NINDS Common Data Element (CDE) Project
Stroke Version 2.0 Public Review
Long Term Therapies Subgroup Materials

Case Report Forms:

- Antithrombotics and Risk Factor Controlling Medications
- Lifestyle Modification Therapies
- Rehabilitation Therapies
- SAH Surgical/Procedural Interventions
- Stroke Surgical and Procedural Interventions
- UIA Management

Antithrombotics and Risk Factor Controlling Medications

[Study Name/ID pre-filled] Site Name:

Subject ID:

For some studies (e.g., clinical trials) it may be important to record the details of each medication administered during the study on a Prior and Concomitant Medications form. The General CDEs include a Prior and Concomitant Medications template form.

In-Hospital Medications

1. **Did the participant/ subject receive ~~arterial dose~~ anticoagulants? ☐ Yes ☐ No

   **IF YES, type(s) of anticoagulants received: (choose all that apply)

   - ☐ Unfractionated heparin IV
   - ☐ Full dose LMW heparin (Enoxaparin, Others)
   - ☐ Warfarin (Coumadin)
   - ☐ **Direct oral anticoagulant: (dabigatran, rivaroxaban, apixaban, others)
     - ☐ Direct Thrombin Inhibitor
     - ☐ Factor Xa inhibitor
   - ~~☐ Fondaparinux (Arixtra)~~
   - ☐ Other, specify:

2. **Did the participant/ subject receive ~~arterial dose~~ antiplatelet~~s~~ agents? ☐ Yes ☐ No

   **IF YES, type(s) of antiplatelet~~s~~ agents received: (choose all that apply)

   - ☐ Aspirin
   - ☐ Aspirin/Dipyridamole (in separate formulations or as Aggrenox)
   - ☐ Clopidogrel (Plavix)
   - ~~☐ Ticlopidine (Ticlid)~~
   - ☐ Cilostazol
   - ☐ Other, specify:

3. Was the participant/ subject diagnosed with VTE? ☐ Yes ☐ No (Skip to 4)

   (VTE = extracranial venous thromboembolism)

   A. IF YES, diagnosed with which type(s): (choose all that apply)

      - ☐ Deep venous thrombosis (DVT)
      - ☐ Pulmonary embolism
      - ☐ Other, specify:

   B. IF YES, type(s) of VTE prophylaxis used: (choose all that apply)

      - ☐ Low dose unfractionated heparin (LDUH) ~~(Answer 3C)~~
      - ☐ Low molecular weight heparin (LMWH) ~~(Answer 3C)~~
      - ☐ Intermittent pneumatic compression devices (IPC) e.g. Venous Foot Pump
      - ☐ ~~Factor Xa Inhibitor~~ Direct oral anticoagulant

Antithrombotics and Risk Factor Controlling Medications

[Study Name/ID pre-filled] Site Name:

Subject ID:

- ☐ Direct Thrombin Inhibitor
- ☐ Factor Xa inhibitor
- ☐ ~~Warfarin~~
- ☐ ~~Venousr foot pumps (VFP)~~
- ☐ ~~Oral Factor Xa inhibitor~~
- ☐ Other, specify:

~~C. IF heparin (i.e., LDUH/ LMWH) used, provide dose: (include units)~~

Discharge Medications

4. Specify discharging location:
   - ☐ Acute hospital
   - ☐ Intensive Inpatient rehabilitation facility (IRF) including distinct rehabilitation units of a hospital: three hours or greater of therapy per day
   - ☐ Skilled nursing facility (SNF)/ subacute rehab: less than two hours a day of therapy with Medicare certification in anticipation of skilled care
   - ☐ Medicare certified long term care hospital (LTCH)
   - ☐ Hospice- home or medical facility providing hospice level of care
   - ☐ Other not defined above:
5. **Which class(es) of medications was the participant/ subject prescribed at ~~hospital~~ discharge? (choose all that apply)
   - ☐ Anticoagulant~~s~~ agents (Answer 5A and Skip 6)
   - ☐ Antiplatelet~~s~~ agents (Answer 5B and Skip 6)
   - ☐ Antihypertensive~~s~~ agents (Answer 5C and Skip 6)
   - ☐ Anti-diabetic agents (Answer 5D and Skip 6)
   - ☐ Lipid lowering agents (Answer 5E and Skip 6)

   A. **IF anticoagulants prescribed, specify type(s): (choose all that apply)
   - ☐ ~~Unfractionated heparin IV~~
   - ☐ ~~Full dose~~ Low molecular weight heparin (LMW~~H~~) (Enoxaparin, o~~O~~thers)
   - ☐ Warfarin (Coumadin)
   - ☐ Direct oral anticoagulant (dabigatran, rivaroxaban, apixaban, others)
     - ☐ Direct Thrombin Inhibitor
     - ☐ Factor Xa inhibitor
   - ☐ ~~Fondaparinux (Arixtra)~~
   - ☐ Other, specify:

