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

**Application Form for non-Drug- and non-Medical Device Studies**

**– Review of Ethical and Legal Aspects of Research Involving Human Subjects by the Institutional Review Board of Hannover Medical School –**

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. **Study Information** |

|  |  |
| --- | --- |
| Study Title  (Acronym, if applicable) |  |
| Study Register No. |  |

|  |
| --- |
| 1. **Principal Investigator[[1]](#footnote-1)** (if Student Project: Name of Supervisor) |

|  |  |
| --- | --- |
| Academic Title, Full Name |  |
| Name and Address of Department |  |
| Phone |  |
| Fax |  |
| Email |  |

|  |
| --- |
| 1. **Contact[[2]](#footnote-2)** |

|  |  |
| --- | --- |
| Academic Title, Full Name |  |
| Name and Address of Department |  |
| Phone |  |
| Fax |  |
| Email |  |

|  |
| --- |
| 1. **Bill Recipient** (for Sponsor-Initiated-Trials) |

|  |  |
| --- | --- |
| Addressee  (Company Name) |  |
| Contact Person |  |
| Postal Address |  |
| Phone |  |
| Fax |  |
| Email |  |

|  |
| --- |
| 1. **Submitted Documents** |

|  |  |
| --- | --- |
|  | **Document Name / Date and Version** (if not applicable: please mark accordingly) |
| Cover Letter |  |
| Study Synopsis (based on template) |  |
| Study Protocol |  |
| Participant/s Information Sheet(s) |  |
| Participant/s Consent Form(s) |  |
| Additional Material for Participants |  |
| Report(s) of other Institutional Review Board(s) (copy) |  |
| If necessary: Statement from the Data Protection Officer |  |
| If applicable: Insurance Certificate(s), CE-Certificate(s), Technical Information, Instruction for Use |  |

**Note:**

**Even with an approval of the Institutional Review Board of Hannover Medical School, the project leaders and their staff remain medically and legally responsible.**

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

Name and Signature of the Principal Investigator[[3]](#footnote-3) Place, Date

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

Name and Signature of the Head of Department[[4]](#footnote-4) Place, Date

1. If needed: expand table for additional principal or co-investigators. [↑](#footnote-ref-1)
2. If needed: expand table for additional contacts. [↑](#footnote-ref-2)
3. If needed: add Signature, Place and Date Fields for additional Principal or Co-Investigators. [↑](#footnote-ref-3)
4. If needed: add Signature, Place and Date Fields for additional Institutions. [↑](#footnote-ref-4)