|  |  |
| --- | --- |
| IRB No.  (issued by IRB) |  |

**Study Synopsis for non-Drug and non-Medical Device Studies**

Address:

Sekretariat der Ethikkommission der Medizinischen Hochschule Hannover (OE 9515)

Carl-Neuberg-Straße 1

30625 Hannover

Phone: 0511 532 3443 / 9812

Fax: 0511 532 163443

Email: ethikkommission@mh-hannover.de

|  |  |  |
| --- | --- | --- |
| **1** | **Principal Investigator** (Acad. title, name, affiliation) |  |
| **2** | **Sub-Investigators** (Acad. title, name, affiliation) |  |
| **3** | **Person involved in biometric planning and evaluation** (Acad. title, name, Affiliation) |  |
| **4** | **Title of Study** |  |
| **5** | **Medical Condition** |  |
| **6** | **Study Characteristics** (Check all that apply) | [ ] prospective [ ] retrospective  [ ] therapeutic [ ] observational  [ ] diagnostic [ ] biobank/biomarker study  [ ] prophylactic  [ ] monocentric [ ] multicentric  [ ] open-label [ ] blind or [ ] double-blind  [ ] parallel group comparison [ ] randomized  [ ] single arm [ ] cross-over  [ ] ionizing radiation (StrSchV) [ ] X-rays (RöV)  [ ] other: |
| **7** | **Intervention** (If not applicable note: n.a.) | experimental group:  control group:  duration of intervention per patient: |
| **8** | **Vulnerable Subjects** (Check all that apply) | [ ] children  [ ] pregnant or lactating women  [ ] individuals > 75 years of age  [ ] patients in palliative care  [ ] legally non-competent individuals due to acute illness  [ ] legally non-competent individuals due to chronic disease  [ ] imprisoned or otherwise legally detained individuals  [ ] nursing home inhabitants |
| **9** | **Key Inclusion Criteria** (Mandatory: age/sex) |  |
| **10** | **Key Exclusion Criteria** |  |
| **11** | **Key Procedures** |  |
| **12** | **Objective(s)** |  |
| **13** | **Outcome(s)** (If not applicable: n.a.) | primary endpoint:  key secondary endpoint(s):  assessment of safety: |
| **14** | **Statistical Analysis** (If not applicable: n.a.) | Efficacy/test accuracy:  Description of the primary endpoint/test accuracy analysis and population:  Safety:  Secondary endpoint(s): |
| **15** | **Sample Size** | to be assessed for eligibility: n =  to be assigned to the trial: n =  to be analysed: n =  case number at MHH: n = |
| **16** | **Sample Size Justification** |  |
| **17** | **Trial Duration** | recruitment period (months):  first participant in to last participant out (months): |
| **18** | **Discussion of Perceived / Expected Risks and Benefits** |  |
| **19** | **Data Monitoring Committee** | [ ] yes [ ] no |
| **20** | **Insurance** (Company, Address) |  |
| **21** | **Participation Fee** (Amount in EUR) |  |
| **22** | **Participating Centres** |  |
| **23** | **Previous IRB Submission(s)** |  |

If applicable, add further remarks not specified in the Synopsis Form:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and Signature of Principal Investigator Place, Date