   B. **IF antiplatelet~~s~~ agents prescribed, specify type(s): (choose all that apply)

Antithrombotics and Risk Factor Controlling Medications

[Study Name/ID pre-filled] Site Name:

Subject ID:

- ☐ Aspirin
- ☐ Aspirin/Dipyridamole (in separate formulations or as Aggrenox)
- ☐ Clopidogrel (Plavix)
- ☐ ~~Ticlopidine (Ticlid)~~
- ☐ Cilostazol
- ☐ Other, specify:

C. **IF antihypertensive medication prescribed, specify type(s): (choose all that apply)

- ☐ Beta-blocker (atenolol, metoprolol, propranolol, others)
- ☐ Calcium channel blocker (amlodipine, diltiazem, nifedipine, verapamil, others)
- ☐ Diuretic (chlorothiazide, hydrochlorothiazide, chlorthalidone, others)
- ☐ ACE-inhibitor (enalaopril, lisinopril, ramipril, others)
- ☐ Angiotensin II receptor blocker (candesartan, losartan, valsartan, others)
- ☐ Alpha blocker (doxazosin, prazosin, terazosin)
- ☐ Combined alpha and beta-blocker (carvedilol, labetalol)
- ☐ Central agonist (alpha methyldopa, clonidine, others)
- ☐ Other, specify:

D. **IF anti-diabetic medication prescribed, specify type(s): (choose all that apply)

- ☐ Insulin
- ☐ Amylin analogs (Pramlintide)
- ☐ Sulfonylureas (glimepiride, glipizide, glyburide, others)
- ☐ Meglitinides (nateglinide, repaglinide)
- ☐ Biguanides (metformin)
- ☐ Thiazolidinediones (pioglitazone, rosiglitazone)
- ☐ Alpha-glucosidase inhibitors (acarbose, miglitol)
- ☐ Dipeptidyl peptidase inhibitors (alogliptin, linagliptin, others)
- ☐ Sodium-glucose co-transporter 2 inhibitors (canagliflozin, dapagliflozin, others)
- ☐ Oral combination drugs
- ☐ Other, specify:

E. **IF lipid lowering medication prescribed, specify type(s) (choose all that apply)

- ☐ Statin (atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin)
- ☐ PCSK9 inhibitors (alirocumab, evolocumab)
- ☐ Selective cholesterol absorption inhibitors (ezetimibe)
- ☐ Bile acid sequestrants (cholestyramine, colestipol, colesevelam)

Antithrombotics and Risk Factor Controlling Medications

[Study Name/ID pre-filled] Site Name:

Subject ID:

- ☐ Fibrates (gemfibrozil, fenofibrate, clofibrate)
- ☐ Niacin
- ☐ Omega-3 fatty acid ethyl esters (Lovaza, Vascepa)
- ☐ Marine-derived omega-3 polyunsaturated fatty acids
- ☐ Other, specify:

6. Reason(s) antithrombotic therapy (i.e., anticoagulants or~~and~~ antiplatelet~~s~~ agents) was not prescribed at ~~hospital~~ discharge:(choose all that apply)

   - ☐ Allergy ~~to or complication related~~ to aspirin, ~~ticlopidine,~~ clopidogrel, dipyridamole, warfarin, direct oral anticoagulant or heparin~~s~~ (history or current)
   - ☐ Patient/Family refused
   - ☐ Risk for bleeding ~~or discontinued due to bleeding~~
   - ☐ Discontinued due to bleeding
   - ☐ Serious side effect to medication, specify:
   - ☐ Terminal illness/Comfort measures only
   - ☐ Other, specify:

Antithrombotics and Risk Factor Controlling Medications CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements related to antithrombotics and other medications the participant/ subject is treated with while in the hospital for the stroke event or is prescribed upon discharge from the hospital. Several of the elements were taken from are taken from the Get With The Guidelines® Stroke Patient Management Tool and/or the Paul Coverdell National Acute Stroke Registry.

Some of the CDEs are Supplemental- Highly Recommended based on study type, disease stage and disease type as indicated by asterisks below. Please refer to Start-Up document for details.

**Element is classified as Supplemental – Highly Recommended

The remaining data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

The CRF includes most of the instructions available for the data elements at this time. One element has some additional instructions not included on the CRF:

- Reason(s) for no antithrombotic therapy – If reasons are not mentioned in the context of antithrombotics, do not make inferences (e.g., do not assume that antithrombotics are not being prescribed because of a bleeding disorder unless documentation explicitly states so).

