**BIH CRU Clinical Research Grant**

Instructions for completing the form are printed in grey. Grey text is to be replaced by the applicant. Only text printed in black needs to appear in the final version. Please upload the completed document as one PDF file with a maximum size of 4 MB at the [online application portal](https://application.mdc-berlin.de/) until **12 August 2015 at 3 pm**.

**Title page**

<Short title Clinical Trial - Acronym>

<Full title>

Principal Investigator: <Name>

Co-PI\*: <Name>

Total amount of funding requested\*\*: <Sum> €

\* for clinical trials according to AMG a Co-PI (Stellvertreter) is required

\*\* direct costs for the two-years funding period

**Part I: Project outline for the proposed Clinical Trial**

Please address the following items (**max. 2 pages, excluding title page and references)** to describe the clinical trial project:

* The major research question(s), e.g. medical problem or knowledge gap, that will be addressed during the funding period, highlighting how the application fits into the mission of and the general framework of translational research and systems medicine.
* Innovative elements of your research program, e.g. if the proposed project challenges established models on the basis of novel hypotheses, approaches or methodologies.
* The potential of the project to develop new diagnostic, therapeutic and preventive procedures.
* Brief overview of the preliminary work.
* Expected contribution to the improvement of the CRU infrastructure, and added value resulting from the collaboration between clinical research and basic science, preferentially MDC and Charité for BIH scientists beyond the scope of the individual application.
* Expected establishment of BIH-cohorts, and added value resulting from central use and operation of BIH core facilities and the CRU.
* Study rationale, study hypothesis, study objectives and endpoints including outcome measures (divided into primary, secondary and exploratory).
* Study design, incl. regulatory aspects (clinical trial according to AMG etc., phase, diagnostic trial, blinded, randomized), location (mono-/multicentric), study population, planned enrollment period, type of application: IIT or additions to ongoing clinical trials (Clinical Trial-associated Science).
* Anticipated overall study duration including recruiting phase, follow up phase per patient, preparation phase and analysis/reporting phase.
* Biostatistics: estimated number of subjects.
* If applicable please describe subprojects and how the subprojects will be interlinked.
* Involvement of early-career/female/basic scientists .
* Own contribution (this can be personell or budget), additional external funding.
* A bibliography of all references cited at the end of the text.