|  |  |
| --- | --- |
| 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