**CHECKLIST EVALUATION EXPERIMENTS**

(COMMERCIAL/NON-COMMERCIAL INTERVENTIONAL/NON-INTERVENTIONAL CLINICAL TRIALS)

**EC AZ SINT-LUCAS BRUGGE OG 064**

**ACCREDITATION NUMBER 140**

A study will only be discussed at the EC meeting after written request to the President Dr. Rob Schildermans ([rob.schildermans@stlucas.be](mailto:rob.schildermans@stlucas.be) - tel. +32 50 36 51 55 - fax +32 50 36 51 59).

The investigator will personally present the study during the meeting.

|  |  |
| --- | --- |
| **1.** | **Study Title** |
|  |  |
|  | **Acronym** |
|  |  |
|  | **Protocol number** |
|  |  |
| **2.** | **EudraCT-number or BUN-number** |
|  |  |
| **3.** | **Investigator and investigational staff** |
|  | Name:  Hospital department / Function:  Phone number:  Email: |
| **4.** | **Sponsor (company, university)** |
|  | Internal (AZ Sint-Lucas Brugge):  External:  Company  Institution  Other:  **Contact Details:**  Street:  Number:  Town:  Postal code:  Country:  Phone number:  Email: |
| **5.** | **Type of study** |
|  | Non-commercial (academic) trial  Commercial trial |
|  | Retrospective trial  Prospective, Non-interventional trial  Prospective, Interventional trial  Monocentric  Multicentric  Follow-up  Amendment to ongoing trial |
|  | **Study Phase:**  I  II  III  IV  Other: |
| **6.** | **Clinical relevance** |
|  |  |
| **7.** | **Feasibility of the trial including suitability of the infrastructure** |
|  |  |
| **8.** | **Financial agreement between sponsor and investigator/hospital** |
|  |  |
| **9.** | **Financial compensation for patient** |
|  |  |
| **10.** | **Insurance for patient and investigator** |
|  |  |
| **11.** | **Participation of children or patients unable to give consent** |
|  |  |
| **12.** | **Participation of patients in emergency situations** |
|  |  |
| **13.** | **Payment**  In order for the hospital to provide a correct invoice, please give the correct invoice details to the EC:   * Study name: * Protocol n°: * PI at AZ Sint Lucas Brugge: * Site n°: * Study reference: * Invoice address: * VAT n°: * Email address: * Company contact person: |
|  | € 159,35 (excl. VAT) for commercial non-interventional trials  € 477,98 (excl. VAT) for commercial interventional trials |

In attachment:

Protocol

Investigator’s Brochure

Informed Consent (Dutch)

Patient information and questionnaires

Protocol Synopsis (Dutch)

EudraCT Application form

CV local investigator

CV national investigator

GCP certificates investigators

Contract

Insurance document

Advice of FGOV (medical devices)

Checklist EC AZ Sint-Lucas

Invoice information

**Undersigned, principal investigator of this trial**

declares that the protocol provides support by AZ Sint-Lucas Brugge services (tick in the list below) and confirms that the relevant services are sufficiently informed about this trial to enable the investigations or to provide support according to the modalities included in the protocol.  
  
The following services will be involved in the trail

Coordination clinical trial Mrs. Mary Glorieux (050 36 57 11)

Nursing Support Mrs. Annelies Catoor (050 36 58 77)  
Mr. Franky Degrendel (050 36 58 75)  
Mrs. Sarah Vandekerckhove (050 36 58 76)

Mrs. Leen Van Hoeymissen (050 36 58 78)

Pharmacy Mrs. Michelle Vannieuwenhuyssen (050 36 54 81)

Mr. Kris Loots (050 36 54 74)

Laboratory Dr. Johan Robbrecht (050 36 53 46)

Radiology Dr. Koen Geldof (050 36 54 13)  
Mrs. Heleen Van Meenen (050 36 53 95)

Pathology Dr. Marie-Astrid Van Caillie (050 36 53 45)

Cardiology Dr. Dirk Verleyen (050 36 51 55)

Other services:

Declares that there will be no need for support from personnel or services from AZ Sint-Lucas Brugge.

|  |  |
| --- | --- |
| Date: | Signature investigator: |
|  |  |