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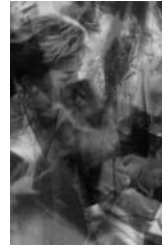
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Research Ethics Review and the Sociological Research Relationship

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ABSTRACT

For years, sociologists working in other countries or UK-based medical sociologists have complained about the effects of having to seek approval from a research ethics committee (REC) or its equivalent before starting work. With the arrival of the ESRC's Research Ethics Framework, concern about ethics review has expanded to sociologists working on a wider range of topics. This article uses ethnographic data from a study of UK RECs to examine how these bodies assess applications from social scientists, particularly those proposing qualitative research (which opponents claim is given an especially hard time by such committees). These data challenge the idea that RECs are somehow ideologically biased against qualitative research and that they cannot give an adequate assessment of applications from sociologists and other social scientists. The article concludes by suggesting sociologists' time would be better spent studying the institutional nature of the university RECs stimulated by the ESRC.

KEY WORDS

ethnography / governance / national health service / research ethics

Sociologists' objections to the ethics review of proposed research by some form of committee are not new. In the US they date back to the 1970s, and in the UK, particularly among those who work in medical sociology, concerns have been noted since the early 1990s when research ethics committees (RECs) began to expand their review of social science research in the National Health Service (NHS). Yet with the publication of the ESRC's *Research Ethics Framework* (REF) in 2005, the issue of research ethics review has come to the fore when we think about the relationship between sociologists as researchers

and those we research: the introduction of such a review introduces a mediated element to the research relationship. It is no longer just the sociologist and the participant, but rather a three-way relationship, with the actions of the researcher constrained, in some part, by the need to gain ethics approval.

Yet the spread of ethics review to most social science research in the UK comes at a time when the whole idea of 'anticipatory' review of, especially qualitative, sociological research, has come under attack as never before. While this article does not attempt a review of this literature, there are recent noteworthy individual contributions (e.g. Dingwall, 2006a, 2006b, 2007) and wider explorations of the attitudes of the social science research community that suggest these views are not unrepresentative (Crow et al., 2006; Richardson and McMullan, 2007).

The aim of this article is to draw on empirical research looking at how RECs in the NHS make decisions about social science research in order to think about the possible impact of the ESRC's Research Ethics Framework on the research relationship. Since, historically and institutionally, these committees employ a 'biomedical model' of research ethics that social scientists complain so much about, they make a good site to test some of the claims being made about the impact of ethics review on sociological research. How such committees think about social science, particularly qualitative social science, may provide a useful test of the dire predictions being offered of the impact of the ESRC's REF on how sociologists do their research.

My central claim is that traditional sociological discussions of REC review have tended to misrepresent what RECs do and how they treat qualitative research, and as a result have distorted understandings about how REC review impacts on the research relationship. Most importantly, they have over-emphasized the difference between sociologists and other, mainly biomedical, researchers in an attempt to distance sociological research from the need for ethics review. While there are differences between different kinds of research, they are differences of degree, and do not exclude sociologists from the belief underpinning the REC system that, however well intentioned researchers (of whatever kind) are, they are not the best people to decide on the risks and benefits of their research.

Underpinning the sociological critique of ethics review is an alarming methodological lacuna. While the early years of sociological exploration of research ethics review were characterized by rigorous empirical data gathering (Barber et al., 1973; Gray et al., 1978), with a few exceptions (De Vries et al., 2004; Dyer, 2004) more recent work has tended to rely on a basic 'input/output' model of research, whereby inputs (the application form) and the outputs (the committee's decision) serve as data from which assumptions are drawn about REC decision-making and internal processes (Gelling, 1999; Herdman, 2000; Hunt, 1992; Lyttle, 1998; Truman, 2003; Williams, 1997). By drawing on observations and interviews, data 'internal' to the REC process, this article provides a wholly different perspective. Thus the aim is not to provide a judgement of whether particular RECs' decisions were 'fair' or 'unreasonable', but

rather to provide information to allow one to compare the internal practices of such committees (regarding their attitude towards qualitative research, for example) with sociologists' claims about such practices, based on external information.

