at least three steps should be followed. First, the nature and magnitude of efficacy of the intervention studied in humans has to be critically assessed. Second, the anticipated clinical improvement in actual patients should be assessed, assuming that the intervention is efficacious. This means that it has to be asked whether treatment effects are meaningful, both from a medical and individual perspective, and that they have to be weighed against factors that may hamper beneficial effects, such as adverse effects and ease of use. Third, the nature and magnitude of the anticipated improvement on the well-being of patients, individuals in society and society should be evaluated. This assessment is contextual: the social value of the intervention is the expected improvement relative to other considerations, such as

[41] R. Bernabe et al., 'The Risk-Benefit Task of Research Ethics Committees: An Evaluation of Current Approaches and the Need to Incorporate Decision Studies Methods', (2012) *BMC Medical Ethics*, 13(1), 6.

[42] Ibid.

[43] N. King, 'Defining and Describing Benefits Appropriately in Clinical Trials', (2000) *The Journal of Law, Medicine, and Ethics*, 28(4), 332–343.

[44] M. Habets et al., 'The Unique Status of First-in-Human Studies: Strengthening the Social Value Requirement', (2016) *Drug Discovery Today*, 22(2), 471–475.

treatment alternatives, number of patients and costs etc. Ultimately, determining what has social value constitutes a moral judgment.[45]

To characterise progressive value[46] we argue that at least two elements should be evaluated: (1) whether there is a reasonable probability that an intervention could progress to the next stages of research at all; and (2) whether the trial is designed such that the yielded results can contribute to progression to the next stage of research (typically Phase II). The assessment of estimated efficacy can contribute to the assessment of both elements. Evaluators should therefore judge whether they find the estimated efficacy as presented by investigators to be substantive.

For trials to have translational value they should be hypothesis-driven. Preclinical and reference class evidence form the basis for the generation of hypotheses and the context for the subsequent interpretation of both positive and negative findings.[47] For instance, if a positive result in animals is followed by a negative result in humans, this difference can lead to further explorations of this difference and/or which modifications to the intervention have to be made to overcome translational hurdles. Furthermore, the determination and evaluation of reference class evidence helps researchers to put their findings in a broader context and to communicate their findings to other areas of research. Evaluators should thus judge whether investigators base their hypotheses on a solid assessment of preclinical and reference class evidence.[48]

4.6.2 *Benefit Evaluation*

We contend that investigators and evaluators should be transparent about the weight they ascribe to the different types of benefits (and harms). Progressive and translational value are not necessarily mutually exclusive, however, they may require a different trial design.[49] Therefore, it should be made explicit how a trade-off between different types of benefits and harms are made.

4.6.3 *Benefit Treatment*

After benefit assessment, RECs need to judge whether measures need to be implemented to modify – and ideally to maximise – benefits. The following measures can be taken to enhance the translational value of a trial. If hypotheses are insufficiently supported by evidence, investigators can be prompted to conduct additional preclinical testing. Alternatively, evaluators can demand more thorough gathering and assessment of existing preclinical and reference class evidence. Methods of PPI can show whether or not patient-relevant outcome measures have been used. Furthermore, open sharing of the assessed preclinical and reference class evidence can enhance the collateral value of a trial. Additionally, amendments to the trial design can spur the translational value.

4.6.4 *Decision-Making*

Finally, RECs have to decide whether benefits truly outweigh the risks. The three steps of benefit analysis, evaluation and treatment contribute to the transparency of decision-making. It

[45] S. Boers, 'Organoid Technology. An Identification and Evaluation of the Ethical Challenges', *PhD thesis* (Utrecht University, 2019).
[46] J. Kimmelman, *Gene Transfer and the Ethics of First-in-Human Research* (Cambridge University Press, 2009).
[47] Kimmelman, *Gene Transfer*.
[48] Boers, 'Organoid Technology'.
[49] Kimmelman, *Gene Transfer*.

has been claimed that it matters whether the research is funded with public money or not. We disagree: even when privately funded, we can see no justification for burdening participants with research that has no social value.

4.7 CONCLUSION

The term 'social value' strikes the necessary balance between scientific advancement, equitably responding to human conditions and realising the human right to health. The requirement of social value bridges the gap between conducting commendable science and making a contribution to the health of the populations where health research is being carried out. The concept of social value is the ethical justification for doing health research involving humans.