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*J. Med. Ethics* 2004;30;313-317
doi:10.1136/jme.2003.004051

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Local issues should be addressed through the governance framework and not through the research ethics committee system

Abstract

Local review of research by ethics committees in the UK has long been held to be an important right of the local research ethics committee and, even with the introduction of the European Clinical Trials Directive, the governance arrangements for research ethics committees continue to allow for local review of multicentre studies. There is no requirement for local review in either the European Union directive or in the guidelines on good clinical practice, and there is little evidence of it anywhere else in Europe. The idea that there can be “local”, as opposed to “central” ethical issues in research is an interesting one, which raises important issues about the nature of research ethics and ethical review. The aim of this paper is to argue that there are no such things as local issues in research ethics, and suggest that those questions currently addressed as local issues properly belong within the research governance framework.

Even within the MREC-LREC system the right of local committees to review multicentre studies for “local issues” was retained and, from the perspective of the intended cooperative working arrangements set out in the 1991 guidance, it could be argued that “local ethical issues” were invented at this point. The recent European Clinical Trials Directive seeks to streamline the process of review and requires that “Member States shall establish a procedure providing, notwithstanding the number of Ethics Committees, for the adoption of a single opinion for that Member State”. The directive also stipulates that the ethics committee “shall consider”, among other things, “the suitability of the investigator and supporting staff” and “the quality of the facilities” although there is no mention in the directive of this being done at any specifically local level, or other than as part of the single opinion for the Member State.

The Department of Health Governance Arrangements for Research Ethics Committees (GAFREC) sets out the framework for review of locality issues, which are limited to:

- the suitability of the local researcher
- the appropriateness of the local research environment and facilities
- specific issues relating to the local community, including the need for provision of information in languages other than English.

The role of the research ethics committee is also discussed in the latest draft of the guidelines on good clinical practice (GCP). These guidelines state that: “One of the responsibilities of the Ethics Committee is to safeguard the rights, safety and wellbeing of all trial subjects and to provide public assurance of that protection by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of the facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent. Special attention should be paid to trials that may include vulnerable subjects.”

However, there is once again no specific reference to local review, only the requirement that “Member States shall establish a procedure for the adoption of a single Ethics Committee opinion for each Member State”. In providing for the possibility of the local review of multicentre studies in the UK, the DoH in GAFREC currently does appear to be going beyond the requirements of the European directive and of the GCP guidance.

It is, of course, entirely possible for different individuals, acting from
sound moral principles, to come to
different conclusions about the ethical
acceptability of any given research
study. However, there is an inherent
tension in the idea that there can be
local ethical issues (as opposed, one
must presume, to “central ethical
issues”) that render a study ethically
sound in one place and not in another.
The intention in this article is to
argue that there are no such things as
local ethical issues and that the
review of matters currently described as
“local issues” should not be the
responsibility of a research ethics
committee.

ARE LOCAL ISSUES ETHICAL IN
NATURE?
The ethical review of research must
address several issues. These include,
but may not be confined to, the safety
and protection of the vulnerable human
participant, questions of equipoise and
the value of the research, the appropri-
ateness of the methods and balance of
risk and benefit, and the arrangements
for a proper, informed consent by
participants who have the capacity to
give consent. These issues are mostly
determined when a study is in the
design stage. Investigators must be able
to justify the research on the grounds
that there is a worthwhile question, to
which we do not know the answer. They
must be convinced that the question is
capable of being answered, in ways that
do not involve unacceptable danger to
participants, and must create a design
that makes appropriate use of methods
such as randomisation,blinding, placebo,
takes into account availability of
other treatments for the condition in
question, is based on an adequate
sample with power to detect a signifi-
cant difference in outcome, and so on.
They then have to produce an explana-
tion of the study and all its implications
that is comprehensible to all likely
participants. In doing this they should
have in mind the probable age and
mental status of participants, and the
possible likelihood of involvement of
participants from varied ethnic or cul-
tural backgrounds. These questions
will have scientific importance, as they will
impact upon the homogeneity of the
sample and the introduction of con-
 founding variables. They will also be of
ethical significance and will be the
issues that a lead or main ethics
commitee will consider. The ethical
acceptability of the study design or
protocol will not, however, vary in virtue
of the locality in which the research is to
take place. We may disagree about the
use of placebo, the additional battery of
tests over and above normal treatment,
the risks that arise from the withdrawal
of standard treatment, or the accept-
ability of the use of deception, but if we
find these things acceptable or unaccept-
able we should be of the same opinion
regardless of the area in which the study
is to take place.