Method and Sample

This article presents results from the UK arm of a four-country comparative ethnography exploring the impact of European legislation on research ethics review (Hedgecoe et al., 2006).¹ In addition to ethnographic observation of committee meetings, this research involved semi-structured interviews with 58 people from a range of relevant backgrounds: policy-makers, pharmaceutical industry researchers and executives, and, most pertinently for this article, members of research ethics committees themselves.

There are currently around 150 NHS RECs in the UK; these were first set up in the late 1960s and review all pharmaceutical clinical trials, as well as any research involving NHS patients, staff or premises, medical records and human tissue. Coordinated by the National Research Ethics Service (NRES), these RECs have between 12 and 18 members (with a mix of medical experts and 'lay' members), meet monthly and are supported by administrators. There is a nominal difference between Local RECs (LRECs) and Multicentre RECs (MRECs), but these are steadily being removed under a series of recent changes.

Prior to access being sought from committees, the study itself received ethical approval from an NHS REC (not connected with the research) after which individual RECs were approached to see if they were interested in taking part. It is worth noting that initially the REC that reviewed this research did not think that this study required ethics review (I had not made it clear enough that observations would be carried out on NHS property, and NHS staff interviewed), and had to be persuaded to formally accept my application. This does not conform to the 'ethics creep' model proposed by some social scientists, where regulatory systems expand to cover new activities and disciplines (such as the social sciences) (Haggerty, 2004; see also Lederman, 2006). If anything, this an example of 'ethics withdrawal'.

Two RECs were approached but declined to take part. Subsequently, permission was given, research carried out and members interviewed at three different RECs.² St. Swithin's LREC is named after a teaching hospital known internationally for its medical research. The committee, like all RECs, has no formal link to the hospital and is answerable to the relevant Strategic Health Authority and NRES, yet it can trace its origins back to the original REC set up at the hospital in the late 1960s, and can thus be seen as more institutionally situated than most other RECs in the UK. Northmoor and District LREC is the result of the merging of two LRECs (a year prior to my observations starting) in and around the town of Northmoor. The majority of the committee meetings are held in the hospital in the middle of town (a District General hospital of 500

beds), although some meetings are held in the hospital in nearby Greendale. Both hospitals carry out some research. Coastal MREC is one of the original 10 Multicentre RECs set up in 1997. As such it has never had any institutional affiliation. It meets in a room rented from a learned society in a town conveniently located for its members, whom it draws from a far wider geographical area than the LRECs.

While I cannot make claims for these committees as *statistically* representative of NHS RECs they do cover a range of characteristics which mean they can be considered 'typical'. All three committees reviewed a wide range of studies, from pharmaceutical-backed clinical trials (phases II–IV), through surgical trials, public health research, qualitative social science and student (post and undergraduate) research. They all conformed to the Department of Health's 'rules' regarding the composition and processes of the committee. The only area where there is a gap is that none of these committees was designated 'Type 1', meaning that they did not review Phase I, first in human clinical trials, although St. Swithin's regularly reviewed basic physiological research, which shares many of the same issues (around safety, for example) as Phase I studies.

My role in the committee meetings was as an observer (rather than participant-observer). I sat at the same table as the REC members and took extensive notes (including verbatim quotes) over the course of each monthly meeting (which usually lasted between three and four hours). My observations (and subsequently my interviews) were not focused on any one aspect of REC practice, but rather sought to provide a detailed description of what goes on in an REC meeting. Obviously my approach was partly structured around the project funding (how has European legislation, the Clinical Trial Directive, impacted on REC practice? How are clinical trials applications dealt with?), but also the wider debates within the literature such as the roles different kinds of expertise play in committee meetings (Dyer, 2004), and how RECs arrive at decisions (Moreno, 1995).

While all REC members were aware of, and had approved, my research (RECs regularly have observers in meetings, so my presence was not unusual), applicants to the committees, who are normally asked to come to meetings to answer questions on their proposed research, were largely unaware of my status. While one of the RECs used name places to indicate my observer role, this was not brought to applicants' attention, and for most applicants I was probably just another committee member.

In addition to my observations, informal discussion with members took place before meetings started and over lunch, a sandwich buffet which was served before (St. Swithin's and Northmoor LRECs) or midway through the meeting (Coastal MREC). I also met and spoke with members of these, and other, RECs at various training events and conferences organized by COREC (Central Office for Research Ethics Committees, NRES'S predecessor) and AREC (Association for Research Ethics Committees), the independent organization that represents the REC community.

