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| IRB No.  (issued by IRB) |  |

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

Address:

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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