

FDA Inspection Information

The U.S. Food and Drug Administration [FDA] has the right to show up on our doorstep through a scheduled inspection or unannounced arrival. In light of recent experiences, we want to take this opportunity to highlight initial steps that should be followed if the FDA arrives unannounced.

- 1) Immediately inform UW Medicine Compliance of the inspection. They can be reached at 206-543-3098.
- 2) Request the 482 form and a business card from each inspector.
- 3) Notify the sponsor to allow them the option of sending representation.
- 4) Contact the Human Subjects Division at 206-543-0098 and ask to speak with the staff person that supports the IRB committee overseeing your research.
- 5) Contact pharmacy, lab medicine, and any clinics or centers that could be part of the audit.

For additional information, please refer to Good Clinical Practice Training at www.uwmedicine.org/Research/ClinicalResearch/gcp.htm