

Wellcome Trust Lecture 6 Questions

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Lecturer: Dr Hugh Davies

Q: Often when people do research, they feel that if they have been through an Ethics Committee they are covered with respect to any negligence. But maybe that's not the case. So for example, if a lesion was missed on a brain scan, and somebody came back 2 years later and you had followed all the procedures and you said you were covered by your Ethics Committee, but the person decides they will pursue a legal case for negligence, who is the responsible person? Where does the buck stop?

A: The favoured opinion of the Research Ethics Committee is, I suspect, part of what the court would regard as part of your defence, if the processes and procedures you set up were appropriate and defensible. So I think that's part of your defence. The legal responsibility for research rests with the sponsor and researcher.

Comment: I think the answer to that last question is definitely the Sponsor but in terms of either NHS or University based regulations, most sponsors will have no fault liability things in place, so you've got an insurance. Certainly KCL does, UCL does I know most and I assume all NHS Trust have. If you are working within them, you state on your information sheet or some how otherwise inform people, that there is a way of obtaining compensation if they feel there has been harm and you hope that your employer sticks up for you. That's my understanding at least.

Q: Your talking about this with your NRES hat on (obviously) but a lot of research we do here won't be going through NHS committees, and is there any way that we can make sure that we hit all research committees, and that we have common guidelines so that it doesn't depend on whether you have an NHS patient or not as to what you got asked?

A: One would answer No. We have a responsibility for the NHS Committees which review research under the Governance arrangement which is mainly NHS research plus research that has to be reviewed by a recognised committee by law. So clinical trials, research in which we are using human tissue, research that involves the mental capacity act has to be reviewed by an NHS committee, but the University committees are outside our remit and I accept your comment.

Q: I have a sort of general comment about the whole morning. Are we assuming that all these volunteers have capacity and if not what are we doing about it? I remember years ago visiting the Ely Lilly Hospital in Indianapolis, 6 floors, 500 men, different orange coloured jump suit on each floor and these all male volunteers being paid to take part in research, and the scanning was going on. Casting a sort of brief psychiatric eye over them, I would say that a 1/3 to 1/2 clearly lacked mental capacity and were not given any informed consent, even though they were filling in the forms. I haven't heard anyone mention that this morning. Are we just assuming that because we give someone an

information sheet and they sign the form they are compos mentis? If so it is very dangerous.

A: I think that if I went into this issue of capacity, I expect it would be a lot longer and a lot more complicated. I focused particularly on identification of coincidental findings. If you then have identification of coincidental findings in those who lack capacity then it adds an extra layer of complexity to it.

Q: Can I just go back to Gareth's comment about the separation between NHS REC versus University REC. If we were to go down the point of view, where by everything was reviewed clinically by a Radiologist, does that not extend the argument that the Trust for which they work has accepted some form of liability and therefore all studies, whether they are healthy controls or not, should then come under NREC scrutiny?

A: I think in that situation I would get into considerable detail about what kind of contract that person has and whether it is a contract with a research organisation. If the research work is within the University and they are undertaking review for the University then I think they wouldn't be regarded as NHS staff and so it would not come under our remit. There would be shady details there that would be difficult to disentangle.

Q: I was wondering whether it would be the role of the Ethics Committee to supervise whether appropriate measures are taken to make sure that relevant findings are being detected? Because as I understand it right now, a number of studies are being conducted in which there is no involvement of people who are qualified to read scans, and I'm not saying trained Radiologists, but those that have basic skills in reading scans and if you would make a paragraph for animal research where an Ethics committee for animal research would require researchers to have certification for animal handling, wouldn't you, if you make a parallel, require certification for basic skills of reading these scans amongst of the researchers?

A: The committee would like to know who is going to be reading the scans, and what their professional role is. So if the images are going to be reviewed by a Radiologist that will be part of the information. If they are not going to be read by a Radiologist that's the information they would expect up-front, at least for the participant to know about. I think there is a role for a group such as this to say, well what is the reasonable moral process and what should we provide. I think the presentation has demonstrated that on the one hand there are people who feel there should be a formal image up-front, others argue that this is not going to be commensurate and appropriate in other studies. May be it's the group here who have got to decide and it's then going to be down to the individual researcher when they present their particular project to the committee to say, "We have adopted this strategy because", and then they have got to argue their case. I would always say "It's the salmon that John West rejects that makes John West the best". It's actually the 5 studies you have rejected or the 5 methodologies you have put to one side that makes your methodology perhaps the best because you have thought it through. That is

going to be a discussion that I think should be engendered and should be focussed on in the ethics committee.

Q: Inaudible question

A: Not in that detail, no.

Q: Just a little comment about sharing of information between the NHS research ethics committees and the University research ethics committees. There is the Association of Research Ethics Committees that has 2 joint sub-committees, one is for NHS and one is for University committees. So there is quite a committee base there for sharing best practice amongst ethics committees in the NHS and University sectors. The University sector does meet, has a forum and discusses similar issues and just tries to seek best practice. I think if there was to be a framework that was passed out in the NHS, then I think it would be quite well received by the University as well to take into consideration because each side (NHS/Universities) is hoping for consistency across the board.

A: I agree, I hadn't thought through the AREC is certainly a useful sort of vehicle to share these views.

Comment: Re responsibilities, of course the Ethics committee is only part of the governance process and good Trusts will obviously have their R&D Departments check everything including contracts and capabilities of individuals signed up within those contracts before research can be carried out. So to make sure that the responsibility lies with the Sponsor and they are appropriately trained.