



Ethical guidelines on sourcing specimens for evaluations

This document has been reviewed by the National Research Ethics Service (NRES, Ref 041/01) which has advised that the guidance given in this document follows ethical practice and is suitable for circulation. In the circumstances described, patient consent and separate ethical approval is not indicated.

The Health Protection Agency's Microbiological Diagnostics Assessment Service (HPA-MiDAS) evaluates and provides reports, information and advice on diagnostic kits, instrumentation and healthcare products relevant to microbiology. Evaluation outputs are used to improve purchasing decisions which in turn contribute to improvements in patient care

HPA-MiDAS needs to source specimens to use in evaluations of commercially available microbiological assays. While many diagnostics laboratories are willing to send specimens to HPA-MiDAS, assurance is needed that the process follows ethical guidelines and that all parties are working within the law as laid out in the Human Tissue Act.

NRES has advised us that we do not need to seek individual patient consent to use residual sample for evaluation of diagnostic kits. If the samples are being collected for diagnosis of a particular diagnostic marker, then the residue may be used for evaluation of kits for that marker.

We ask that laboratories sending specimens to HPA-MiDAS adhere to the following guidelines:

- Send excess specimens that are no longer required for diagnostic testing at the source laboratory
- For each specimen, indicate which diagnostic marker HPA-MiDAS is permitted to test for.
- Anonymise specimens. Remove patient identifiers *ie* name, hospital numbers. The specimen bottle must not be labelled with the patient name.
- Place publicity posters in areas where specimens are taken, so that patients have the opportunity to ask questions and to withhold specimens from evaluations if they so wish.

Explicit consent and ethical approval may be required if extra specimens are taken specifically for evaluations *ie* not residue.

Microbiological Diagnostics Assessment Service
21st September 2007