

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
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Policy No. 103.19	Title: Pharmacy & Therapeutics Review	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB requires review and approval by a representative of the Pharmacy and Therapeutics (P&T) Committee for any use of drugs, biologics, or complimentary and alternative medicines (CAMs) in a research protocol prior to final IRB action on a protocol. This objective will be accomplished by ensuring that IRB FC shall have a member who is also a member of the P&T Committee. When a P&T member for the IRB FC must be absent from a meeting, a P&T Committee alternate may serve as a designated alternate and attend the meeting. In cases where a P&T IRB member or alternate cannot attend a convened meeting, the IRB will table applications that include drugs used in clinical investigation until the next meeting when the P&T IRB member can attend. JHSPH IRB X reviews research that qualifies as a minimal risk activity which may be reviewed through an expedited review process. JHSPH IRB X may review applications that include a marketed drug only if it obtains a written consult from a P&T/IRB member from IRB FC. The P&T IRB members will provide information to the P&T Committees of the three JHM hospitals (JHH, JHBMC, and HCGH) to assure proper communication regarding drug research approved for conduct at the Hospitals.