Scientific Board eligibility criteria for access to clinical project services

Declaration for submissions to the ECRIN Scientific Board

I acknowledge that access to ECRIN clinical project services requires compliance with the following eligibility criteria.

ELIGIBILITY CRITERIA

1 Multicentre study run in at least in two ECRIN Member or Observer countries

2 Rules for transparency:
   a. Commitment to register the study in a public register *
   b. Commitment to post trial results in a public register **
   c. Commitment to publish results irrespective of findings
   d. Commitment to share individual patient-level data as described in the data sharing plan
   e. Disclosure of interests

3 Commitment to fairly describe the contribution of ECRIN and its national partners in the trial registry (clinicaltrials.gov or any other WHO-ICTRP-compliant registry) and in the publications ***

I DECLARE THAT

- The current version of the protocol does not comply with <u>all the eligibility criteria</u> and cannot be changed at this stage. Therefore, I commit to include them on the occasion of the earliest protocol amendment. ☐
- <u>All the eligibility criteria</u> are already met and addressed in the current version of the study protocol. ☐

....., ...

Date Signature of the Coordinating Investigator

* before inclusion of the first trial participant, according to the WHO ICTRP or ICMJE recommendations, for example on EudraCT or Clinicaltrials.gov (https://www.who.int/ictrp/en/ and http://www.icmje.org/recommendations/). Registration of observational studies is also recommended

** one year after the trial is completed, i.e., last follow up of the last patient for the primary variable, according to the WHO ICTRP recommendations

*** in the acknowledgement section or as co-author, depending on the contribution in the trial design, planning and publication