

Instructions for Study Documents Requiring NETT-CCC Review

Informed Consent

- 1) Reference the SHINE Informed Consent template (located in SHINE Toolbox).
- 2) Write the Hub/Spoke SHINE Informed Consent Form considering the template guideline language and local IRB requirements.
- 3) Add a new version ID and date in the footer of the document (e.g., SHINE ICF v2.0 04/11/2011).
- 4) Return to the NETT-CCC for review via shine-milestone@umich.edu
- 5) Once returned, please review and incorporate changes and provide the NETT-CCC with a final copy **PRIOR** to submitting to the IRB. For contingencies, please contact NETT-CCC for modifications made to the ICF.
- 6) Upload IRB approved copy (with version ID and date in the footer) along with documentation of IRB approval in WebDCU.

Recruitment Plan

- 1) Reference the SHINE Recruitment plan guidance (located in SHINE Toolbox).
- 2) Prepare Hub/Spoke Recruitment plan (in prose format), addressing the questions and explaining site processes in detail, as referenced in the guidance document.
- 3) Add the HUB/Spoke name in the Header. Add date and version ID footer of the document (e.g., "SHINE Recruitment Plan for University of Virginia" for the Header; for the footer "v2.0 04/11/2011").
- 4) Return to the NETT-CCC for review via shine-milestone@umich.edu.
- 5) Once returned, please review and incorporate changes. Provide the NETT-CCC with a final copy **PRIOR** to uploading as a single pdf file in WebDCU to confirm the readiness call.

Readiness Checklist

- 1) For sites requesting a tentative SHINE Readiness call, USE the SHINE Readiness Checklist Template (located in SHINE Toolbox).
- 2) Complete the readiness checklist, including the checkboxes and site attendee information in the first 3 pages, adding in comments where appropriate.
- 3) Add a version ID and date in the footer of the document (e.g., SHINE Readiness Checklist v1.0 04/11/2011).
- 4) Return to the NETT-CCC for review via shine-milestone@umich.edu
- 5) Once returned, please review and incorporate changes as appropriate.
- 6) Provide the NETT-CCC with a final copy at least 48 hours prior to the scheduled readiness call. (This document doesn't need to be uploaded into WebDCU).

Pharmacy Plan and Orders

- 1) Reference the SHINE Pharmacy Plan Guidance template (located in SHINE Toolbox).
- 2) Consult with site pharmacy to create Hub/Spoke SHINE Pharmacy Plan using the Pharmacy guidance document.
- 3) Consult with site pharmacy to create Hub/Spoke SHINE pharmacy Orders using the Pharmacy guidance document.
- 4) Add a new version ID and date in the footer of the document (e.g., SHINE Pharmacy Plan v2.0 04/11/2011).
- 5) **A Pharmacy Plan document is required to set up a tentative Readiness call and will be reviewed by Askiel Bruno (abruno@augusta.edu) and NETT-CCC shine-milestone@umich.edu.
- 6) **Once returned, please review and incorporate changes and provide the NETT-CCC with a final copy to confirm the readiness call.
- 7) Upload FINAL copy (with version ID and date in the footer) in one pdf file in WebDCU.

****For questions regarding the documents referenced above, please email shine-milestone@umich.edu or the SHINE Site Manager at rlewis@med.umich.edu**