References

Barnes GD, Ageno W, Ansell J, Kaatz S; Subcommittee on the Control of Anticoagulation of the International Society on Thrombosis and Haemostasis. Recommendation on the nomenclature for oral anticoagulants: communication from the SSC of the ISTH [published correction appears in J Thromb Haemost. 2015;13(8):1539]. J Thromb Haemost. 2015;13(6):1154–1156.

Kim BJ, Kwon SU, Park JH, Kim YJ, Hong KS, Wong LKS, Yu S, Hwang YH, Lee JS, Lee J, Rha JH, Heo SH, Ahn SH, Seo WK, Park JM, Lee JH, Kwon JH, Sohn SI, Jung JM, Navarro JC, Kim HY, Kim EG, Kim S, Cha JK, Park MS, Nam HS, Kang DW. Cilostazol Versus Aspirin in Ischemic Stroke Patients With High-Risk Cerebral Hemorrhage: Subgroup Analysis of the PICASSO Trial. Stroke. 2019. STROKEAHA119023855. doi: 10.1161/STROKEAHA.119.023855. [Epub ahead of print].

Lifestyle Modification Therapies

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Indicate whether or not the participant/ subject received any of the following interventions during the hospitalization or at discharge.

Note: NC = None–contraindicated.

1. Specify discharging location:

   ☐ Acute hospital

   ☐ Intensive Inpatient rehabilitation facility (IRF) including distinct rehabilitation units of a hospital: three hours or greater of therapy per day

   ☐ Skilled nursing facility (SNF)/ subacute rehab: less than two hours a day of therapy with Medicare certification in anticipation of skilled care

   ☐ Medicare certified long term care hospital (LTCH)

   ☐ Hospice- home or medical facility providing hospice level of care

   ☐ Other not defined above:

2. Counseling to stop smoking/vaping or smoking cessation advice: ☐ Yes ☐ No ☐ NC ☐ Unknown

   If YES, specify the type(s) of smoking cessation treatment received:

   ☐ Direct discussion with the patient or caregiver about stopping smoking

   ☐ Institution of a structured nicotine withdrawal protocol/program during acute hospitalization

   ☐ Prescription of smoking cessation aid (e.g., Habitrol, NicoDerm, Nicorette, Nicotrol, Prostep, Zyban)

   ☐ Prescription of Wellbutrin (~~/~~bupropion), Chantix (varenicline), or alternative FDA-approved smoking cessation medication if prescribed ~~as~~ for smoking cessation

   ☐ Referral to smoking cessation class/program

   ☐ Smoking cessation brochures/handouts/video

   ☐ Education provided to patients and caregivers about second hand smoke exposure

3. Counselling for w~~W~~eight loss ☐ Yes ☐ No ☐ NC ☐ Unknown

   If yes, specify intervention(s):

   ☐ Provision of educational materials
   ☐ Direct education of overweight patients to achieve healthy weight loss goals
   ☐ Development of individualized plan to achieve weight loss goals
   ☐ Referral to a dietitian for weight loss
   ☐ Referral to a structured program for weight loss

4. Recommendations to increase physical activity: ☐ Yes ☐ No ☐ NC ☐ Unknown

   If yes, specify intervention(s):

   ☐ Provision of educational materials

Lifestyle Modification Therapies

[Study Name/ID pre-filled] Site Name:

Subject ID:

- ☐ Direct discussion with the patient to reduce sedentary behaviors and work towards increased activity goals (as tolerated)
- ☐ Development of individualized plan to achieve physical activity goals
- ☐ Referral to a regular structured exercise program
- ☐ Other, specify:

5. Dietary recommendations: ~~(e.g., put on TLC diet or DASH diet):~~ ☐ Yes ☐ No ☐ NC ☐ Unknown

   If yes, specify intervention(s):
   - ☐ Provision of educational materials
   - ☐ Direct discussion with the patient or caregiver to adopt a healthy diet
   - ☐ Initiation of an individualized diet (includes TLC, DASH, diabetic or heart healthy)
   - ☐ Formal dietary counseling or initiation of a structured diet plan

6. Counselling to avoid high sodium intake ☐ Yes ☐ No ☐ NC ☐ Unknown

   If yes, specify intervention(s):
   - ☐ Provision of educational materials
   - ☐ Direct discussion with the patient or caregiver to reduce sodium intake
   - ☐ Referral to a dietitian or a formal education program

