Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom

The Faculty of Pharmaceutical Medicine is a charity which works to advance the science and practice of pharmaceutical medicine for the benefit of the public.

The Faculty is pleased to submit comments to the Nuffield Council on Bioethics consultation on 'Human Bodies in Medicine and Research'.

Our responses to selected questions are as follows:

Q5. Again first in human trials are essentially a subset of Phase I trials in that by definition, Phase I trials do not provide any therapeutic benefit to the participant whether healthy volunteer or patient. These trials are now safer than ever following the publication of the Duff Report in December 2006 following the TGN 1412 trial which ended with severe adverse events for five of the participants in March 2006. Phase I trials in the UK were already very safe but the recommendations of the Duff report have made them safer still.

There is always a risk in taking part in an interventional clinical trial of an unlicensed medicine as part of its development programme and the risk is greatest at the first in human stage as the data available on the medicine can by definition only relate to pre-clinical experience. Generally there is absolutely no therapeutic benefit to the participant in a first in human study, however if the participant is a patient with the disease for which the medicine is likely to be indicated, there is a theoretical potential for benefit although it is highly unlikely as the dosage of the medicine under investigation is likely to be less than what the therapeutic dose eventually turns out to be.

With all first in human studies there is a potential benefit to society as a whole in that the data may well lead eventually to a newly licensed medicine that will have benefits for patients.

Q8. By definition the medicine in a first in human study will be innovative because it will not have been tested in humans before. If it is in a class already known and tested then it should be considered to have likely advantages over other members of the class. It should be being developed for a significant disease where there is clear medical need for new interventions.

Q10. The potential for maximising health and welfare should be a major priority

Q11. Volunteering for a first in human trial is probably morally best done for free but the current UK system of payment for healthy volunteers is appropriate and recognises compensation for discomfort. Furthermore all payments are considered and approved by the relevant ethics committee.

Q12. After death, it is my view that all human beings should be prepared to donate organs. I believe that organ donation should not require consent but that individuals should opt out if they do not wish their organs to be donated after death.

Q13. We think that there is a moral duty to participate in first in human vaccine trials. In that situation, it is quite likely that participants will get therapeutic benefit from taking part.

Q15. No

Q16. Payment for organs is unethical.

Q17. Risk-based payment for trials is inappropriate. Extra payment for discomfort is ethical but encouraging participants to take increased risk by paying a premium is unethical.

Q19. Compensation for economic losses can be provided ethically for all trials but payment for inconvenience and discomfort should only be considered for healthy volunteer studies.

Q23. Yes but there must be Research Ethics Committee approval and/or approval from the National Information Governance Board. This circumstance may well occur where the person whose tissue it is cannot be contacted or if contactable the contact might cause distress. Wherever possible, the tissue should be anonymised as to ownership. Ideally, these situations can be avoided by obtaining consent for further ethically approved use at the time of original consent.

Q25. Family members should not be able to prevent donation if it is clear that the deceased wished to make a donation after death.

Q28. Companies who benefit commercially from tissue donation or clinical trial outcomes should not be required to share the proceeds but they should publish the results of their research whether positive or negative for society as a whole to have access to the data.

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