

Hemodialysis Fistula Maturation Study

Forms Completion Schedule

Enrollment/Baseline

- Form 201 – Screening Form
- Form 202 – Demographics, Comorbidities, and Exposures Form
- Form 203 – Baseline Pre-operative Physical Exam Form
- Form 204 – Renal, Dialysis Access History Form
- Form 205 – Medication Data Form (only one form entered at baseline)
- Form 206 – Baseline Lab Data Form
- Form 207 – Patient Future Linkage with USRDS Form
- Form 208 – Pre-Operative Physical Activity Form
- Form 240 – Baseline Drop Out Form (if needed)

Pre-Op Imaging Studies and Vascular Function Studies

- Form 210 – Getting Ready for Vascular Study Form
- Form 211 – Venous Plethysmography Study – Local Results Form
- Form 212 – Arterial Pulse Wave Velocity – Local Results Form
- Form 213 – Brachial Artery FMD/NMD Image Study – Local Clinical Center Form
- Form 214 – Brachial Artery FMD/NMD Image Study – central core results form (completed and entered by Core)
- Form 216 – Local Ultrasound Imaging and Transmission Form
- Form 217 – Receipt of Ultrasound Form (completed by Core)
- Pre-Operative Ultrasound Data (Left) (Worksheet completed by Core)
- Pre-Operative Ultrasound Data (Right) (Worksheet completed by Core)

Surgery

- Form 230 – AVF Creation Surgery Notification Form
- Form 231 – Details of the Surgery Form

Post-Op Day 1 Ultrasound

- Form 216 – Local Ultrasound Imaging and Transmission Form (Completed by Study Coordinator)
- Post-Operative Ultrasound Data (Left) (Post-Op AVF US Core Worksheet)
- Post-Operative Ultrasound Data (Right) (Post-Op AVF US Core Worksheet)

Post-Op Week 2 Ultrasound

- Form 216 – Local Ultrasound Imaging and Transmission Form (Completed by Study Coordinator)
- Post-Operative Ultrasound Data (Left) (Post-Op AVF US Core Worksheet)
- Post-Operative Ultrasound Data (Right) (Post-Op AVF US Core Worksheet)

Monthly Follow up

- Form 300 – Monthly Follow-Up (from surgery until 3 months after the study fistula has been abandoned)
 - Form 302 – Cannulation Form (for the first attempted cannulation and for **each** attempt at cannulation up until and including the first successful cannulation)
 - Form 305 – Assess Clinical Maturation Form (from the first successful cannulation, for every dialysis session until notified by the DCC to use another frequency))
 - Form 503 – Long Term and Post-Abandonment Clinical Outcome Form (every six months after the date of abandonment, from abandonment until the end of the study or following DCC recommended timing for patients no longer providing data for the monthly Form 300.
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- Form 421 – Non-Study Access Event Form (as needed)

Week 6 & 10+ Ultrasound

- Form 216 – Local Ultrasound Imaging and Transmission Form (Completed by Study Coordinator)
- Post-Operative Ultrasound Data (Left) (Post-Op AVF US Core Worksheet)
- Post-Operative Ultrasound Data (Right) (Post-Op AVF US Core Worksheet)

Study Fistula Forms

- Form 422 – Study Fistula: Access Event Form
- Form 423 – Study Fistula: Access Intervention Form
- Form 424 – Study Fistula: Diagnostic Study Form
- Form 425 – Study Fistula: Used for purpose other than dialysis
- Form 426 – Study Fistula Abandonment Form

Mailing Forms

- Form 606 – Mailing Serum Specimen to Fisher (NIDDK) Biosample Repository Form
- Form 607 – Mailing Blood to NIDDK DNA Repository
- Form 608 – Mailing of Vein Tissue with RNA Later Preservative and with Proteomics Preservative on DRY ICE to NIDDK Biosample Repository Form
- Form 609 – Mailing of Frozen Vein Tissue on Dry Ice to the Histology Core at the University of Washington Form
- Form 610 – Mailing of Formalin Fixed Vein Tissue in Ethanol at Room Temperature to the Histology Core at the University of Washington

Long Term Outcome/Hospitalization/Death/SAE

- Form 503 – Long Term Clinical Outcome Form
- Form 511 – Clinical Center Hospitalization Notification Form
- Form 512 – Clinical Center Final Hospitalization Form
- Form 521 – Clinical Center Death Notification Form
- Form 531 – Serious Adverse Event Form
- Form 550 – Outcome Committee Maturation Review Form (completed by DCC)
- Form 560 – Outcome Committee SAE Review Form (completed by DCC)

- Form 570 – Patient Transfer Form (as needed)