7. Counselling to avoid high alcohol consumption: ☐ Yes ☐ No ☐ NC ☐ Unknown

   If yes, specify intervention(s):
   - ☐ Provision of educational materials
   - ☐ Direct discussion with the patient or caregiver to avoid excessive alcohol intake
   - ☐ Referral to a regular structured rehabilitation program to overcome excessive alcohol intake

8. Counselling to discontinue recreational or prescription drug abuse ☐ Yes ☐ No ☐ NC ☐ Unknown

   If yes, specify intervention(s):
   - ☐ Provision of educational materials
   - ☐ Direct discussion with the patient or caregiver to avoid recreational drug use
   - ☐ Referral to a regular structured rehabilitation program for drug addiction
   - ☐ Use of alternative treatment to overcome prescription drug abuse
   - ☐ Other, specify:

9. Counselling relating to contraceptive/hormone replacement treatment: ☐ Yes ☐ No ☐ NC ☐ Unknown

   If yes, specify intervention(s):

Lifestyle Modification Therapies

[Study Name/ID pre-filled]

Site Name:

Subject ID:

☐ Direct discussion with the patient to discontinue treatment, if not prescribed for medical indications

☐ Utilization of alternative contraceptive/hormonal treatment or approaches

Lifestyle Modification Therapies
CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements related to lifestyle modifications/ interventions the participant/ subject received while in the hospital for the stroke event or is prescribed upon discharge from the hospital. Several of the elements were taken from /are taken from the Get With The Guidelines® Stroke Patient Management Tool and/or the Paul Coverdell National Acute Stroke Registry.

It may be important for some studies to assess how well the participant/ subject followed the lifestyle modification recommendations at subsequent follow up visits. For those studies, the Patient-Centered Assessment and Counseling for Exercise (and Nutrition) [PACE] instrument is recommended. It contains questions related to exercise, nutrition, and smoking. The PACE is copyright protected by the San Diego State University Foundation and San Diego Center for Health Interventions, LLC. Please contact this organization [Project PACE, Student Health Services, San Diego State University, 5500 Campanile Drive, San Diego, CA 92182-470; Pace Project] for a copy of the instrument that contains the code list/ permissible values and other important definitions and instructions.

Important note: None of the data elements included on this CRF is considered Core (i.e., strongly recommended for all stroke clinical studies to collect). Rather, all of the data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Counseling to stop smoking or smoking cessation advice – If the patient refused smoking cessation advice or counseling during this hospital stay, select "Yes". If the patient has a history of cigarette smoking within the year prior to arrival date but the patient does not currently smoke, they should be advised to continue not smoking. For these patients, if this advice/counseling was not done, select "No". If the patient is prescribed Wellbutrin (bupropion), it should not be assumed that this is a smoking cessation aid unless specifically noted as such. It is sometimes used as an antidepressant unrelated to smoking. If a reason for non-treatment was documented in the medical record (e.g. not indicated, contraindicated, patient/family refused), select “NC.”
- Type(s) of smoking cessation treatment received – No additional instructions
- Weight loss and/or increased physical activity recommendations – Patients who are overweight or obese (BMI 25 or greater) are candidates for intervention in weight management or increased physical activity. Patients who exercise less than three (3) days a week for 30 minutes should receive a written activity recommendation or referral to stroke rehabilitation involving increased activity.
- Dietary recommendations (e.g., put on TLC diet or DASH diet) – No additional instructions
- Counseling to avoid high sodium intake
- Counseling to avoid high alcohol consumption
- Counseling to discontinue recreational drug use
- Counseling relating to contraceptive/hormone replacement treatment
- ~~Formal dietary counseling – No additional instructions~~

Rehabilitation Therapies

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Date information collected: (mm-dd-yyyy format) ____/____/_____

1. **~~Current l~~ Location ~~of post-~~acute hospital discharge:**
   - ☐ ~~Own home with self care~~
   - ☐ Home with no in-home services
   - ☐ Home with home care services
   - ☐ Another family member's/ friend's home
   - ☐ Intensive Inpatient rehabilitation facility (IRF) including distinct rehabilitatio units of a hospital: three hours or greater of therapy per day ~~Short term/ general hospital for inpatient care~~
   - ☐ Skilled nursing facility (SNF)/ subacute rehab: less than two hours a day of therapy with Medicare certification in anticipation of skilled care
   - ☐ ~~Designated Cancer Center or Children's Hospital~~
   - ☐ ~~Home under care of organized home health service organization~~
   - ☐ Medicare certified long term care hospital (LTCH) ~~Expired~~
   - ☐ ~~Court/ law enforcement facility~~
   - ☐ ~~Federal health care facility~~
   - ☐ Hospice- home or medical facility providing hospice level of care ~~Hospice- home~~
   - ☐ ~~Hospice- medical facility providing hospice level of care~~
   - ☐ ~~Hospital- based Medicare approved swing bed~~
   - ☐ Other not defined above: _____ ~~Inpatient rehabilitation facility (IRF) including~~
   - ☐ ~~Medicare certified long term care hospital (LTCH) rehabilitation distinct part units of a hospital~~
   - ☐ ~~Nursing facility certified under Medicaid but not certified under Medicare~~
   - ☐ ~~Psychiatric hospital or psychiatric distinct part unit of a hospital~~
   - ☐ ~~Critical Access Hospital (CAH)~~
   - ☐ Expired ~~Another type of health care institution not defined above~~
2. **Resource Utilization Group Version IV (RUG IV):**
   (please specify 3-letter alpha-numeric code)_____