Local issues as implied by the
European Union (EU) directive and set
out explicitly in GAFREC, are confined
to the suitability of the local researcher,
the appropriateness of the local research
environment and facilities, and specific
issues relating to the local community,
including the need for provision of
information in languages other than
English. It would of course be unethical
to allow an incompetent investigator to
run a clinical trial at a particular centre.
It would also be unethical to present the
local ethnic community, many of whom
do not speak English, with information
and consent materials printed only in
English, or to expect an English speak-
ing child of the family to interpret these
materials for the non-English speaking
parents. But it would be equally unethi-
cal for the local NHS trust or general
practice to allow an incompetent clin-
ician to have responsibility for patient
care, or to present members of the local
ethnic community with surgical consent
forms printed only in English and to
expect the child to interpret information
about surgery or other treatment for the
parent. These are not questions of
research ethics, they are simply bad
to do things. They are of course unethi-
cal, but the ethical standard is one that
is set at the national or international
level, and not at the local.

This argument is supported by pro-
cedures that have been in place for
some time to deal with epidemiological
research and other types of study in
which there is no local researcher.
These guidelines, issued by COREC in
November 2000, observe that in many
types of study there is no need for there
to be a local investigator, even in some
instances in which there is patient
contact by a local clinician and the
collection of data including tissue sam-
ples. The guidelines note that “Many
LRECs themselves have questioned the
need for a local REC opinion in these
cases, as long as sufficient safeguards
are confirmed to be in place during the
ethical review of the protocol by another
REC in the NHS”. The guidelines there-
fore establish the principle that if there is
no local investigator, there is no need
for LREC approval and thus, we must
assume, no local issues. All questions
regarding the ethical conduct of the
research are addressed by a single,
central review and any local committees
are simply notified for information.

If the key factor determining whether
or not a study needs local review is the
presence or not of a local investigator,
and it is accepted that all other ethical
questions about the conduct of the
study can be addressed centrally, this
would seem to support our argument
that all research ethics questions of
design, method, information, consent,
patient safety, and so on, can be reviewed
centrally by one committee.

None of these matters rest with the local
investigator. The only matters that could
be said to rest with the local investigator
are those things that he or she brings to
the study, which is to say his or her
expertise, conduct, and competence, and
any facilities or resources he or she may
be required to provide. The question for
local review thus is not whether the
study is ethical, but whether the local
investigator is a fit person, with ade-
quate facilities. And these questions,
of course, are not ethical but empirical.

It might be generally agreed for example
that, to be an acceptable local investi-
gator, a researcher should have an
appropriate higher degree and some
evidence of previous successful involve-
mement in research, perhaps in the form of
peer reviewed publications. The local
question of the suitability of any specific
investigator can then be answered by
reading his curriculum vitae to look for
empirical evidence of his qualifications
and publication record.

In a recent survey,” Megone and
colleagues highlight the variation across
the EU in the local responsibilities of
RECs. Of those that are local they found
two kinds: those that oversee a local
area (as in the UK) or those that are
institutionally based (for example a
hospital committee). Apart from the
UK, only Germany, Greece, and Spain
had local RECs of the first kind and, like
the UK, consequently have a large
number of committees. A similar analy-
ysis emerges from a Council of Europe
Survey,” which says very little about the
need for local review among the 28
countries that responded. In most coun-
tries (15 of 28) RECs were hospital or
university based and in 13 they were
based on professional bodies. Most
ethical review of research within
Europe therefore takes place without
any perceived need to review “local”
ethical factors.

