Ethics in action: Approving and improving medical research with human subjects

de Jong, Jean Philippe

Citation for published version (APA):

General rights
It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations
If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: http://uba.uva.nl/en/contact, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.

Download date: 12 Dec 2018
DISCUSSION

(Dis)approving and improving in action

7.1 Introduction

This thesis deals with ethical oversight on medical research with human subjects. In the prologue to this thesis I recounted the story of Jan. Jan was suffering from prostate cancer and chose to participate in a scientific study in order to help improve the treatment of this disease. Unfortunately, the study led to severe side effects for Jan. Although Jan did not feel that his physician or the researchers were culpable for his situation, he was left with many questions. Had it been a good idea to allow an alteration of his treatment based on the MRI? Was he informed properly about the risks or could additional information have changed his mind? Was the knowledge gained by this study worth the risks to him and other patients? And he also wondered: Who decides about all of these issues? Who ensures that these things are in order? And how do they do that?

In most countries a system for ethical oversight on medical research has been in place for many years. This system aims to ensure that the ethical quality of research is in order and that subjects are protected. Research Ethics Committees are considered the key components in this system. However, the practice of ethical oversight is not transparent, but rather a 'black box': we know little about what is going on inside the system. The central aim of this thesis is to open this black box and to help understand how ethical oversight, especially by Research Ethics Committees, works in practice. A secondary aim of this thesis is to help improve the functioning of ethical oversight. In the previous chapters, I have therefore studied various aspects of the practice of ethical
oversight in The Netherlands and the U.S., focusing especially on the work of Research Ethics Committees.

In this concluding chapter, I work towards a deeper understanding of ethical oversight. Based on a synthesis of the contrasts uncovered in the studies in this thesis, I argue that there are two philosophies for doing good in ethical oversight: ‘(dis)approving’ and ‘improving’. Subsequently, I reflect on the research methods used in this thesis and I discuss the strengths and weaknesses of both approaches to oversight. Finally, I discuss how the two approaches to oversight interact, and how they can best be combined.

7.2 Synthesizing a deeper understanding of ethical oversight

So what understanding of ethical oversight emerges from my studies? As explained in the introductory chapter, I chose to study ethical oversight in practice and focused on contrasts – oppositions that emphasize differences – as a way of getting into the ‘black box’ of oversight. In chapter two and three this led me to mark out two contrasting ways of doing ethical oversight: in chapter two I distinguished working within a repertoire of rules from working within a repertoire of production, and in chapter three I distinguished compliance monitoring from quality improvement monitoring. In chapter six I discussed the ethical implication of two philosophies behind research methods: I contrasted the philosophy of standardization in randomized controlled trials with the philosophy of adaptation in qualitative research. Furthermore, in chapter four I compared published with non-published studies, and I discussed two different ways of dealing with non-publication: disapprove a proposal or discuss concerns with investigators. Finally, although chapter five dealt predominantly with oversight on tissue storage and not on research, looking back on this study we can see a tension between approaching this issue from the perspective of principles available in the ethical and legal literature and from the perspective of the practical aspects of the actual storage of tissue.

I argue here that these contrasts signify a more general contrast in oversight. Analyzing my findings in conjunction shows that they fit into two philosophies for
Table 1: Two philosophies for ethical oversight – (Dis)approving and Improving

<table>
<thead>
<tr>
<th></th>
<th>(Dis)approving</th>
<th>Improving</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aim</td>
<td>(Dis)approval</td>
<td>Improvement</td>
</tr>
<tr>
<td>Activities</td>
<td>Ensuring</td>
<td>Advising</td>
</tr>
<tr>
<td>Relationships</td>
<td>Authority</td>
<td>Equality</td>
</tr>
<tr>
<td>Objects</td>
<td>Documents</td>
<td>Practice</td>
</tr>
</tbody>
</table>

doing good in ethical oversight: ‘(dis)approving’ and ‘improving’. I distinguish these two approaches to oversight on the basis of how they differ on four aspects: their aim, the sort of activities; the kinds of relationships; and the kinds of objects (Table 1).