Table 1 Information on observations and interviews

	Observations			Interviews with members		
	Start date	End date	Total number	Expert	Lay	Total
St. Swithin's LREC	July 2005	June 2006	10	9 (inc. Chair)	2	11 + administrator
Northmoor & District LREC	November 2005	November 2006	12	6 (inc. Chair)	2	8
Coastal MREC	September 2005	August 2006	11	7 (inc. Chair)	5	12 + administrator
Totals			33	22	9	33 (31 members + 2 administrators)

Note: Information on interviewees and committee membership has been limited to maintain anonymity. Listing the expertise on a committee would almost certainly identify the committee (and hence members) concerned.

Interviews were sought with members toward the end of the observation period, when some form of relationship had been established and I had enough experience of the way in which committees went about their work (as well as individual differences between the RECs) to be able to ask in-depth questions. In addition, I interviewed four other REC members, whom I identified because of their role (lay chair of a REC), the committee that they sat on (a specialist children's hospital) or their long experience of sitting on RECs and hence an insight into how things have changed over time. All interviews were recorded, transcribed and analysed with the help of Nvivo QDA software.

Results

It might come as some surprise to social scientists that members of RECs share much of their scepticism about the way in which qualitative research is or has been dealt with by such committees. For example one member of St. Swithin's LREC suggested that 'We probably don't feel we have the expertise to fully understand the aims and motives and methods of qualitative research', and because of its historical links with a major medical research institution, this REC reviews few qualitative applications. Similarly, members of Coastal MREC clearly thought that qualitative research was, at least historically, problematic for NHS RECs. For example, one lay member compared Coastal favourably to her experience at another REC, noting that: 'I think this REC fortunately has enough sense to see that it is valid and viable if it's properly done. But certainly I've attended a meeting where people were saying "well this isn't science".' It is also worth noting that at least two members of this committee and one member of Northmoor LREC suggested that one of the reasons they joined a REC in the first place was their belief that qualitative research was being dealt with harshly and needed more informed members to speak up for it.

Yet the framing of this discourse on the part of REC members is largely historical, something that is rarely admitted in social science discussions of REC review. RECs are not static, in terms of their institutional context (the UK ethics review system has undergone continual change since the early 1990s), their membership (people come and go on individual committees; their make-up and expertise change over time) or the kinds of decisions the 'same' REC can make. While committees are aware of their previous decisions and wish to avoid being seen as inconsistent, their concerns and ideas change and develop over time.

While some medical members of these committees did emphasize their lack of familiarity with qualitative research, none expressed hostility. In addition, all these committees had members who were experienced in qualitative research and who could explain the more technical issues to other members. This is true even in St. Swithin's where one member was happy to contribute to discussions on qualitative research but was reluctant to be seen as a qualitative 'expert' lest this allow his medical colleagues on the committee to duck their responsibility to get to grips with this kind of research. And when it comes to the more technical issues (around the kinds of things that ethnography can explain, for example) these members do what many REC members with specific experience tend to do, which is inform their colleagues of the (possibly) idiosyncratic features of a particular way of doing research. This is what oncologists, or others with experience in cancer care, do when they explain to their colleagues on a REC that very often clinical trials for cancer drugs do not measure success in terms of life expectancy but rather may use proxy measures (such as tumour shrinkage), or what psychiatrists do when they explain how a particular set of standardized questions tests a particular mental state. In this respect, contra the prevailing discourse in sociology which is one of difference and separation (how different sociological research is from biomedical research), RECs deal with qualitative research in the same way as they deal with other kinds of research; they may query specific practices and allow experts in the areas concerned to clarify and set them in context.

This becomes clear if we consider what members think RECs are for. While complaints from both biomedical and social scientists tend to represent ethics review as a 'hurdle' or impediment to research, REC members see their role as one of supporting or encouraging research, in addition to the more obvious duties of protecting patients and ensuring informed consent. For example, one expert member of Coastal MREC suggested that:

It's part of the ethics of being on a Research Committee. If you actually are obstructive of research, this is not an ethical way of doing your business. The opposite is facilitating, that's what we're taught, that facilitating the research is the job of the Committee.