Acute Hospital Rehabilitation Services

3. **Assessed for ~~or received~~ rehabilitation services?** ☐ Yes ☐ No (Skip to 10) ☐ Unknown (Skip to 10)
4. **~~Type(s) of~~ Were rehabilitation therapy/services received?** (choose all that apply)

Rehabilitation Therapies

[Study Name/ID pre-filled]

Site Name:

Subject ID:

☐ Received rehabilitation therapy ~~rehabilitation services~~ during hospitalization

~~☐ Transferred to rehabilitation facility~~

~~☐ Referred to rehabilitation services following discharge~~

☐ Did not ~~Ineligible to~~ receive rehabilitation therapy ~~rehabilitation services~~ because symptoms resolved

☐ Ineligible to receive rehabilitation therapy ~~rehabilitation services~~ due to impairment severity or medical issues

~~☐ Ineligible to receive rehabilitation services because of insurance issues~~

☐ Referred to rehabilitation services following discharge

☐ Other, specify: _____

5. **Type, location and amount of therapies received ~~Type(s) of rehabilitation therapy disciplines received:~~** (choose all that apply)

~~☐ Speech/ Language~~

~~☐ Occupational~~

~~☐ Vocational~~

~~☐ Physical~~

~~☐ Psychological~~

~~☐ Dietary~~

~~☐ Recreational~~

~~☐ Other, specify~~

Type(s) of rehabilitation therapy disciplines received:	**Where were rehabilitation services received?**	**Estimated amount of rehabilitation therapy:**	*****Start Date:**
Speech/ Language	☐ Inpatient ☐ Acute Hospital ☐ Rehabilitation Facility ☐ Outpatient (following acute hospital discharge)	Estimated number of weeks _____ Estimated number of sessions/week_____ Estimated total sessions_____	(mm/dd/yyyy)
Occupational	☐ Inpatient ☐ Acute Hospital ☐ Rehabilitation Facility ☐ Outpatient (following acute hospital discharge)	Estimated number of weeks _____ Estimated number of sessions/week_____ Estimated total sessions_____	(mm/dd/yyyy)

Rehabilitation Therapies

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Type(s) of rehabilitation therapy disciplines received:	Where were rehabilitation services received?	Estimated amount of rehabilitation therapy:	***Start Date:
Vocational	☐ Inpatient ☐ Acute Hospital ☐ Rehabilitation Facility ☐ Outpatient (following acute hospital discharge)	Estimated number of weeks _____ Estimated number of sessions/week_____ Estimated total sessions_____	(mm/dd/yyyy)
Physical	☐ Inpatient ☐ Acute Hospital ☐ Rehabilitation Facility ☐ Outpatient (following acute hospital discharge)	Estimated number of weeks _____ Estimated number of sessions/week_____ Estimated total sessions_____	(mm/dd/yyyy)
Psychological/Cognitive	☐ Inpatient ☐ Acute Hospital ☐ Rehabilitation Facility ☐ Outpatient (following acute hospital discharge)	Estimated number of weeks _____ Estimated number of sessions/week_____ Estimated total sessions_____	(mm/dd/yyyy)
Dietary	☐ Inpatient ☐ Acute Hospital ☐ Rehabilitation Facility ☐ Outpatient (following acute hospital discharge)	Estimated number of weeks _____ Estimated number of sessions/week_____ Estimated total sessions_____	(mm/dd/yyyy)
Recreational	☐ Inpatient ☐ Acute Hospital ☐ Rehabilitation Facility ☐ Outpatient (following acute hospital discharge)	Estimated number of weeks _____ Estimated number of sessions/week_____ Estimated total sessions_____	(mm/dd/yyyy)
Other, specify	☐ Inpatient ☐ Acute Hospital ☐ Rehabilitation Facility ☐ Outpatient (following acute hospital discharge)	Estimated number of weeks _____ Estimated number of sessions/week_____ Estimated total sessions_____	(mm/dd/yyyy)

