

Documents for submission of a research proposal to a WMO review committee

- Cover letter to reviewing committee¹; (16 X)
- Research protocol; (16 X)
- Signed research contract between the party organising the research (sponsor) and the investigator and/or institution (16 X)
- Investigators brochure²; (3 X)
- Information for patients and research subjects (incl. Informed Consent) (16 X)
- ABR-form signed and dated; online registration required³ (16 X)
- Insurance certificate for WMO research with human subject insurance or written request for exemption from insurance obligation (16 X)
- Proof of coverage of investigator or sponsor, for example liability insurance (16 X)
- Any advertising texts or other enrolment materials (16 X)
- Questionnaires, patient diaries, patient cards (if applicable) (16 X)
- Independent doctor résumé (signed and dated) (16 X)
- Investigator résumé (signed and dated) (16 X)

In case of drug studies:

- EudraCT application Form: on paper (signed and dated) and in XML format⁵ (3 X)
- IMPD⁶ (incl. list of relevant research with the medicinal product being researched) (3 X)
- Other Applicable statements/licenses (16 X)
- VWS license is required when the research medicinal product is being imported from a non-EU country (16 X)

In case of a multicentre trial:

- Coordinating investigator résumé (signed and dated) (16 X)
- List of participating centres and principal investigators (16 X)
- Local feasibility declaration from the Board of Directors/Management per centre⁷ (16 X)

¹ to be signed by the principal investigator. All other doctors/hospital departments involved in the trial have to sign the letter

² in case of research with medicinal products or medical aids

³ <http://www.toetsingonline.nl>

⁴ the investigator and the independent doctor may not participate in the same partnership

⁵ online <https://eudract.ema.europa.eu/>

⁶ in case of a not registered medicinal product.

⁷ the party organising the research (sponsor) sends a request to the Board of Directors/Management for local feasibility declaration

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