When an application is rejected there is no sense of celebration on the part of REC members, but rather regret and disappointment that this decision had to be made. This attitude is not just about being pro biomedical research, but

rather carries over into a supportive attitude towards whatever research comes before the committee, even qualitative social science.

So, for example, when reviewing an application proposing qualitative interviewing of nursing staff working on a cancer ward about the impact of their work on their lives, Coastal MREC presented the applicant with a technical bureaucratic problem caused by the researcher's independent status. The chair's reaction to the researcher's concern over this point was to say, 'This is not a problem we are throwing at you, but a problem we are trying think round', and indeed the solution suggested by one member (which was to affiliate with an academic institution the researcher had previously collaborated with) solved this particular problem.

For the committees I observed, it was part of their role to support research and to offer advice that allowed it to progress (rather than place hurdles in its way). Though on occasion social scientists have accepted that REC review improved their research (Kent et al., 2002), such a view is not typical of the discussions that researchers make (Richardson and McMullan, 2007), and, I suggest, one of themes underpinning this is the need to emphasize the difference between social scientific and biomedical research. To admit that RECs may play a supportive role for research is to admit that sociologists may have more in common with other researchers than they may wish to admit.

Similar issues are raised by those sociologists who resist the need for REC review on the grounds of risk, and who claim that we do not harm people in the same way as biomedical researchers. Even if we accept this, and it is important to note that such a position downplays the nature of such harms (Bosk and De Vries, 2004; Evans et al., 2002; Singer et al., 2000), it is only a matter a degree. And, in the same way that biomedical researchers sometimes play down the risks that arise from their research, so can sociologists overlook the possible harms that might result from their work.

A good example of this is the issues faced by a REC when NHS staff carry out social science research as part of an educational degree (usually an MSc or PhD). Often these researchers wish to explore topics relating to their own professional practice; for example, the views of their own professional group on a specific piece of legislation, or how such professionals implement particular policies. St. Swithin's LREC has even coined a phrase for this situation, called the 'nurses study', after a senior nurse applied to do research as part of an MSc, looking at nurses' attitude towards performance-related pay. Although the study was going to be on the nurse's own team, the committee was generally inclined to approve the application since the results would be restricted to a dissertation. But when the applicant came before the committee it became clear that she had wider goals for the results of this work, including feeding into policy decisions. She also made statements that worried the REC, about wanting to work with 'people I trust and who trust me'. The REC suggested that the applicant study a team at another hospital, to avoid the issues of conflict of interest, but the applicant was not happy, claiming the REC was 'stifling research'. The committee directed her to the head of nursing research and apparently the applicant went so far as to complain to COREC, NRES's predecessor.

What worries RECs most about such studies (and these kinds of concerns were expressed in all three committees I observed) is that when researchers choose to research those members of a professional group that they work directly with, often in a supervisory role, researchers are often oblivious to the potentially coercive nature of supervisors asking those they manage to take part in research, especially research which may require them to reflect on their practice.

From the perspective that sees ethics review as a form of 'censorship' (Dingwall, 2006a), it maybe possible to see a REC's request that such research should be carried out on groups of professionals over whom applicants have no supervisory role as 'unreasonable'. Yet for RECs, seeking to avoid the possible coercion of research participants and the kinds of risks and harms that might occur when someone's role is blurred between that of researcher (who may deal with revelations concerning practice in one way) and supervisor (who may respond quite differently) balances the interests of researchers and potential participants in a deft manner.³

The kind of 'blind spot' that means sociologists miss these types of risk occurs, not because these sociologists are bad people, but rather because they are *researchers*, and, if 40 years of REC review has taught us anything, it is that researchers are not the best people to decide on the risks and benefits of their work, having, as they do, a tendency to underestimate the former and overestimate the latter.