The (dis)approving approach works towards (dis)approval of research by ensuring that research is ethical, is carried out within relationships based on authority, and focuses on documents. The improving approach on the other hand, works towards improvement of the ethical quality of research, is carried out within relationships based on equality, and focuses on actual practices, i.e. instead of on the paperwork that describes a physical reality, on the physical reality itself.

Before elaborating on how a (dis)approving and an improving approach to ethical oversight differ, I first want to stress that their higher goals are identical. Both approaches are concerned with the ethical quality of research: they strive to protect the interests of human subjects in medical research while allowing scientific progress to help future patients. It is also important to note that the distinction between the two approaches to ethical oversight is of an analytical nature: in practice, their differences will be a matter of degree and not clear-cut. For example, in reality, a (dis)approving approach will not necessarily be restricted to documents but will also be concerned with actual research practices. However, my point is that a (dis)approving approach will focus relatively more on documents and less on the actual research practices. Conversely, an improving approach will not necessarily be restricted to actual research practices but will also be concerned with documents. However, an improving approach will focus relatively more on actual research practices and less on documents. This
notwithstanding, to get a clear picture of the (dis)approving and improving approaches, I will focus on their contrasts in the next two sections.

7.3 (Dis)approving medical research

The (dis)approval approach to ethical oversight is defined by the fact that its main activity consists of ‘ensuring’ that research is ethical and that it aims to come to an ‘approval’ or ‘disapproval’ of research. Ensuring means that parties work on safeguarding the ethical quality of research, making certain that research is ethical by setting up some sort of external controls. Approval or disapproval is the official endpoint of this process, the guarantee that research is ethical. For example, chapter two showed that Research Ethics Committees (working within a repertoire of rules) ensure that research is ethical by applying rules and regulations, the legitimacy of which is ensured by democratic processes. Furthermore, reviewing proposals in the repertoire of rules results in a final and official approval (or disapproval) of research proposals. This gives patients certainty that research is safe and controlled by independent authorities. In chapter three we saw how research institutions have set up compliance monitoring programs, by some called the “IRB police”, to ensure that researchers comply with rules and the approved proposal when research is ongoing. And finally, in chapter six we described the activity of ensuring with regard to research methodologies. Randomized controlled trials aim to ensure that a study provides a clear and definitive answer by standardizing the study approach and the execution of the study.

A further defining aspect of the (dis)approval approach to ethical oversight is that relationships are based on ‘authority’. The highest levels of authority are the law and governmental oversight bodies, and below that there is the authority of Research Ethics Committees over research and of the research institution over its researchers. These authoritative relationships help to ensure that research is ethical. Chapters two and three, for example, showed that the relationship between researchers and parties involved in oversight on ongoing studies, Research Ethics Committees or other offices at research institutions, is based on authority. Researchers ‘must’ clarify, motivate or
change their research proposals, and in compliance monitoring programs, researchers can be disciplined and obliged to take corrective actions. I also discussed the hierarchical relationship between Research Ethics Committees and researchers in chapter four, where I discussed whether a committee should withhold approval based on the likelihood of non-publication, or could even sanction non-publication.

The final aspect of the (dis)approval approach to ethical oversight is that the main objects of this type of oversight are ‘documents’ that describe research and prescribe research oversight, or in other words: ‘paperwork’. Documentation is used as a means to ensure that research is ethical. For example, documents (i.e. regulations) grant committees the authority to oversee research and prescribe how the ethical quality of research should be ensured. Committees in their turn use documents (i.e. letters) to transfer this authority to research proposals; the approval letter ensures that a study is ethical. Documents are also used for (legal) accountability: committees should be able to show proper documentation of their decisions to the outside world, and researchers should be able to show that their research is ethical by having the approval documents in place. This is not to say that a (dis)approval approach cannot, for example, focus on the practice of ongoing research, but does mean that in doing so, it will focus predominantly on research documents and not on the actual practices and physical reality of research. This point is illustrated by chapter three, where I describe how ‘compliance monitoring’ programs, which aim to oversee the actual conduct of research, focus solely on the documentation of research. Furthermore, chapter two described how the input for ethical review by the Research Ethics Committee consists of documents: rules, regulations, forms, research proposals and letters from researchers. The output of the review process also consists of documents: a letter to the researcher with questions and/or a (dis)approval decision. Furthermore, in chapter three I discussed how compliance-type monitoring will result in reports that describe the quality of a study, and how these will lead to follow-up reports by researchers. A final illustration of the focus on documents can be found in chapter five. Although this chapter was not primarily concerned with the ethics of research conduct, but rather with the ethics of dealing with objects of clinical research (in this case residual tumor tissue), here too, ethical problems are dealt with by focusing on documentation: creating a guideline, based on scientific literature.
7.4 Improving medical research

