PLEASE NOTE: This consultation response has been submitted by the ABPI on behalf of *one* ABPI Member Company. It does not constitute the views of the general ABPI membership.

NOTE: All responses relate to the undertaking of research

1. Nature of human bodily material and first-in-human trials

Human bodily material

1. Are there any additional types of human bodily material that could raise ethical concerns

Although not a 'type' of bodily material, genetic analysis (of DNA) can raise concerns for some, and as such should be clearly included in the consent procedure. However, although genetic analysis may have specific characteristics i.e. inheritable, it should not be assumed that the resultant data has a greater impact on healthcare status than other biological measurements. For example, any assumption that genetic determination of cytochrome polymorphisms to establish the dosing strategy of warfarin, will automatically has a greater impact on the individual than a clinical diagnosis of disease cannot be justified.

2. Should any particular type(s) of human bodily material be singled out as 'special' in some way?

Materials collected from vulnerable populations, including embryonic and foetal material, should be subject to governance frameworks that reflect both ethical principles and advances in medical research.

3. Are there significant differences between providing human bodily material during life and after death?

Yes, in the sense that material provided after death has no consequences for the donor. Dependent on the type of material and the nature of the research analysis undertaken, consequences may exist for family members or partners.
Material collected from both the living and the deceased should be treated with respect and subject to the terms of the consent and/or ethical approval.

4. What do you consider the costs, risks or benefits (to the individual concerned, their relatives or others close to them) of providing bodily material? Please distinguish between different kinds of bodily material if appropriate.

Elements to consider include the potential physical components of giving research material (e.g. bruising, swelling or infection associated with blood donation) and the time necessary to provide the bodily materials.

Participation in first-in-human trials

5. What do you consider the costs, risks or benefits (to the individual concerned, their relatives, or others close to them) of participating in a first-in-human clinical trial?

This is a well documented topic - see ABPI Guidelines for Phase 1 Clinical Trials 2007. Costs relate to impact on lifestyle (e.g. time off work to participate). Risk includes impact of physical intervention e.g. blood sampling, and possible side effects of the experimental medicine.
Benefits to patients may include access to potentially beneficial treatments.

2. Purposes of providing bodily material / volunteering in a trial

Please note: The provision of bodily materials for research may be used in a further way – not described in the introduction to this Section. Namely, the material may be collected for both specified immediate use and for specified future use, where both conditions are included in the initial consent procedure.

6. Are there any additional purposes for which human bodily material may be provided that raise ethical concerns for the person providing the material?
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7. Would you be willing to provide bodily material for some purposes but not for others? How would you prioritise purposes?*
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8. Would your willingness to participate in a first-in-human trial be affected by the purpose of the medicine being tested? How would you prioritise purposes?
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3. Ethical values at stake

9. Are there any other values you think should be taken into consideration?
Different drivers will exist for individuals wanting to participate in research. These will range from altruism, through an interest in research, to an opportunity to received payment in return for their participation.
Researchers however should focus on the principles of the ethical conduct of research. Researchers should also ensure that biological materials collected for research are subject to a quality control management system that governs the practical conditions for sample storage, maintenance and access.

10. How should these values be prioritised, or balanced against each other? Is there one value that should always take precedence over the others?
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11. Do you think that it is in any way better, morally speaking, to provide human bodily material or volunteer for a first-in-human trial for free, rather than for some form of compensation? Does the type or purpose of bodily material or medicine being tested make a difference?

Currently, large amounts of biological material are discarded as clinical waste following clinical or surgical procedures. Such materials could be used for research purposes – so avoiding destruction of this valuable resource. Hospitals should be supported in establishing procedures which facilitate ethical and routine collection of this material and its supply (along with critical medical information such as disease diagnosis) to researchers, in a manner that protects patient confidentiality.

12. Can there be a moral duty to provide human bodily material, either during life or after death? If so, could you give examples of when such a duty might arise?
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13. Can there be a moral duty to participate in first-in-human trials? If so, could you give examples of when such a duty might arise?
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4. Responding to demand

Supply and demand

14. Is it right always to try to meet demand? Are some 'needs' or 'demands' more pressing than others?

All materials are of value to research – each having relevance according to the disease or drug being studied. Some material are however difficult, if not impossible to collect in a research setting. The routine collection of clinical waste and a more considered approach to post mortem collections would help to address this wastage.