At the heart of sociologists' claims of the 'difference' of their research, and hence the inappropriateness of ethics review, is ethnography, where the problem revolves around committees' requests that informed consent be sought, and that such committees require applicants to be able to list all the possible risks and harms that might arise, an apparent impossibility given ethnography's inherent 'flexibility':

In ethnography, both the research focus and the research design typically emerge during the course of the research ...the researcher is rarely able to give a full account at the outset of what the research will involve. Flexibility of research design, and capacity to respond to insights emerging from early empirical work, are distinctive contributions of ethnography, but complicate the process of obtaining prior informed consent. (Murphy and Dingwall, 2007: 2227)

Presumably the same issues of flexibility and ambiguity occur when ethnographers apply for funding to carry out their research. When putting together a funding application, an ethnographer has to explore the possible directions the research will take, the issues that may arise and the methodological approaches that may be taken. It is not clear why the requirements for this kind of explanation on the part of funding bodies are perfectly reasonable (or at least not a fundamental threat to the nature of ethnography) while on the part of ethics committees, such requests (which from my observations do not require the detailed breakdown of risks suggested by critics) are unacceptable.

Based on my observations, it is not clear that UK NHS RECs operate the kind of inflexible attitude towards informed consent as portrayed in sociologists' complaints. For example, it is not clear that RECs insist on 'anticipatory consent'; in one case, Coastal MREC was reviewing a proposal to study specialist paramedics with a view to evaluating the role, seeing whether it reduced the number of people who were repeatedly admitted to A&E (so called 'frequent flyers'). One of the methods used was the observation of paramedics in practice. An issue for the REC was that although the paramedics themselves would have signed informed consent forms prior to the research taking place, it was not clear that the same could be said for patients the paramedics were treating. When asked about this, the applicant agreed, stating: 'The point is that it's the practitioner who's being observed rather than the patient: obviously the patient will still be there. I will give them information as we leave, to not interfere with clinical care.' The committee debated some solutions including the use of 'proxy consent', with the practitioner him/herself taking consent on behalf of the patient. This option was rejected in favour of an agreement that the study allow for retrospective withdrawal from the research, if, when contacted later, a patient decided that they did not wish to be included. Such a solution, which allows the research to go ahead yet also acknowledges patients' rights to informed consent, balances the interests of researchers and participants in a way that readers of sociological critiques of RECs might scarcely think possible.

It is even possible for RECs to approve ethnographic research carried out without the informed consent of some of the people being observed. This is most obviously the case in my own research. When I sought and received REC approval for my research on RECs the need for informed consent covered the committees themselves (it was made clear that the whole committee had to approve; my presence could not be cleared just by the Chair), and the interviews with individual committee members and administrators (for which I produced specific participant information sheets and consent forms), yet there was no requirement that I seek consent from applicants to committees, whose applications I heard being discussed and whom I observed if they attended the meeting. Clearly this approach was acceptable not just to the REC that gave me the original approval, but also to the three committees that allowed me into their meetings.

One condition of my presence was that I sign a confidentiality agreement requiring me to seek approval from each REC for use of material gathered during meetings.⁴ In this way the RECs can double-check applicants' anonymity in my publications, and ensure that no commercially sensitive data are released. This situation is, of course, strongly reminiscent of normal ethnographic practice, whereby practical constraints mean that consent cannot be sought from everyone one meets. Rather, the ethnographer ensures, through anonymizing people, places and events, that individuals are protected from possible harm. That this approach was approved by *four* separate NHS RECs suggests that the characterization of such committees as incapable of accommodating ethnography is somewhat misleading.

Discussion

The main point of this article has been to emphasize that NHS RECs are not inherently hostile to social science research, especially qualitative research. As a result of these committees' origins in professional self-regulation, they may not have the same expertise in qualitative research that they have in medical topics, yet this does not translate into hostility to this work. Interviews with members make clear that if in the past committees have given qualitative research a rough ride, this may be more to do with a lack of knowledge on the members' part rather than the ideological objection to qualitative research claimed in so many articles from social scientists. One obvious problem is a lack of clarity over how researchers intend to analyse qualitative data. As one member suggested: '[qualitative] language is dense, and it's a technical language, isn't it, when you say how you are going to analyse qualitative data?' For some social scientists, it is unreasonable for committees to ask researchers to explain the meaning of technical terms such as 'snowball sampling' (Tolich and Fitzgerald, 2006). Yet applications to UK RECs are required to be written in non-technical language, not just for the lay members of the committee, but also for the expert members: the specialized nature of modern medicine means that descriptions written in technical language may have limited comprehensibility, even among medically trained REC members. The idea that social scientists should not have to explain their technical language smacks of special pleading.

