

The protocol should be arranged as follows:

A. Module I

1. PI's Application letters
2. All other letters (Introduction, support, permission, etc)
3. Statement to comply with ethical principles
4. ERC Administrative form
5. ERC Checklist

Module II

6. Main document (protocol)
7. Participant Information sheet(s)
8. Consent form (s)

Module III

9. Study tool(s) and other study materials
10. All CVs and GCP Certificates where applicable

Kindly note that the entire document should be attached as one PDF file with the "**Module Numbers**" as divisions and sent via this email.