The improving approach to ethical oversight is defined by the fact that its main activity consists of 'giving advice' on research and that it aims to 'improve' the ethical quality of research. Advice consists of recommendations on how to improve the information to subjects, how to decrease burdens and risks, how to improve the research methodology, and how regulatory requirements could be met. For example, in chapter two I described that Research Ethics Committee members do not consider research proposals as a given to which they can only say 'yes' or 'no', i.e. approve or disapprove. The committee will give researchers advice on how to better protect the interests of subjects, and how to make proposals fit regulatory requirements or the local research setting. This approach helps make disapproval of research proposals very rare. I encountered the same attitude in chapter three: monitors involved in quality improvement programs worked towards improvement of the actual conduct of research. Furthermore, the attitude of giving advice also works the other way around: quality improvement monitors can collect information on the needs and wishes of researchers, and use this to help improve the arrangements and facilities for research at the institution.

A further important aspect of the improving approach to ethical oversight is that relationships are based on 'equality'. Researchers and parties involved in oversight, such as Research Ethics Committees, work together on a more or less equal footing at improving the ethical quality of research. Communication between parties takes the form of advice. In chapter two I discussed the relationship between Research Ethics Committee and researchers and concluded that they were (also) co-workers, both parties working on the ethical quality of research in a collegial fashion. The committee gives advice to researchers, enters in discussions with researchers and can also make use of informal forms of communication because committee members are in close contact with researchers. Chapter four described an example of how a Research Ethics Committee can discuss ethical issues on an equal basis: I suggested that committees could use information on probable non-publication for discussing their worries with researchers. As a final example: in chapter three I described that quality improvement monitoring can only be done properly if monitors work together with researchers in an
atmosphere based on trust. This is a relationship between equals, both parties giving each other feedback on how to improve research and research oversight.

The final defining aspect of the improving approach to ethical oversight is that the main objects of this type of oversight are 'practice'. Although paperwork can also be seen as being part of a practice, the point here is that the improving-type of oversight strives to go beyond paperwork and focuses on the actual practices and physical reality of research. For example, I described in chapter two how a committee can work within a repertoire of production, busying themselves with the practical consequences of oversight, down to a concern for the time and money involved in research and oversight. Furthermore, the committees will take the time to review research proposals in multiple rounds, delving into the practical consequences of ethical considerations in order to give tailor-made advice. Another illustration of a concern with actual practice can be found in chapter five. The issue of proper storage and use of residual (tumor) tissue was put on the agenda, inspired by an actual case from clinical practice. Furthermore, the analysis of this case was fed by knowledge about the practicalities of managing tissue storage. And finally, although the quality improvement programs described in chapter three looked at paperwork (research records) and resulted in paperwork (quality improvement reports), they also went beyond paperwork and focused on practice: monitors would see to the actual conduct of research and discuss their findings in person with researchers, leading to practical advice.

7.5 Reflection on the research methods

I have used several methods in this thesis to answer my research questions and have discussed their specific strengths and weaknesses in the corresponding chapters. Here I reflect on the approach of this thesis as a whole.

