



**Prins Leopold Instituut voor Tropische Geneeskunde**  
**Institut de Médecine Tropicale Prince Léopold**  
**Prince Leopold Institute of Tropical Medicine**  
**Instituto de Medicina Tropical Príncipe Leopoldo**

Stichting van openbaar nut | BE-410.057.701

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Dr. A. Erhart  
Department of Parasitology

IRB/AB/ac/089

8 June 2011

Dear Colleagues,

**Re:                   Mixed-methods study on clinical trial participation and the informed consent process in vulnerable populations**

**Our ref:           11 21 5 774**

I am pleased to inform you that the IRB has approved the protocol of the above mentioned study during its meeting of 7 June.

The protocol does not need to be submitted to the EC of UZA.

Kind regards,

Prof. Anne Buvé  
Chairperson IRB a.i

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Anne Buvé – Chairperson Institutional Review Board  
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<b>IRB number :</b>	<b>11 21 5 774</b>
<b>Title project/study:</b>	<b>Mixed-methods study on clinical trial participation and the informed consent process in vulnerable populations</b>
<b>Investigator:</b>	<b>Dr. A. Erhart Departement Parasitologie</b>
Background and study objectives (rationale and relevance):	No problem.
Approach for the recruitment of the study subjects:	Not detailed for this quantitative part.
Study costs:	
Study procedures:	Sampling not provided.
Risk evaluation:	OK
Benefit evaluation:	OK
Confidentiality and privacy:	OK
Informed consent:	
- language	Ok
- description of the content of the study	Ok
- foreseeable risks & benefits	Ok
- confidentiality	Ok
- privacy	NA
- medical treatment	OK
- contact information	OK
- voluntary participation & refusal	NA
- legal representative	
Final remarks:	
<b>Conclusion</b>	<b>Favourable (= IRB approval). The study does not need to be submitted to the EC of UZA.</b>

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