

Changes that IDS has made in response to the COVID-19 outbreak as of 3-17-20

At this time the IDS pharmacy will not be making any changes to our staffing model or hours of operation but I wanted to reach out to update you on some changes that IDS has made in response to the COVID-19 outbreak.

Sponsor/monitor visits: If your research requires monitor visits to the IDS pharmacy, per **Policy on Conduct of Human Research Activities during COVID-19 Operations March 16, 2020**, all sponsor and monitor visits will be moved to remote visits. Monitor visits that are already scheduled in the coming weeks/months should be moved to remote only visits. Starting immediately, sponsor representatives and CRAs will no longer be admitted to the IDS pharmacy for site qualification visits, site initiation visits or record/inventory review (exceptions need to be cleared by the IDS pharmacy on a case-by-case basis). The IDS pharmacy can answer sponsor questions about our services and resources via email or conference call if required.

Subject IP returns: Starting immediately, the IDS pharmacy will no longer be conducting return accountability on subject investigational product (IP) returns. Remaining IP and empty kits/bottles can still be returned to the pharmacy, but they will be placed directly into a biohazard bag and put into storage. IDS will work with study teams and sponsors to ship returns to distributors, or they can be stored in biohazard bags until they can be reconciled by monitors at a later date. Moving forward please try to bag returns up before bringing them to the pharmacy. **This change does not impact our process for retaining used vials from sterile product compounding. In addition, medications that do not leave study team custody team custody and the institution, can be returned to the pharmacy and redispensed if part of the existing study workflow.**

Mailing of IP: The Brigham and Women's Hospital Pharmacy Department is not licensed as a mail order (non-resident) pharmacy and thus will not be able to mail new supplies of IP to subjects. Study teams can continue to send medication orders and prescriptions to the IDS pharmacy, but they will need to pick up the IP from the pharmacy and coordinate mailing or courier services on their own.

These new measures are obviously temporary, but I am hesitant to provide an end date as no one knows how long this outbreak will last. I will update you as soon as research and pharmacy administration decide it is safe to roll back these new precautions.

Please email BWHRXIDS@partners.org or call 617-732-6410 if you have any questions or concerns regarding the above.

Thank you,
Kevin Zinchuk PharmD
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Investigational Drug Service