Exempt Determination

• If the study is minimal risk, the Research Compliance Manager evaluates submissions that claim exemption from IRB review, and the IRB Chairperson provides consultation in the review of claims of exemption.

• Research activities involving human subjects are exempt from the requirement for IRB review as identified in 45 CFR 46.101(b)(1)-(6), 45 CFR 406.301(a), 45 CFR 46.401(b) and 21 CFR 56.104(d).

• Only the IRB may determine which activities qualify for an exempt review.

• Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must contact the IRB concerning the status of proposed research or changes in ongoing research.

• An Investigator may request a particular category of exemption, but the final determination of applicability will be made by the IRB.

• Research may be granted exempt status by the IRB if all research activities involve procedures listed in one or more of the specific categories under 45 CFR 46.101(b).
  • NOTE: These categories do not apply to research involving prisoners and categories 1-5 do not apply to FDA regulated research.

• For Exempt Categories and more information please see MMC SOP FO 302