The Royal College of Pathologists

Use of specimens from healthy volunteers

August 2005

This position statement was produced by the Ethics Committee in March 2005 and, in accordance with the College's publications policy, was placed on the Fellows' and Members' area of the College website for consultation from 29 March to 29 April 2005. Eight detailed comments were received and forwarded to the lead author, Dr Phil Dyer. He and the Ethics Committee considered the feedback and agreed that the document needed no amendments. Please email publications@rcpath.org if you wish to see Dr Dyer's annotated responses to the feedback received.

Professor John A Lee
Director of Publications

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Introduction

It is established common practice to obtain specimens such as blood, saliva, semen, skin biopsies, hair and urine from healthy volunteers for use in quality assurance testing and research. Sometimes donors are paid to compensate for their inconvenience. A clear explanation of the use to which these specimens will be put and of their storage has not always been given. Informed consent must be obtained. It is important that ethically approved practices continue, since many diagnostic and life saving clinical tests depend on continued donation of these specimens.

Ethics Committee approval

It will be necessary to comply with Clinical and Research Governance by obtaining appropriate Ethics Committee approval before any specimens are obtained from healthy volunteers. Declaration of details of any payment must be made and records must be kept.

Supporting organisations

The organisations Volunteers in Research and Testing (www.vrt.org.uk) and Consumers for Ethics in Research (www.ceres.org.uk) offer supporting advice to those seeking healthy volunteer donations and those wishing to donate.

Best practice

Appropriate recording should take place, including the potential for donor traceability and identification. Donors should be given clear and accurate information of the reasons why they are being asked to volunteer to donate, in writing and with oral explanation. They must sign and date a form recording their consent to donate a sample, and must be given a copy. The use to which their donated specimens will be put must be recorded and explained to the donor and their consent recorded. A request for general consent for future use of specimens is acceptable, but there must be a strategy to deal with unexpected findings that may have clinical relevance to the donor. If medical information is collected from a donor, it must be treated in a manner identical to clinical notes and subject to the same confidentiality practices (Caldicott Guardianship). Only competent practitioners should collect medical information.

Information and consent

This must contain full contact details of the donor and a statement that the donor has been informed of the purposes for which the specimen has been donated, and the possible implications for the donor's lifestyle and health. The donor must sign and date the form and be issued with a copy and accompanying explanatory text. Contact details of the recipient laboratory and the name of a senior staff member must be provided. A record of payment must be made and the donor must sign for receipt of payment. Outline details of Ethics Committee approval must be provided to the donor, including contact details of the Ethics Committee office.

Compiled by Dr Phil Dyer and Madeleine Wang

Ethics Committee

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Approved by Council March 2005

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