

Section 03: Protocol Application Type

In this section, you must choose the type of study application you are submitting. The IRB will determine whether your study review can be expedited, or whether it requires full committee review. More information on studies that qualify for expedited review can be found here: <https://irb.duhs.duke.edu/policies-and-regulations/policies/expedited-review>

Even if you believe your study should be exempt from IRB review, you must still submit an Application for Exemption from IRB Review. More information on studies that qualify for exempt review can be found here: <https://irb.duhs.duke.edu/node/4091>

03. Protocol Application Type

User Guide

<p>* Select the type of protocol you are creating:</p> <p><input checked="" type="radio"/> Regular Study Application <i>Most common. The IRB will determine if the study is eligible for expedited review or requires full board review upon submission.</i></p> <p><input type="radio"/> Application for Exemption from IRB Review <i>Includes Exempt (45 CFR 46.101 (b)), Not Human Subject Research (45 CFR 46.102 (f)), & Not Research (45 CFR 46.102 (d)).</i></p> <p><input type="radio"/> External IRB Application <i>Includes phase II, phase III, phase IV protocols that are industry sponsored multi-site studies, and includes selected DCRU phase I protocols.</i></p> <p><input type="radio"/> Trainee Research While Away from Duke <i>Research conducted by medical students overseen by the Office of Curriculum & other student/trainee research away from Duke.</i></p> <p><input type="radio"/> Emergency Use of a Test Article <i>Emergency use of an investigational drug or biologic, emergency use of an unapproved device.</i></p>	<p>Please see additional criteria and information in the policy titled "Reliance on the IRB of Another Institution, Organization, or an Independent IRB" on the IRB web site.</p>
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