

Standard Operating Procedure for Protocols Involving the Administration of Pharmaceuticals

A research pharmacist, as part of the General Clinical Research Center Advisory Committee review process, will review all protocols that involve the administration of any pharmaceutical by any route. For this purpose a pharmaceutical shall be defined as any substance administered by any route, other than food administered orally.

The pharmacist will comment on the pharmacy content of protocols and consent forms to be implemented at the University Park GCRC. Specifically the review will focus on recommendations about specific aspects of the administration process of the pharmaceutical, including storage, preparation, labeling, dispensing and disposal of unused products. The research pharmacist is specifically excused from commenting on aspects of the protocol and consent form not related to the pharmaceutical.

In addition specific questions for the pharmacist concerning the protocol can be submitted by the scientific reviewers, RSA, and GCRC staff or administration.

The pharmacy review will be available at the GAC review of the protocol.