To study ethical oversight on medical research with human subjects in practice, I studied Research Ethics Committees because they have a central position in the system for ethical oversight, but I also collected data regarding other offices at research institutions responsible for oversight. My data came from several U.S. and Dutch research institutions and Research Ethics Committees. Much of the in-depth data from
The Netherlands came from one large academic medical center and its corresponding Research Ethics Committee. My thesis is thus based on data from a limited number of settings. However, by collecting data from various sources, ranging from literature databases to ethnographic studies, I was able to get a rich understanding of those settings. Furthermore, by using a multi-method approach in this thesis, I could compare (‘triangulate’) the outcomes of different studies and test the internal validity of my findings. Comparing the findings of previous chapters to the two types of oversight presented in this concluding chapter, I have not found important inconsistencies. The validity of my findings was further supported by discussing them with people who worked in the settings I studied.

However, in qualitative research, where the generation of data through observation and the subsequent interpretation of data depends heavily on the individual researcher, the researcher can be an important source of distortion of the outcome of a study. It is therefore important to reflect on the assumptions and initial hypotheses I brought into this thesis. My initial assumption about Research Ethics Committees was that their core activity consisted of discussing how to support a decision to (dis)approve a research proposal, and that members were solving differences of opinion by justifying their opinions to each other. Taking these discussions and difference of opinion as a focus point also fitted well with my methodological approach of looking for contrasts. This interest in how people justify decisions and opinions led me to the book ‘On Justification, Economies of Worth’ which argues that people justify their actions to others within six different ‘worlds’ (Boltanski and Thévenot 2006). This idea of a moral pluralism fitted well with my intuition, inspired by a thesis on public debate about ethical issues in medicine (Trappenburg 1993), that Research Ethics Committee discussions consisted of some sort of pluralism (or more precisely, a dualism). My earliest conception of this duality in ethical oversight derived from interviews with people involved in monitoring ongoing research during a visiting scholarship at New York University. I hypothesized then that there were two ways to perform ethical oversight, ‘justice’ and ‘education’. This hypothesis fueled later studies and evolved finally into the distinction between (dis)approving and ‘improving’. This insight challenged my initial assumption that Research Ethics Committees are predominantly involved in justificatory discussions in order to (dis)approve research proposals. I had to
conclude that, yes, one of their activities focuses on ‘(dis)approval’, but there is also another way of doing oversight, ‘improving’.

I have discussed the generalizability of my findings on specific aspects of ethical oversight in each corresponding chapter, so here I focus on the question whether the overall distinction between *(dis)approving* and *improving* might apply outside the settings I studied. My finding that Research Ethics Committees use two approaches to oversight can be explained by the fact that they are positioned between two worlds: on the one hand they are part of the judicial world of government regulation, in which approval and disapproval of research is of legal significance, and on the other they are part of the world of the research industry (this includes research institutions for medical research). Since many Research Ethics Committees are similarly positioned, I believe they might use these two approaches to oversight too.

Another reason why I think my findings might apply more broadly, is that many Research Ethics Committees are alike with respect to the kind of research proposals they review, their composition, their legal status, and the process of ethical review (Centrale Commissie Mensgebonden Onderzoek 2007, Centrale Commissie Mensgebonden Onderzoek 2010, De Jong et al. 2010, Decullier et al. 2005, Dickersin et al. 1992, Easterbrook et al. 1991, Easterbrook and Matthews 1992, Fitzgerald et al. 2006, Hall et al. 2007, Stern and Simes 1997). On the other hand, committees also differ. Committees are known to differ with respect to their decisions about particular research proposals, their workload, and the degree to which they are organized, e.g. in terms of working procedures and office support (Abbott and Grady 2011, Centrale Commissie Mensgebonden Onderzoek 2010). For example, my findings on oversight on ongoing research should be generalized with caution, because I found considerable differences between monitoring programs, especially with regard to the position of Research Ethics Committees.

