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| 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)

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| **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** | **Hypothesis** |       |
| **7** | **Key Inclusion Criteria**(Mandatory: age/sex) |       |
| **8** | **Key Exclusion Criteria** |       |
| **9** | **Trial type** | [ ] interventional [ ] observational [ ] retrospective[ ] retrospective[ ] diagnostics [ ] biobank [ ] monocentric [ ] multicentric[ ] open-label [ ] blind or [ ] double-blind[ ] randomized[ ] ionizing radiation (StrSchV) [ ] X-rays (RöV) |
| **10** | **Intervention**(If not applicable note: n.a.) | experimental group:      control group:      duration of intervention per patient:      follow up per patient:       |
| **11** | **Vulnerable Subjects** | [ ] children[ ] pregnant or lactating women[ ] legally non-competent individuals [ ] nursing home inhabitants |
| **12** | **Key Procedures** |       |
| **13** | **Outcome(s)**(If not applicable: n.a.) | primary endpoint:      key secondary endpoint(s):      assessment of safety:       |
| **14** | **Statistical Analysis**(Statistical methods used to compare groups for primary and secondary outcomes:Methods for additional analyses, such as subgroup analyses and adjusted analyses. Sample Size Justification) |       |
| **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** | **Trial Duration** | recruitment period (months):      first participant in to last participant out (months):       |
| **17** | **Discussion Expected Risks and Benefits** |       |
| **18** | **Insurance**(Company, Address) |       |
| **19** | **Participation Fee**(Amount in EUR) |       |
| **20** | **Participating Centres** |       |
| **21** | **Previous IRB Submission(s)** |       |

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

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Name and Signature of Principal Investigator Place, Date