WHO SHOULD BE RESPONSIBLE
FOR LOCALITY ISSUES?
The assumption that underlies the sys-
tem of local review by RECs is that,
because of their local nature, members
of an REC will have personal knowledge
of their local investigators, local health
services facilities, and the local health
"www.jmedethics.com economy. This may have been true
when RECs were first established 20
years ago, and may sometimes be true
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today. However, recent changes in the NHS in England and Wales have undermined this position. A Health Authority was a large entity, typically covering a population of around 200,000 people, and employing around 30,000 staff. Although the proportion of staff involved in research must be small, the dozens or so members of the REC (a proportion of whom would be lay) could not have been expected to have good personal knowledge of every local researcher. Where members did have personal knowledge, it was as likely to be because of a professional or social relationship with the individual, a situation that in today’s climate would require at the very least a declaration of a possible conflict of interest.

The recent changes have required a redefinition of the research site, for the purposes of defining a single or multicentre study, in England by the creation of the Strategic Health Authority, and in Wales by the abolition of health authorities and the creation of local health boards. It is likely that in Wales the definition of a site will be by reference to three regional offices for the NHS in Wales. In both instances, the geographical area encompassed within a single centre study will be greater than that covered by the former health authorities. Because one committee will be required to consider a study taking place within one of these areas, the probability that REC members will have personal knowledge of the applicants’ competence, facilities, and resources is accordingly diminished.

If researchers, who are likely to have considerable personal investment in the success of an application in financial, academic, or professional career terms (or all three), are to have their competence and suitability assessed by the REC, they are surely entitled to know by what standards and criteria, and on what evidence this assessment is to be made. Given the new legal status of the RECs, a disappointed applicant, rejected as unsuitable, would be entitled to seek judicial review of the decision and, given the present lack of standards or criteria, or any systematic process of assessment, one might suppose that the courts will take a dim view of the REC decision making process.

When participants are recruited to a study through an NHS organisation, or by virtue of their status as NHS patients, they are entitled to expect the relevant NHS organisation to accept responsibility for their well being in the same way as they expect to be properly treated as patients in receipt of care. The management responsibility in, for example, an NHS trust, will rest with the chief executive and the board of directors, but will usually be exercised through a research and development manager, a local research and development committee, and the research governance framework. The governance framework sets out the various responsibilities. For example, the governance framework for the NHS in Wales identifies the responsibilities of the participant, the researchers, the principle investigator, funders, the sponsor, employing organisations, care organisations, the responsible care professional, and the research ethics committee. The principle investigator is responsible for ensuring that the governance framework for the NHS in Wales identifies the responsibilities of the participant, the researchers, the principle investigator, funders, the sponsor, employing organisations, care organisations, the responsible care professional, and the research ethics committee. The principle investigator is responsible for ensuring that the chief executive of the care organisation involved in the research is informed and that “their approval is given before the research commences”.

The research sponsor is “the organisation taking primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting; the sponsor is usually, but does not have to be, the main funder”. In some instances the sponsor will be the care organisation. The sponsor is responsible, among other things, “for ensuring the quality of the research environment within which the research will be undertaken and the experience and expertise of the principal investigator and other key researchers involved”. It is the responsibility of the organisation providing care to ensure that any research involving their patients, users and carers, or staff meet the standards set out [in the framework], in particular that it has an identified research sponsor willing and able to discharge its responsibilities, and that clear and documented agreements are in place about the allocation of responsibilities between all parties involved. Accountability for this lies with the chief executive or agency director.

Pharmaceutical industry sponsors, in particular, have concerns about investigator competence and probity, given that they are often paying substantial sums to local investigators. This is part of the reason for monitors, inspections, and so on, which have highlighted a number of high profile cases of research fraud. The local REC has rarely, if ever, had a direct role in this and lacks the resources and the expertise to take on such a role. Similarly, while many pharmaceutical sponsors offer investigator training to ensure the quality of investigator recruitment, the local REC is not placed to make such assessment and actually has never effectively done so.