Current regulatory framework

15. Should different forms of incentive, compensation or recognition be used to encourage people to provide different forms of bodily material or to participate in a first-in-human trial?

Many trials are demanding of the subject and involve long periods of residence in the research unit, repeat visits to the centre, urine collections, multiple blood tests and other procedures that can cause discomfort. Lifestyle restrictions may also be required eg dietary restrictions. It is therefore appropriate to pay subjects in FTIH studies for more than just the direct expenses they incur. The amount should be related to the duration of residence in the unit, the number and length of visits, lifestyle restrictions, and the type and extent of the inconvenience and discomfort caused – See ABPI Guidelines for Phase 1 Clinical Trials 2007.
Payment must never be related to risk.

Increasing supply

16. Are there forms of incentive that are unethical in themselves, even if they are effective? Does it make any difference if the incentive is offered by family or friends, rather than on an 'official' basis?

See Q15.

17. Is there any kind of incentive that would make you less likely to agree to provide material or participate in a trial? Why?*
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18. Is there a difference between indirect compensation (such as free treatment or funeral expenses) and direct financial compensation?
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19. Is there a difference between compensation for economic losses (such as travelling expenses and actual lost earnings) and compensation/payment for other factors such as time, discomfort or inconvenience?

See Q15

Alternatives to increasing supply

20. Are you aware of any developments (scientific or policy) which may replace or significantly reduce the current demand for any particular form of bodily material or for firstin-human volunteers? How effective do you think they will be?

• Advances in medical science and research will likely lead to advancement in treatment for diseases that were previously poorly managed. In some instances these diseases will be rare.

• Continued research into biomarkers (including genetic) to predict/diagnose disease and guide treatment decisions.

Research into both of these topics will be dependent on access to a range of relevant materials. There is currently no in vitro substitute for these materials.

5. The role of consent

Valid consent

21. In your opinion are there any forms of encouragement or incentive to provide bodily material or participate in first-in-human research that could invalidate a person's consent?

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22. How can coercion within the family be distinguished from the voluntary acceptance of some form of duty to help another family member?

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Consent for future unknown ('secondary') uses of bodily material

23. Are there circumstances in which it is ethically acceptable to use human bodily material for additional purposes for which explicit consent was not given?

Yes, when the research proposal has been approved by an ethical authority – as per the Human Tissue Act

Role of families: living donation

24. Is there a difference between making a decision on behalf of yourself and making a decision on behalf of somebody else: for example for your child, or for an adult who lacks the capacity to make the decision for themselves?

Decisions made on behalf of any vulnerable individual should be given special consideration and subject protection. In general, the written consent of the person's legally authorised representative should be obtained.

Role of families: donation after death

25. What part should family members play in deciding whether bodily material may be used after death (a) where the deceased person's wishes are known and (b) where they are unknown? Should family members have any right of veto?

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6. Ownership & control

Property rights

26. To whom, if anyone, should a dead body or its parts belong?

Consent forms should identify the governance mechanisms of materials so that the research participant is made aware of these. This may included any opportunity to self manage these materials e.g. any provision to request sample destruction. Consents should identify the owner of the results.

27. Should the laws in the UK permit a person to sell their bodily material for all or any purposes?

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28. Should companies who benefit commercially from others' willingness to donate human bodily material or volunteer in a trial share the proceeds of those gains in any way? If so, how?

Consent forms should inform the potential participant of the commercial involvement in the study - i.e. if the study has a commercial sponsor, the potential for patents and any payments that the participant may (or may not) receive in relation to these.
Given that many academic institutions and non-commercial researchers are also involved in commercial applications, this consent requirement should be applicable to research in both the private and the public sector – so that the participant is equally informed prior to participation.

Control

29. What degree of control should a person providing bodily material (either during life or after death) have over its future use? If your answer would depend on the nature or purpose of the bodily material, please say so and explain why.

Consent forms should permit a clear understanding of the scope and general time period of research, so that the subject can decide if they wish to participate according to the terms. Given the robust framework under which research is conducted e.g. the Human Tissue Act, GCP, and that biological materials and any associated medical information are primarily used in a format that protects subject confidentiality, more provisions should be made for generic and enduring consents to be used routinely in research.