Previous research provides some further confidence that the distinction between *(dis)approving* and *improving* is valid and could apply more broadly. Noah, for example, has discussed whether U.S. Research Ethics Committees are more like adjudicatory bodies making final, legal decisions on research proposals, or more like peer review mechanisms providing iterative feedback to improve research proposals (Koski 2007, Noah 2004, Weijer et al. 1995). Other authors have distinguished a
compliance philosophy from a quality assurance philosophy (Dyck and Allen 2013, Koski 2007, Weijer et al. 1995). Dyck and Allen, for example, have recently discussed the role of Research Ethics Committees and argued that instead of promoting compliance with inflexible and universal rules, the role of a committee should be to facilitate and resource the reflective practice of researchers. They argue that a simple, but significant, shift would be to move ethical review from approving a proposed project to providing guidance and feedback on submitted projects (Dyck and Allen 2013). Also, scholars in the field of ethical oversight supported the validity of (dis)approving and improving in conferences and interviews where I presented my findings. Moreover, my conceptualization of (dis)approving versus improving fits a much broader sociological distinction between ‘civic’ and ‘industrial’ worlds (Boltanski and Thévenot 2006). Still, I have studied only a limited number of settings and I did not investigate other parties involved in ethical oversight besides Research Ethics Committees and research institutions, such as governmental organizations, sponsors and research leaders. Therefore, prospective testing of my analysis of ethical oversight is needed to see whether (dis)approving versus improving captures a clear distinction and to what extent it applies to other settings.

7.6 (Dis)approving and improving in action

In this section I discuss several strengths and weaknesses of both approaches to ethical oversight. In the ensuing section I discuss how the two approaches to oversight interact: how they interfere with each other and how they can be combined.

A major strength of the (dis)approving approach is that it aims to ensure that every research proposal has undergone an ethical evaluation and that the same rules and standards are applied in each case. This can help to protect research subjects from excesses in medical research and can also be beneficial to researchers: they know what to expect from research oversight and can see to it that their research complies with ethical standards. On the down side, the effort involved in complying to detailed rules and standards can slow down scientific progress, and the rigidity of regulatory requirements can impede research with regard to special situations (e.g. emergency

The fact that relationships in the (dis)approval approach are based on authority can be both a strength and a weakness. A strength of this kind of relationship is that it allows oversight bodies to prevent, stop, and correct research that does not conform to ethical standards, and allows for disciplining researchers who have been involved in severe research misconduct. However, oversight that is perceived as policing can hamper public trust, and the use of punitive measures can destroy the ‘informal monitoring system’, i.e. people helping voluntarily with oversight by identifying problems (Holmberg 2004, Levine 1980, Weijer et al. 1995). Finally, relegating the question of whether research conforms to ethical standards to an authority (the Research Ethics Committee) may cause researchers to feel less responsible for the protection of human subjects.

The focus of the (dis)approval approach on documents (e.g. research proposals, approvals, and informed consent forms) can help make explicit to patients, researchers, committees, institutions and other oversight bodies what a particular study entails. This can help ensure that ethical standards are met. However, having detailed documents in place can lead to the erroneous belief that this automatically leads to an adequate protection of the interests of subjects: e.g. detailed informed consent forms are notoriously difficult to understand (Flory et al. 2008). Furthermore, relying on documents can lead to a false sense of security: it is not evident that the paperwork of research (and research oversight) corresponds to the actual practice of research (and research oversight), and thus whether the interests of subjects and science are adequately protected. A benefit of a focus on documentation is that it helps to efficiently transfer research and oversight from one setting to the next, for instance in the case of multi-center studies. And finally, having research and oversight decisions on record protects researchers and research institutions from legal liability and interference by other, ‘higher’ oversight bodies.

