

Review Type

Review Type: What is it and why do I need to know?

Before starting an eProtocol application, investigators must identify the appropriate Review Type. This determines which questions are prompted for on the application. There are four types of form type: Regular, Expedited, Exempt, and a streamlined Chart Review form.

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Regular review	Protocols that involve more than minimal risk or do not meet the criteria for Exempt or Expedited. They are reviewed at a convened IRB meeting. Examples of protocols requiring initial regular review are studies using FDA investigational test articles, randomized double-blind placebo-controlled studies, Phase I, II, III and IV clinical trials, and studies using x-rays.
Expedited review	Minimal risk studies meeting specific criteria (pdf). Protocols are generally reviewed by one primary IRB reviewer. Protocols approved under Expedited review are subject to IRB continuing review.
Exempt review	Studies meeting specific criteria (pdf). These studies are exempted from IRB <i>continuing review - not from initial review</i> . The IRB determines whether the claim for exemption is appropriate and whether it will be granted. Exemption from IRB continuing review continues unless the protocol is to be modified such that it no longer will meet the criteria for exemption.
Chart review	Use for chart review studies that only involve the use of materials (data, documents, records) that have been collected for research or non-research purposes, or will be collected for non-research purposes. Do not use if a study involves interaction/intervention with participants, evaluating safety and effectiveness of a drug or device, or obtaining/analyzing specimens: This must be submitted on an Expedited or Regular form (see below).