Yet acknowledging RECs' generally supportive attitude towards all research (including social science) is not in the interests of social scientists who, like all researchers, resent external restrictions on their work. This position was neatly summed up by the Chair of Northmoor and District LREC, who also has research interests, when he said:

I've been a member and a chair of a REC but I also had the experience of putting in applications and having the frustrations of, of applications being rejected or amended ... and I suppose when I'm in the position of a researcher, I do feel some of those emotions [i.e. negative attitudes towards RECs], you know, to be, to be quite honest, but I, I, and I think that's almost inevitable, you know. You've, you've spent ages working on your project. You can't see what's wrong with it, or if anyone else could possibly see that there was wrong with it, and the truth is that you're too close to it to, to see the thing.

It is interesting that for all social scientists' attempts to distance their work from biomedical research, they tend to rely upon the same kinds of arguments as biomedical scientists when disputing the need for ethics review. This is not a new observation; Judith Swazey pointed this out nearly 30 years ago (1980). The point is rather that it is time for social scientists including sociologists to accept that we *are* like other researchers and that the values expressed in RECs are the values of our profession (Lacey, 1998; Mills, 2002). After all, as Bosk and DeVries point out: 'none of us truly objects to the goals of IRB [i.e. REC] review – we all wish subjects to be treated with respect, protected from harm, and saved from embarrassing exposure' (2004: 256).

If social scientists accepted ethics review as a legitimate part of the research process and accepted that RECs have a role to play in the research relationship we have with those people we study, then we could begin to examine the university RECs, which have become firmly established as a result of the ESRC's REF, with a genuinely critical eye. One of the important differences between the NHS REC system and the Institutional Review Board (IRB) system in the USA is that NHS RECs are not formally associated with specific research institutions. While some of them, such as St. Swithin's LREC, may have a long-term relationship with a specific hospital, the committee is not answerable to the hospital, but rather to the far higher, and less local, Strategic Health Authority. This means that many US social scientists' complaints about IRB review, which centre on how such committees act to protect the institution from research exploring sensitive topics (Bosk, 2007: 200), are largely irrelevant to NHS RECs.

Yet it has largely escaped the notice of those commenting on the rise of ethics review in UK social science that British university RECs *are* institutionally located, and there is already some preliminary anecdotal evidence that such committees are prepared to act against researchers investigating potentially controversial topics such as paedophilia (Goode, 2007) or student involvement in sex-work (Roberts et al., 2007). This is a far more detailed and nuanced threat to British sociological research than the general worries about ethics review being a form of 'censorship', and committees not being able to 'handle' ethnography. It is a problem that requires many of the skills and much of the knowledge about investigating institutions and social relations that sociologists can provide, yet a solution requires us to accept the legitimacy of ethics review in principle, and the fact that, as just another kind of research, qualitative social science can be reviewed by a REC.

With the arrival of the ESRC's REF, most sociologists in the UK join those of us focused on medicine and health in being required to submit our applications to ethical review. The research relationship of the future is a little more crowded. Yet, based on empirical research on committees that can fairly be described as *less* sympathetic to qualitative research than the university or faculty committees envisaged by the ESRC, it is not clear that this is necessarily something to be worried about. The issue facing sociologists in the UK today is not about research ethics review *in principle*, but rather the specific institutional form that RECs reviewing the majority of social science research currently take. There is a pressing need for sociologists to move away from an empirically unsupported critique of RECs as a whole, towards an engagement with the issues that may genuinely threaten the research relationship.

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Notes

- 1 Only the data from the UK are presented here. Firstly, in two out of the four countries (Hungary and Portugal) the committees observed did not review any social science research; while committees in Sweden did do so, experience of comparative ethnography, and the unfortunate way in which differences between ethics review systems tend to get erased in broader discussion in this area (e.g. Tolich and Fitzgerald, 2006) led to a focus on the UK in this article.
- 2 The names of these committees have been changed to make them anonymous.
- 3 On a personal note, I suspect that if one's complaint about such a decision is based not on your research being stopped but simply being asked to research on another group of people (perhaps even on the same site), then one's standards for unreasonable behaviour are set rather low.
- 4 Such agreements are standard documents for RECs, which often have observers attending meetings, rather than being specifically drawn up for my research.

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