Rehabilitation Therapies

[Study Name/ID pre-filled]

Site Name:
Subject ID:

~~6. **Frequency of rehabilitation therapy: (please specify) visits in (please specify) weeks**~~

~~7. **Timeframe of rehabilitation therapy:**~~
~~☐ **Within the first 3 months** ☐ **Between 3 - 12 months** ☐ **More than 12 months**~~

~~8. **Average duration of rehabilitation therapy visit: (please specify) minutes**~~

~~9. **Setting for rehabilitation therapy:** ☐ **Inpatient** ☐ **Outpatient** ☐ **Home health**~~

10. **Provided with assistive ~~mobility~~ devices?** ☐ Yes ☐ No ☐ Unknown
IF YES, current type(s) of assistive ~~mobility~~ devices: (choose all that apply)
☐ AFO/ brace/ prosthetic/ orthotic/ splints
☐ Cane (Straight/ Tripod/ Quad) ~~cane~~
~~☐ Quad cane~~
☐ Walker
☐ Power wheelchair
☐ Scooter
☐ Manual wheelchair
☐ Adaptive or Activities of Daily Living (ADL) equipment (e.g. modified eating utensils, reachers, etc.)
☐ Other, specify:

11. **Received or receiving adjunctive treatments?** ☐ Yes ☐ No ☐ Unknown
IF YES, type(s) of adjunctive treatments: (choose all that apply)
☐ Feeding/ gastrostromy tube placement
☐ Botulinum toxin for spasticity
☐ Intrathecal baclofen
☐ Functional electrical stimulation
☐ Tracheostomy
☐ Tendon lengthening or transfer
☐ Contracture release
☐ Surgical procedure for drooling, specify:
☐ Potential function enhancing drugs (SSRIs, stimulants, antidepressants)
☐ Other, specify:

~~12. Provided with positioning devices? ☐ Yes ☐ No ☐ Unknown~~
~~IF YES, type(s) of positioning devices: (choose all that apply)~~
~~☐ Wrist splints~~
~~☐ Ankle/foot orthosis~~

Rehabilitation Therapies

[Study Name/ID pre-filled]

Site Name:

Subject ID:

☐ ~~Other upper extremity device~~

☐ ~~Other lower extremity device~~

☐ ~~Adaptive or Activities of Daily Living (ADL) equipment~~

☐ ~~Other, specify:~~

13. ***Provided with supportive ~~durable~~ medical equipment? ☐ Yes ☐ No ☐ Unknown

***IF YES, type(s) of supportive ~~durable~~ medical equipment: (choose all that apply)

☐ Bedside commode

☐ Hospital bed

☐ Bathroom grab bars

☐ Stair lifts

☐ Raised toilet seats

☐ Shower seats

☐ Suction devices

☐ Oxygen

☐ Ramps

☐ Other, specify:

Follow-up Care

14. **Follow-up care from the following specialists? (choose all that apply) ~~stroke specialist?~~

☐ Neurologist, non-vascular

☐ Vascular neurologist

☐ Primary care provider

☐ PM&R or other rehabilitation physician

☐ Other, specify:

~~Error! Bookmark not defined.~~ ~~☐ Yes ☐ No ☐ Unknown~~

~~15. Follow-up care from primary care physician?~~ ~~Error! Bookmark not defined.~~ ~~☐ Yes ☐ No ☐ Unknown~~

~~16. Follow-up care from rehabilitation doctor? ☐ Yes ☐ No ☐ Unknown ☐ Not applicable~~

Rehabilitation Therapies CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements related to rehabilitation therapies and other follow-up care the participant/subject receives for the index stroke event. Most of the data elements are meant to be collected after the participant/ subject is discharged from the acute hospital stay following treatment for the index stroke event.

Some of the CDEs are Supplemental- Highly Recommended based on study type, disease stage and disease type or Exploratory as indicated by asterisks below. Please refer to Start-Up document for details.

**Element is classified as Supplemental – Highly Recommended
***Element is classified as Exploratory

The remaining data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

The CRF includes most of the instructions available for the data elements at this time. One element has some additional instructions not included on the CRF:

- Location post-acute discharge – It is suggested that this data element be collected at 3, 6, and twelve months post-acute discharge.
- Rehabilitation therapy start date – Investigators can choose to include this item if it is relevant to the study.

