OnCore Use Guideline

The use of a single institutional clinical trials management system will promote the safety of study participants and allow for greater efficiency in conducting studies. The following provides guidance to ensure consistency and best practices in the management of clinical trials with the use of OnCore. Predesignated required fields in OnCore allow for metric and benchmark tracking in Insights.

Minimum footprint of OnCore use for all Clinical Trials:

1. All required fields in the protocol console completed (PC console) with system signoffs and participating affiliated institutions
2. Regulatory approval events (ie. Initial IRB approval, amendments and continuing reviews) completed
3. Registration of all Consented Subjects in CRA Console
4. Accurate study status to ensure proper display on public WVU Clinical Trial search feature: https://www.hsc.wvu.edu/ctru/current-clinical-trials/search
5. Protocol and subject deviations, including reports for appropriate reporting
6. Safety reporting of Serious Adverse Events, including completed printed report
7. Regulatory and protocol document storage (protocol, informed consent form, Investigator Brochure (IB), FDA IND/IDE approval letter as applicable).

Optional activities in OnCore:

1. Protocol Calendar
2. Task Lists for key activities (ie. Activation, study close-out)
3. Financials console
4. Subject tracking through calendar visits
5. Staff profiles and credentials
6. Electronic Data Capture (EDC)/Forms Module
7. Auditing/Monitoring functions
8. Staff Effort Tracking

For questions or to request OnCore training, please contact Lisa Powroznik,
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