

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.

.....,
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/ictip/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