SAH Surgical/Procedural Interventions (New for Stroke)

[Study Name/ID pre-filled] Site Name:

Subject ID:

1. Multiple aneurysms:
   - ☐ Yes
   - ☐ No
2. Number of aneurysms treated:
3. **Type of vessel repaired:
   - ☐ Ophthalmic/paraclinoid
   - ☐ Pcomm
   - ☐ AChoA
   - ☐ ICA terminus
   - ☐ Dorsal ICA
   - ☐ ACA - A1
   - ☐ ACA - Acomm
   - ☐ ACA -Pericallosal/callosomarginal
   - ☐ MCA – M1
   - ☐ MCA - bifurcation/trifurcation/anterior temporal
   - ☐ MCA - distal MCA (Distal MCA is beyond the MCA bifurcation or trifurcation)
   - ☐ Vertebral-basilar junction
   - ☐ PCA - P1
   - ☐ PCA - P2
   - ☐ PCA - distal
   - ☐ basilar bifurcation
   - ☐ SCA
   - ☐ AICA
   - ☐ Basilar trunk
   - ☐ PICA – proximal
   - ☐ PICA - distal
   - ☐ Vertebral
4. **Day of intervention from the moment of subarachnoid hemorrhage (SAH) ictus:
5. Intervention time (hours):
6. Ventriculostomy placement for hydrocephalus:
   - ☐ Yes
   - ☐ No
7. Lumbar drain placement:
   - ☐ Yes
   - ☐ No
8. **Intervention - surgery:
   - ☐ Yes
   - ☐ No
   - ☐ Attempt failed
9. **Intervention – endovascular:
   - ☐ Yes
   - ☐ No
   - ☐ Attempt failed
10. Antithrombotic type used during procedure:
    - ☐ Heparin
    - ☐ Aspirin
    - ☐ tPA
    - ☐ Clopidogrel
    - ☐ None
    - ☐ Other

<u>Surgery details</u>

11. SAH surgery type:

SAH Surgical/Procedural Interventions (New for Stroke)

[Study Name/ID pre-filled] Site Name:

Subject ID:

- ☐ Clipping
- ☐ Trapping alone
- ☐ Wrapping
- ☐ Hunterian ligation alone
- ☐ Bypass
- ☐ None/attempted
- ☐ Other

12. Surgical intervention result:
    - ☐ Complete occlusion
    - ☐ Partial occlusion – neck remnant
    - ☐ Partial occlusion – residual fundus
    - ☐ Unsecured
13. Intraprocedural physiological monitoring:
    - ☐ Yes
    - ☐ No
14. Intraoperative rupture:
    - ☐ Yes - major
    - ☐ Yes – minor
    - ☐ No
15. Intraoperative assessment of vessel patency and/or aneurysm occlusion:
    - ☐ Microvascular doppler
    - ☐ Ultrasonic transit-time flowmetry
    - ☐ Fluorescence videoangiography
    - ☐ Intraoperative catheter angiography
16. Type of intraoperative complication:
    - ☐ Vessel thrombosis
    - ☐ Unintended vessel occlusion
    - ☐ Brain swelling caused by surgical trauma
    - ☐ Aneurysm hemorrhage resulting in need for transfusion
    - ☐ Known perforator occlusion at time of surgery
    - ☐ Unintended neural injury at the time of surgery
    - ☐ Other
17. Surgery duration (minutes):
18. Blood transfusion during surgery?
    - ☐ Yes
    - ☐ No
19. Amount of blood lost during surgery (cc):
20. Postoperative complication:
    - ☐ Hemorrhage
    - ☐ Brain swelling related to surgical trauma
    - ☐ Other
21. Type of craniotomy:
    - ☐ Standard

SAH Surgical/Procedural Interventions (New for Stroke)

[Study Name/ID pre-filled] Site Name:

Subject ID:

☐ Minimally invasive

22. Craniectomy performed?
    ☐ Yes
    ☐ No
23. Hematoma evacuation:
    ☐ Yes
    ☐ No
24. Temporary vessel occlusion:
    ☐ Yes
    ☐ No
25. ***Number of temporary occlusions:
26. Maximum duration of temporary occlusion (minutes):
27. Total duration of temporary occlusions:

    Endovascular Intervention details

28. Type of endovascular repair:
    ☐ Coil
    ☐ Coil with balloon remodeling
    ☐ Stent/coil
    ☐ Stent only
    ☐ Vessel occlusion
    ☐ Flow diverter
    ☐ None/attempted
    ☐ Other
29. Evidence of intraoperative rupture?
    ☐ Yes
    ☐ No
30. Endovascular intraprocedural complication type:
    ☐ Perforation
    ☐ Vessel dissection
    ☐ Vessel occlusion
    ☐ Thromboembolism
    ☐ Coil migration
    ☐ Femoral access complication
    ☐ Other
31. Endovascular postprocedural complication type:
    ☐ Femoral access complication
    ☐ Vessel occlusion
    ☐ Vessel dissection
    ☐ Other
32. Endovascular fluoroscopy dose (mGy):
33. Endovascular procedure duration (minutes):

