I. ICH GCP section 3.1.2 – IRB/IEC Essential Documents for Review and Approval

What essential documents does the IRB/IEC need to review and approve before and during the conduct of a clinical trial?	
Essential Documents	☐* Trial Protocol/Amendments(s) ☐* Written Informed Consent Form (ICF) and ICF updates ☐* Subject recruitment procedures (e.g. advertisements) ☐* All written information to be provided to the subject ☐* Subject payments(amount, methods and schedule) if applicable ☐* Investigator Brochure (IB) and other available safety information ☐* Investigator's current Curriculum vitae (CV) and/or other documentation evidencing qualifications ☐* Other documents to ensure patient safety and well-being