Having discussed the strengths and weaknesses of (dis)approving, I now turn to improving. A major strength of improving is that it aims to give researchers practical advice on how to improve their proposals with respect to ethical standards, regulatory requirements and the local research setting. The flexibility of the improvement
approach helps to make advice tailor-made and to find solutions for specific, idiosyncratic problems. \textit{Improving} can also take the form of educational activities, which can help to raise the ethical quality across the entire research community. Furthermore, \textit{improving} works both ways: information from researchers can be used as feedback to improve the quality of the ethical oversight system and the institution’s arrangements for research. However, the flexible nature of \textit{improving} could become a weakness if Research Ethics Committees would be too flexible in how they review research proposals. It could mean that not every research proposal would undergo a proper ethical evaluation; potentially leading to research that does not meet ethical standards. Furthermore, a flexible approach to oversight can make the terms of reference for researchers unclear, which could make it difficult for them to set up their study in such a way that it will be acceptable to all parties. This could especially be problematic for multicenter studies: needing to negotiate proposals for research anew with every committee would grind these studies to a halt.

Furthermore, carrying out oversight within relationships based on equality can be beneficial to both the quality of research oversight and of research, because it stimulates an unrestricted exchange of information between oversight parties and researchers (McCormack et al. 2012). Working within equal relationships supports a constructive discussion between researchers and oversight parties and allows for additional forms of communication outside (formal) meetings and letters. Furthermore, the fact that researchers and oversight parties are on a somewhat collegial footing supports an atmosphere of trust in which an ‘informal monitoring system’ can prosper and can make researchers feel more responsible for the protection of human research subjects (Levine 1980). A major drawback of performing ethical oversight within an equal relationship is that it can be difficult to take corrective actions towards research or researchers when ethical standards are breached.

The improvement approach to ethical oversight focuses on the actual practice of research, which is a major strength. Overseeing the actual conduct of research and how it affects human subjects in practice can lead to practical and tailor-made advice for both researchers and the research institution on how to improve subjects’ protection. The focus on practical aspects of oversight also helps to take into account how oversight is implemented, for example to what efforts and costs oversight amounts,
which can help to make oversight less burdensome to researchers. A weakness of a focus on practice instead of on documents is that there will be less documented information available about research and its oversight, making the system less transparent to outsiders and making it more difficult to exchange information from one research setting to the next (e.g. in multi-center studies). A final weakness of a focus on practice is that if researchers, committees or other parties engage with the law (e.g. governmental oversight bodies or liability cases), the fact that things were in order in practice is not sufficient: the legal system looks at documentation (records), and when documentation is inadequate, parties are vulnerable to legal action.

7.7 (Dis)approving and improving in interaction

Both philosophies for ethical oversight thus have their specific strengths and weaknesses for research subjects, researchers and oversight bodies, so choosing between them is complicated. Moreover, the choice will depend on the specific needs and wishes of a research institution or Research Ethics Committee, on its organizational structure, on the type of research conducted there, and on the research culture. These intricacies make it impossible to give a general advice about which type of oversight to choose. Moreover, little is known about the actual effects of ethical oversight on research subjects’ protection and research, let alone about the effects of different approaches to oversight (Abbott and Grady 2011, Coleman and Bouesseau 2008). This too, makes choosing between them difficult. Based on my findings, I think that the following general advice is appropriate: be aware that it is possible to choose between two approaches to oversight and take heed of their specific strengths and weaknesses. Still, a third option would appear to be not to choose, but to use them both. Is that indeed a viable route? To help answer this question, in the remainder of this section I discuss how the two approaches to oversight interact: how they interfere with each other and how they can best be combined.

The previous chapters have shown that the two approaches to ethical oversight can coexist in a setting without much interaction, for example when the discussions within Research Ethics Committee meetings simply alternate between the two
approaches (chapter two). So, combining the two approaches is possible in principle. However, I also found that when the two approaches to oversight lead to incompatible courses of action, i.e. when they conflict, the (dis)approval approach mostly dominates and will determine the course of action. Examples of this can be found in chapter two, where I described how a Research Ethics Committee decides to formally review and (dis)approve research proposals, even in cases where it is considered a waste of time from a quality improvement perspective. Furthermore, chapter three illustrates how a quality improvement approach to monitoring will quickly be seen as compliance monitoring (a (dis)approval approach), for instance, in case findings will be used by the Research Ethics Committee to punish researchers. Moreover, most of the scientific literature, e.g. the Oxford Textbook on Clinical Research Ethics, I encountered during my studies focuses on the (dis)approval philosophy (Emanuel et al. 2008). Legal documents and ethical guidance documents also air the spirit of (dis)approval, e.g. these documents explicitly vest Research Ethics Committees with the task of approving research.