It would thus seem that, effectively, the responsibility for ensuring the suitability of the local investigator and the research setting rests with the sponsor, the principle investigator, and the care organisation. This has clear advantages. All of these bodies or individuals will have personal knowledge of the researcher, and the opportunity and means to assess his or her competence and suitability. They will also have clear organisational responsibility, accountability, and liability for both the conduct of the researchers and the research in ways that the REC cannot possibly have. The present guidelines, however, would result in duplication of effort. While the Research Governance Framework places the responsibility with the sponsor, the principle investigator and the care organisation, the European directive and GAFREC both charge the ethics committee with responsibility for the suitability of the researcher and the local facilities.

REASSURING THE PUBLIC

One further role of the local REC may be suggested: that it provides reassurance to the local community of the validity of ethical review. Indeed this is explicitly stated in the ICH GCP guidelines, which state that “one of the responsibilities of the Ethics Committee is...to provide public assurance of that protection”. Similarly, in the UK, the Guidelines on the Practice of Ethics Committees in Medical Research from the Royal College of Physicians state: “The objectives [of ethics committees] are...to provide reassurance to the public that this [protection of subjects] is being done”.

From this perspective lay members of RECs particularly might be thought to be there to make the committee more democratically representative, more representative of the community as a whole, or more accountable to the community as a whole. Local review may not alter the ethics of a study, but it could be seen to be a useful check, a reassurance that justice is seen to be done. However, even if we believe this function to be necessary, we might nevertheless question whether the local REC can perform it.

To suggest the need for RECs to be responsible for such a check is to suggest that the REC is the only body concerned with the ethics of a study. This is not the case: research sponsors, NHS bodies hosting research, and the investigators themselves all share this responsibility. RECs may have a key role in ethical opinion making but no one suggests that their role is an exclusive one, or that research sponsors and investigators are not responsible for proposing ethical research. The role of the local REC in providing a further check may therefore be no more than
another obstruction. Not all obstruc-
tions are necessarily a bad thing, but
given an effective system of main ethical
review, a proper governance structure,
and the lack of training of many local
REC members, it is an obstruction that
probably serves no useful purpose and
should be avoided.

It is doubtful in any case that REC
members are, in any meaningful sense,
locally representative. In big cities espe-
cially, they often reside outside the
catchment areas of the institutions in
which the research is to take place. They
are not elected and, in the past, have
often achieved their place on the REC by
invitation. Some—perhaps clergy are a
good example—may have excellent
community credentials, but others, such
as non-executive directors of trusts,
have none and represent another voice
from the articulate middle classes, who
are already well represented by the
professional members. If those objec-
tions were not sufficient, the restruc-
turing of the NHS, with strategic health
authorities in England and the abolition
of health authorities in Wales, means
that the claim that the LREC can
represent a community becomes even
difficult to sustain. It is therefore
hard to see how a local REC could give
adequate reassurance to the local com-


A local REC might be thought to be
best placed to judge such matters of
local acceptability, if it were a truly local
and representative body. On the other
hand, this sort of reservation could
equally apply to an epidemiological
study, where there is no local researcher
and thus no requirement for local
ethical review and so this may be
another example where responsibility
is best devolved to the research and
development structure of a trust or
primary care body. The question is not
about the ethics of the study protocol
itself but about acceptability at a
particular time and place. Such cases are
likely to be very rare and hardly justify
an elaborate system of review by com-
mittee. It should be sufficient simply to
build into the review of all protocols a
requirement for local investigators to go
through local research and development
bodies, who should ensure that an
awareness of local sensitivities forms
part of their decision making. There is
no reason to believe that the local REC
would be any more knowledgeable of
local recent history or other sensitivities,
given its unrepresentative nature and the
extent of the geographical area it must
oversee, so even if such pragmatic
issues were to be viewed as “ethical”,
one can still doubt whether the REC is
the most competent body to deal with
them.

A WAY FORWARD
The recruitment of sites is the respon-
sibility of the principal investigator, who
is also (with others) responsible for
ensuring the suitability of the local
researcher and the local facilities. He or
she must also ensure that the chief
executive of the care organisation
responsible for the care of the partici-
pants gives his or her approval. The chief
executive shares responsibility for
ensuring that the local investigator is
acceptable and that the resources and
facilities are in place, and he or she is
liable for any harm that may befall
patients in his or her care.

