

### **Required documents for the submission to the Ethics Committee University Hasselt**

- Submission letter
- Request form
- Protocol
- Protocol synopsis\*
- Subject Informed Consent (Dutch)
- Subject Informed consent (English/French)\*
- Patient documents/questionnaires (Dutch)
- Investigator's Brochure\*
- Insurance certificate
- CV of Coordinating Investigator
- CV of Principal Investigator
- Clinical trial agreement (draft)\*
- European Clinical Trial Application Form\*
- Receipt of confirmation EudraCT number\*
- List of the participating Belgian sites and ethics committees

\*only for commercial clinical studies

### **Chairman**

#### **Prof. dr. Ivo Lambrichts**

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