SHINE Contracts and Invoicing

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Contract Status

- All contracts sent from University of Virginia to collaborators

- 8 contracts executed

- NETT Hub contracts in queue in the UM contracts office

Study Start-up Milestones

- SHINE sites will receive two milestone-based start-up payments prior to subject enrollment

Study Start-up Milestones

- **MILESTONE 1   (50% of total payment)**
  - Enter Hub and or participating Spoke(s) into WebDCU™
  - Submit site-specific informed consent to the NETT CCC for review/approval
  - Upload copy of above IRB submission into WebDCU™ (document should be titled, "SHINE IRB Submittal")

Study Start-up Milestones

- **MILESTONE 2/3   (50% of total payment)**
  - Reconcile regulatory documents in WebDCU™
  - Confirm that all contracts (site, investigational pharmacy, etc.) and required training are in place
  - Upload IRB approval
  - Complete site readiness call
  - Obtain approval to begin SHINE subject enrollment from the CCC

Study Start-up Milestones

- The SHINE study team will send a confirmation email to the site once all the tasks for a given milestone have been verified as complete

  – All email correspondence regarding milestone task completion from **NETT Hubs** should be sent to the SHINE study team at SHINE-milestone@umich.edu

  – All email correspondence regarding task and milestone completion from **Affiliate Hubs** should be sent to the SHINE study team at SHINE-milestone@virginia.edu

Payments to Clinical Sites

- Sites will receive per-subject payments after completion of visits, entry of data and resolution of data queries

Per-subject Payments

- **Payment 1   (60% of total payment)**
  - Eligible subject is enrolled and completes initial study visit
  - All data for eligible visit is entered into WebDCU™
  - All queries are resolved for the visit
  - Subject visit reads "Ready" in WebDCU™

Per-subject Payments

- **Payment 2   (40% of total payment)**
  – Subject is not lost to follow up
  – Eligible subject completes all requirements of 3-month outcomes visit within the time described in the SHINE MOP
  – All data for second visit is entered into WebDCU™
  – All queries are resolved for the visit
  – Subject visit reads "Ready" in WebDCU™

Payments to Clinical Sites

- The site should request payment by submitting an institutional acceptable invoice to the subcontractor for payment

Questions?

- Affiliate Hub contact Amy Fansler at ACF7H@virginia.edu

- NETT Hubs contact Valerie Stevenson at vwillis@umich.edu