Exemption from IRB Review

Do I need to submit a study to the IRB if I believe it qualifies for exemption?

Yes, only a DUHS IRB Chair/designee can make a declaration of exemption for your study. If you believe your study qualifies for exemption, you must complete a New Study application in iRIS and indicate that you are applying for a declaration of exemption. You cannot initiate any study activities until you have received written notice of the determination of exemption from the IRB.

What are some tools to determine if my project is exempt (relief from further IRB oversight)?

A ?Checklist for Exemption or Relief from Further IRB Oversight? is posted on the IRB website under ?Forms?. The checklist was developed to help Investigators and IRB Reviewers assess whether an activity constitutes research involving human subjects, and whether the activity is subject to IRB oversight. Note that to obtain an authoritative determination of whether an activity is exempt from further IRB review, the Faculty/Staff Member must request confirmation from the IRB that an activity does or does not constitute research with human subjects, and whether the project involving research with human subjects qualifies for exemption from further IRB review or meets the definition of ?not engaged in research?. If you think your project may qualify for exemption, please submit the project to the IRB and choose the option ?Application for exemption from IRB review? in section 03 of the submission form in the eIRB.

How do I close a study that has been declared exempt from IRB review?

In iRIS currently, the way to close an exempt study is to click on the "close exempt" button.

Do I need to submit a Key Study Personnel (KSP) change on a study declared exempt from IRB review?

Yes. Furthermore, any person added to a Key Personnel list on a study must complete the Duke Health CITI module training requirement.