ECRIN 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 publications ***

I DECLARE THAT

➢ The current version of the protocol does not comply with all the eligibility criteria and cannot be changed at this stage. Therefore, I commit to include them on the occasion of the earliest protocol amendment.

➢ All the eligibility criteria are already met and addressed in the current version of the study protocol.

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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