



## Fact sheet

# Commitments DZHK Studies

### Background:

With the full proposal, applicants of DZHK studies submit, using the [CR.4](#) document, commitments of DZHK internal and external sites (national, international) that, on the whole, guarantee that the recruitment goal in respect to recruited participants is achieved. Submitting full commitments (incl. the conflict of interest declaration of responsible individuals) is a prerequisite for the conclusion of the funding agreement of a study.

Due to an average application period of one and a half years (in the past) and the possible changes in, for example, local capacities, inclusion and exclusion criteria, etc., a change in the number of expressly confirmed participants at a site or even the exclusion and inclusion of new sites can occur.

In this case, the study principal investigator/coordinator commits:

- 1) to promptly submit new commitments using a newly obtained document CR.4 to the DZHK Main Office, the Funding Management Department (FMM) and the DZHK infrastructure (DH, TTP, Ethics Project),
- 2) to justify how he nevertheless guarantees that the number of participants expressly confirmed and statistically analysed for the study in question is ensured, and
- 3) to notify the DZHK Main Office and DZHK infrastructure (DH, TTP, Ethics Project) of the closure of already initiated sites.

### Rules:

- The DZHK Main Office and DZHK infrastructure accept any commitment amendments from the respective chief investigator only and then implement them.
- If additional recruiting sites should be included, permission must first be obtained within the DZHK. In particular, it must be clarified whether there will be any additional costs and how these will be covered.
- A subsequent internationalisation of a study must first be put forward for discussion within the DZHK with all affected project partners (additional costs, etc.).