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Part 3

Turning now to the ethical and legal issues relating to biomedical research, the question is: in what way do these differ from those relating to treatment? As with decisions on treatment, while the ethical principles we discussed earlier are key, the legal aspects are equally important. In the UK, for example, local Research Ethics Committees (RECs) are responsible for research governance. Their job is to check research protocols – the guidelines that set out how a study is to be undertaken – and to make sure that they meet the necessary ethical standards.^[1] As part of this, they will evaluate the risks and benefits from a medical perspective, deciding whether the research is worthwhile or too risky.

Ethics committees will also want to ensure that when the participants have consented, it is informed consent. It is quite clear that the research subjects must be given accurate and detailed information on the risks they face, so they can evaluate them for themselves and refuse to participate, if they wish. Informed consent also requires that they are given information about the goals, methods and possible benefits of the research. The confidentiality of the information gathered in the course of the research is also of key importance. In general, ethics committees will want to see details of how data is to be collected, stored and used in order to ensure the privacy of participants is not compromised.^[2] In most developed countries, these requirements all have the force of law. For example, in the UK, since 2007, drug trials cannot be conducted without the agreement of an REC.

Compliance with standards for research ethics, then, is not simply a matter of recognizing participants' moral rights but of legal regulation. The question is: is this legal regulation justified? There are those who claim that imposing this regulation on research only increases the time needed to bring drugs onto the market, which may cost people their lives. I'm afraid that just isn't true. It's quite clear that without this protection, more people taking part in trials could suffer harm and even death. The research has concluded that regulatory regimes do much to protect patients from unsafe and ineffective drugs and help safeguard the health of the volunteers who test them. For example, in 2006 in the UK, the lives of six volunteers in a clinical trial were saved due to the strict protocols under which the trial was conducted. It is my opinion that for this reason the increased cost of regulation can be justified. However, this protection is not uniformly applied. There is evidence to suggest that, increasingly, drug companies are conducting their tests outside the developed world, for example in Africa and Asia,^[3] where research regulatory regimes are less strict.

Perhaps the best example of what can happen without a clearly defined system of regulation for biomedical research^[4] comes from the Tuskegee Study of Untreated Syphilis in the Negro Male, to give it its full title. Initiated in 1932, in the United States, it enrolled 399 participants to act as a control group against which various treatments for syphilis could be evaluated. However, by 1947 penicillin had emerged as an effective cure for syphilis, ending the need for the trial. Despite this, the researchers actively prevented the control group participants from getting treatment for their condition. By the time the research was halted in 1972 due to adverse press coverage, 28 had died of syphilis and another 100 from related conditions. Not only had the researchers failed to obtain informed consent from the participants, they had put the goal of completing the study before that of the participants' welfare, which is clearly against the principle of nonmaleficence. It is not surprising that Katz et al. (2006) referred to the Tuskegee Study as 'arguably the most infamous biomedical research study in US history'. As a result of being famous for the wrong reasons, it has been the subject of an ongoing debate between academics about its effect on the numbers of minorities recruited to clinical trials.^[5]

Well, it looks as if I'm running out of time. Before I finish, I'm going to set you a task that will involve investigating some of the points I've raised. I want you to do some research to identify examples of situations where doctors' decisions regarding patients involve a conflict between two or more of the main ethical principles in medicine. The examples can relate to patients in either research or treatment situations. Try to look into specific cases to substantiate your arguments. If possible, I'd like you to think about whether it is possible to resolve the conflicting principles in the examples identified.^[6]