Still, even though (dis)approval is the dominant approach, this does not mean that improving cannot, or does not, play an important role in oversight. For example, in chapter three I have described how research institutions have set up monitoring programs that work according to an improvement philosophy. Furthermore, in chapter two I described how a Research Ethics Committee employed an improvement approach that was meant to be supportive of a broader (and dominant) (dis)approval philosophy: the committee spent much time on giving researchers advice on how to improve their proposals in order to help get it approved. Using a combination of both approaches can in principle be a viable way to perform ethical oversight.

Nevertheless, whether and how to combine a (dis)approval and improvement philosophy merits careful consideration. The question of how to set up a monitoring program illustrates this aptly. In chapter three I have argued that using an improvement approach to monitor ongoing research is generally the better choice, because it will better contribute to protecting research subjects. However, I also argued that quality improvement monitoring should not be carried out by Research Ethics Committees, but by a separate office. The reason for this is that people are aware that committees are required by law to (also) work according to a (dis)approval approach. So, even if a
committee would want to monitor using a quality improvement approach, researchers will still fear that it will in practice end up in ‘policing’, i.e. compliance monitoring according to a (dis) approval philosophy. This would make it very hard for monitors to be trusted, a precondition for effective quality improvement monitoring. Following the same line of reasoning, I have argued that separate quality improvement offices should not engage in formal, i.e. (dis)approval-type, investigations of research misconduct: if they did, all their activities, including their quality improvement activities, would be perceived as policing, i.e. (dis)approval-type oversight.

So, although combining a (dis)approval and improvement philosophy within oversight bodies and within research institutions is possible and worthwhile, it is not uncomplicated. It should be carefully considered how the two approaches might interact. Explicitly distinguishing between the approaches towards researchers, for instance by having separate offices for each approach, can be helpful in this respect (Timmermans and Berg 2003).

7.8 Conclusion

In this thesis I ventured to open the black box of ethical oversight on medical research. We now return to Jan’s (the research subject mentioned in the prologue) questions about ethical oversight on research. Because we have not performed a detailed study of his case, we are not in a position to answer his first questions (whether it had been a good idea to allow an alteration of his treatment based on the MRI; whether he was informed properly; and whether in his particular case the knowledge gained by the study was worth the risks). However, we can answer his more meta-level questions: who decides about the ethical quality of research; who ensures that the ethical quality is in order; and how do they do that?

These would be my answers to him. Research Ethics Committees have the authority to decide whether to approve or disapprove research, but making approval decisions is not their only aim: they also work towards improvement of the ethical quality of research. Furthermore, ensuring that the ethical quality of research is in order is done by Research Ethics Committees, but also by others, such as governmental
bodies and offices at research institutions. Moreover, ‘ensuring’ is not the only activity in this respect: committees and other bodies also advise researchers. Currently, Research Ethics Committees and other oversight bodies focus mainly on the paperwork of research proposals and less on the actual practice of (ongoing) research, but working together with researchers to improve the practice of research is a viable alternative.

To conclude, although (dis)approving is probably closer to what people would expect a Research Ethics Committees to do and although it is indeed the dominant approach to ethical oversight, improving is a valuable alternative for supporting scientific progress and guarding the interests of research subjects. What is more, distinguishing between a (dis)approval and an improvement philosophy points to a final, more meta-level lesson, relevant to Jan and other parties interested in ethical oversight. A better understanding of the practice of ethical oversight on medical research can itself be used in two ways: to (dis)approve of current practices of oversight or to help improve those practices. My studies indicate that although the first way is likely to be dominant, the second way might be just as valuable.
References


Savulescu, J. (2002) Two deaths and two lessons: is it time to review the structure and function of research ethics committees?, *Journal of Medical Ethics*, 28, 1, 1-2.


