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

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