**MILESTONE 3**

- Continuation of enrollment at the Hub

### 16.5.2 Per Subject Payments

SHINE sites will receive two per-subject payments based on the schedule outlined below. In order to qualify for payment for an individual subject, all associated CRFs must be complete and query free to show as ready for payment. The site is then eligible to request payment by submitting an institutional acceptable invoice document to the subcontractor for payment. Figures provided represent "total payments", and thus include any Indirect Cost recovery.

**Payment 1**

Payment 1 is provided when the following criteria are met:

- 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™

**Payment 2**

Payment 2 is provided when the following criteria are met:

- Subject is not lost to follow up
- Eligible subject completes all required components of 3-month outcomes visit
- All required data for second visit is entered into WebDCU™
- All queries are resolved for the visit
- Subject visit reads "Ready" in WebDCU™

**Contact Information for Milestones and Payments**

For NETT Hubs and Spoke Sites:
All email correspondence regarding milestone payments should be sent to the SHINE study team at SHINE-milestone@umich.edu.

For SHINE Ancillary Sites:
All email correspondence regarding milestone payments should be sent to the SHINE Grants and Contracts Administrator: Emily Gray at shine_invoices@Virginia.EDU.

# 17. Close-Out and Termination Stages

## 17.1 Site Closeout

Site Closeout procedures will be distributed and coordinated by the NETT-CCC Site Manager to ensure regulatory compliance. Contact site manager with questions.

## 17.2 Retention of Study Records

Study records will be retained for a minimum of 5 years from the approval date of the sponsor's final study report in accordance with contract or grant stipulations or until you are otherwise notified by NIH. These include, but are not limited to:

1. Patient CRF binders and informed consent forms
2. Patient medical charts containing progress notes, laboratory reports, etc.

3. Regulatory Binders
4. Study Reference Manual
5. All other personal/site files and documents related to the trial

# 18. Study Policies and Research Conduct

## 18.1 Protection of Human Subjects

Participating sites must maintain a human subjects protection program compliant with 45 CFR 46 and 21CFR 50 and 56 and with state, local or institutional requirements related to the protection of human subjects, an approved Assurance for human subjects research and an IRB registration number. Enrolling local institutions must also ensure the safe and appropriate performance of the research at its institution. This includes, but is not limited to, monitoring protocol compliance, managing any major protocol violations, managing any serious adverse events occurring at the institution, ensuring qualifications of research staff and providing a mechanism by which complaints about the research can be made by local study participants or others. Prior to enrolling subjects in SHINE, each site must submit documentation that the study has been approved by the local IRB, including locally approved informed consent forms.
Written, valid informed consent must be obtained from each SHINE participant as part of the subject enrollment process only after the investigator is satisfied that the participant understands the potential risks and benefits of participation in the study.

See also:
https://nett.umich.edu/sites/default/files/docs/sop_certification_for_protection_of_human_subjects_final01.pdf

## 18.2 The HIPAA Privacy Rule

Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, SHINE investigators are required by the Department of Health and Human Services (HHS) or the Food and Drug Administration (FDA) Protection of Human Subjects Regulations (45 CFR part 46 or 21 CFR parts 50 and 56, respectively) to take measures to protect personal health information (PHI) from inappropriate use or disclosure. PHI includes identifiable health information about subjects of clinical research gathered by a researcher who is a covered health care provider.

Compliance with HIPAA regulations is considered a local context issue and remains the purview of the local institution and local IRB. The HIPAA Privacy Rule is concerned with the risk to the subject's privacy associated with the use and disclosure of the subject's PHI, and permits researchers, as health care providers and therefore covered entities, to use or disclose PHI for research under certain circumstances and conditions, including if the subject of the PHI has granted specific written permission through an Authorization that satisfies section 164.508 and if the PHI has been de-identified in accordance with the standards set by the Privacy Rule at section 164.514(a)-(c) in which case, the health information is no longer PHI.

The individual SHINE IRBs will act as Privacy Boards (required by HIPAA) to review the use and disclosure of PHI and to determine whether subjects should sign a Subject Authorization for Release of PHI for Research in addition to the consent to participate in research, or if a Waiver of Authorization may be granted analogous to a Waiver of Consent under the Common Rule.