When the principal investigator seeks
ethical approval, he or she will include
details of the sites and local researchers
recruited so far with the application. If
the principal investigator is required to
submit that information together with a
signed statement from the respective
chief executives to the effect that the
research has been approved within the
research governance framework for
the care organisations, the REC review-
ing the proposal will know that a
properly responsible and accountable
body has accepted responsibility and
liability for the local researcher and
research facilities in each site. Thus the
study would need no further review
beyond the main ethical review by the
REC. Sites and local investigators
recruited after ethical approval had been
received would be notified to the REC,
with the letter of governance approval
from the chief executive. As an aside, we
note that because RECs are advisory
bodies only (and with respect to ethics,
not monopoly ones), it is possible in
principle that the research and develop-
ment committee or even the chief
executive could prevent the study locally
on ethical grounds, as well as on
grounds of research governance.

For research in NHS hospital trusts
this arrangement would be relatively
straightforward. In primary care, where
general practitioners (GPs) conduct
research either as principal or local
investigators, it may not be quite so
clear. The requirements of the govern-
ance framework are clear enough, but it
is not immediately obvious as to who
should function in the various roles, as
the GP researcher may also be the chief
executive of the care organisation and in
some instances might also be the
sponsor. However, the GP’s patients
are under his or her care by virtue of
the contract to provide general medical
services, and thus it would seem reason-
able for the body that controls and
monitors this contract to accept respon-
sibility for the research activities of GPs
and monitor their performance; in
Wales for example this would be the
local health board. In both the hospital
and the primary care settings there is
also the possibility of conflicts of inter-
est. Research, particularly when funded
by the pharmaceutical industry, may
generate considerable income for the
local investigator, and a successful
research career may also bring consid-
erable prestige and professional advance-
ment for the researcher. Hospital trusts
may rely on research income to sub-
sidise clinical services, members of staff
may depend on it for their continued
employment, and GP practices may
depend on it to fund posts or other
activities. However the governance
structure, while not guaranteeing that
there will be no abuses of the system,
does at least provide a system of
regulation and accountability through
which action can be taken should malpractice be identified.

SUMMARY AND CONCLUSIONS
We have argued in this paper that the only questions of research ethics relating to studies reviewed by RECs are central issues: the REC reviews the ethics of the study. It would be unethical to allow incompetent researchers to conduct research in inadequate facilities, but this is not a question of the ethics of research. The competence of the investigator and the suitability of the facilities are empirical questions that the REC is not competent to address and these are issues that should be outside the responsibility of the REC. The responsibility for the management and conduct of research rests with the sponsor, the principal investigator, and the care organisation and this is well described in the Framework for Research Governance.

The locality issues set out in GAFREC, of the competence of investigators and suitability of facilities, should thus be addressed through the governance framework and not through the REC system. Applicants for ethical review should present their protocols with details of sites and local researchers already approved by the relevant authority through governance procedures, and the convention of local review by the REC should be abandoned. Research ethics committees should, however, be notified of research to be conducted in their area, as they are with current studies where there is no local researcher. As part of the main ethical review, RECs should satisfy themselves that there has been proper scrutiny of the project through the local research governance framework in each of the proposed sites and that the appropriate local manager has accepted responsibility for the conduct of the research. The requirement set out in the European directive for RECs to “consider” such issues as the suitability of the local investigator and quality of facilities can thus be fulfilled by scrutiny of the local governance agreement. This also fulfils the requirements of the Directive that protocols undergo ethical review by a single body.

There may be some concern that governance arrangements are in their infancy and not yet sufficiently robust to provide sufficient reassurance of the protection of the research participant. If this is the case, the problems should be addressed by strengthening the governance system. After all, it is the sponsor, principal investigator, and care organisation who are responsible for the conduct of the research and the safety of all involved and who will be held accountable and liable in the event of any damage to research participants.


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Dr Saunders is Chairman, and Dr Wainwright is a member, of the Multi-Centre Research Ethics Committee for Wales. However the views expressed in this article are personal and do not represent the views of the Committee, or of the National Assembly for Wales.

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Received 17 March 2003
Revised 27 June 2003
Accepted 1 July 2003

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