Ethical issues

The project includes the following ethical issues:
- Introduction of microbiological lab tests to general practice (WP6, WP7, WP8 and WP9).
- Registration of sensible patient data (WP6, WP7, WP8 and WP9)

The introduction of microbiological lab test is not considered an ethical issue as this is an intervention targeted the GP in order to improve the quality of diagnostic procedures in patients with RTI.
Patients will only be indirectly involved in this intervention.
Registration of sensitive personal data will be carried out with respect of national and international regulations on collection of sensible personal data.
The Ethical Issue Checklist is completed below.

Ethical Issues checklist:

	Yes	No	Uncertain
· **Research on human beings**			
Persons not able to give consent		X	
Children	X		
Adult healthy volunteers	X		
· **Human biological samples**			
Human foetal tissue/cells		X	
Human embryonic stem cells		X	
· **Human embryos**		X	
· **Human genetic information**		X	
· **Other personal data**			
Sensitive data about health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction	X		
· **Animals (any species)**			
Non- human primates		X	
Transgenic small laboratory animals		X	
Transgenic farm animals		X	
Cloning of farm animals		X	
· **Research involving developing countries (e.g. clinical trials, use of human and animal genetic resources…)**		X	
· **Dual use**		X	

According to the requirement of an ethical review the following specifications and explanations are given to the ethical questions:

1. Provide justification for such research in terms of the potential benefits of the research in relation to the possible risks to persons.	This is a descriptive study, which does not involve any risk to the patients. The intervention entails getting GPs to improve their performance according to good clinical
2. Indicate the number of persons involved and describe the selection criteria.	400 GPs will participate on voluntary basis. Each of them will register approximately 50 patients.
3. Provide details of the arrangements made for providing information to persons and for obtaining informed consent.	The GPs will be thoroughly informed about the project design and scope, in the participating practices information about the ongoing study will be on display.
4. Specify any payments, inducements or other benefits to be given to the persons concerned.	The GPs will have their expenses in connection with participation reimbursed, but will not actually receive a fee for
5. Describe the compensation and treatment available to subjects for trial-related injuries.	The study does not result in increased patient risk.

Table 13: Ethical question and answers for research involving persons in particular children or persons unable to give consent, pregnant women or healthy volunteers for clinical trials.

	For patients	For professionals
6. Describe the procedure for obtaining informed consent of persons and describe the procedures for protecting the confidentiality of such personal data.	Patient data are not linked to patients' full identity.	Data on GP's behaviour will be handled strictly confidential.
7. Where data are to be shared with other stakeholders the persons whose data are collected should give a specific consent.	Data will not be shared with any other stakeholder.	Data will not be shared with any other stakeholder.
8. Applicants should also describe the process of encoding or anonymisation used and indicate if the collected data will be used for commercial purposes.	Data will not be used for commercial purposes	Data will not be used for commercial purposes
9. Even where only anonymised data are used adequate security measures for storage and handling of such data must be shown.	The data will be stored by P01 RUPO (DK), which complies with the conditions for data storage defined by the Danish Data Protection Agency.	The data will be stored by P01 RUPO (DK), which complies with the conditions for data storage defined by the Danish Data Protection Agency.

Table 14: Protection of personal data.

1. Identification of countries where specific research will be carried out	DK, SE, LT, RU, ES, AR, NO, SI, BE
2. Identification of any important national regulations relating to research in these countries, confirmation that such regulations will be observed and an indication of how key aspects will be applied.	P01 RUPO will ensure the national regulation will be observed (DK: "Lov om behandling af personoplysninger, lov nr. 429 af 31. maj 2000. Persondataloven").
3. Confirmation that, where it is required, the Commission will be informed that local, gional or national ethics approval has been obtained before the research to which it relates	The Commission will be informed that local, regional or national ethics approval has been obtained before the research to which it relates is carried out.

is carried out	
4. Copies of relevant approvals already granted by local, regional or national ethics committees.	NA
5. Identification of any relevant EU legislation and international texts, confirmation that these will be observed and an indication of how key aspects will be applied.	NA
6. Identification of any research on humans or their tissues for which informed consent will be required together with confirmation that such consent will be obtained and details of the information that will be provided to patients, subjects or other volunteers taking part together with any provision made for their support and welfare .	The project does not include research on humans or their tissues (ref Table 13, answer 1).
7. Indication of how any data storage and handling processes will ensure patient data protection and confidentiality.	The patient data are not linked with patient full identity (ref. Table 14)
8. Justification for any use of animals especially where this relates to non-human primates and transgenic animals – this should include justification of numbers and species used and a clear indication of how the principles of reduction, refinement and replacement have been or will be employed.	The project does not include research on animals.
9. Justification for any use of genetically modified organisms and their source; assessment and handling of any safety issues and the application of relevant regulations. FP6 ethical rules state that: "Altering the genetic heritage of animals and cloning of animals may be considered only if the aims are ethically justified and the conditions are such that the animals' welfare is guaranteed and the principles of biodiversity are respected".	The project does not include research on genetic modified organisms.
10. Further information on any ethics management component in the proposal, including details of qualifications of those involved and clarification of the role, remit and integration of that element of the proposal.	All involved researchers shall be qualified by the Project Executive Committee. The PEC is described in section 7.1.

Table 15: List of general ethical issues provided for ethical review June 2006

11. Consider the ethical implications of confidential data handling, particularly in relation to dissemination of the results.	The patient data are not linked with patient full identity (ref. Table 14). The results will be disseminated without references to individual GPs or patients.
12. Clarify all aspects of safeguarding the wellbeing of children.	This is a descriptive study, which does not involve any risk to the patients.

Table 16: List of specific ethical issues provided for ethical review June 2006