SAH Surgical/Procedural Interventions (New for Stroke)

[Study Name/ID pre-filled]

Site Name:

Subject ID:

34. Endovascular intervention result:
    - ☐ Raymond-Roy grade 1
    - ☐ Raymond-Roy grade 2
    - ☐ Raymond-Roy grade 3

SAH Surgical/Procedural Interventions (New for Stroke)
CRF Module Instructions

[Study Name/ID pre-filled] Site Name:

Subject ID:

General Instructions

This CRF Module is recommended to collect information on surgical/procedural interventions for subarachnoid hemorrhage (SAH) studies.

Important note: None of the data elements included on this CRF Module is considered Core (i.e., strongly recommended for all stroke clinical studies to collect). Some elements on this CRF are classified as ~~Core~~, Supplemental – Highly Recommended or Exploratory, as indicated by asterisks below:

~~*Element is classified as Core~~

**Element is classified as Supplemental – Highly Recommended

***Element is classified as Exploratory

~~All remaining elements are classified as Supplemental.~~ The remaining data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- For patient with multiple aneurysms, include documentation of treatment of additional aneurysm, whether ruptured or unruptured, at any time during the episode of SAH care.
- Type of vessel repaired: Location of vessel harboring the target ruptured aneurysm.
- Antithrombotic type: Any antithrombotic medication administered either prior to, during, or after the procedure for procedure-related indications.
- The day of intervention will be timed from the moment of SAH ictus; day of rupture is day 0.
- Intervention time: The start of intervention will be timed from the moment of SAH ictus in hours; start = 0.
- Ventriculostomy placement: External ventriculostomy placement for treatment of hydrocephalus at any time during the episode of care for aneurysmal SAH, placed either at bedside or in the operating room, alone or in combination with other procedures.
- Lumbar drain placement: Lumbar drain placement for treatment of communicating hydrocephalus, at any time during the episode of care for aneurysmal SAH. Placed either at bedside or in the operating room, alone or in combination with other procedures.
- Surgery: Surgery involves craniotomy and microsurgery, including one or more of the following: clipping, trapping, Hunterian ligation, bypass, or wrapping; attempted/failed includes all aneurysms which did not receive definitive treatment via one of the aforementioned modalities; "definitive" means that at the conclusion of the procedure the prevention of immediate re-rupture has been achieved.

SAH Surgical/Procedural Interventions (New for Stroke)
CRF Module Instructions

[Study Name/ID pre-filled] Site Name:

Subject ID:

- Endovascular treatment will include use of coils, stents, and/or other endovascular devices alone or in combination to occlude the aneurysm; attempted/failed includes all aneurysms which did not receive definitive treatment via one of the aforementioned modalities; "definitive" means that at the conclusion of the procedure the prevention of immediate re-rupture has been achieved.
- SAH surgery type: A craniotomy was performed and one or more of the listed techniques was performed. Bypass includes some other treatment for the aneurysm, e.g. trapping.
- Surgical intervention result: Success of surgical intervention describes degree of aneurysm occlusion, as measured by postoperative imaging with diagnostic radiology as gold standard; any residual aneurysm filling is graded as partial occlusion.
- Intraprocedural monitoring: Includes, SSEPs, MEP, BAERs, CN monitoring
- Intraoperative rupture: Any episode of intraoperative rupture of the ruptured aneurysm during the open aneurysm treatment procedure, at any time between incision and closure, whether spontaneous or as a result of microsurgical manipulation. Major - requiring blood transfusion, leading to increased intracranial pressure necessitating additional surgery (e.g. craniectomy, additional bone removal, brain resection), resulting in hypotension. Minor - any other rupture from any treated aneurysm.
- Intraoperative assessment of vessel patency/occlusion: Any imaging or objective method for assessing vessel patency performed at any time during the aneurysm clipping procedure, within the operating room while the patient is anesthetized, prior to completion of surgery.
- Intraoperative complication: Procedure-related complication, directly attributable to the microsurgical procedure.
- Surgery duration: Total microsurgical clipping time in minutes, from skin incision to closure.
- Blood transfusion during surgery: Any administration of blood products during the microsurgical clipping procedure.
- Postoperative complications: Procedure-related complication, directly attributable to the microsurgical procedure and identified after the procedure.
- Craniotomy type: Standard includes: pterional, orbitozygomatic, posterior fossa, subtemporal, modified orbitozygomatic. Minimally invasive includes supraorbital/eyebrow, LSO, mini-pterional.
- Craniectomy: If the bone flap is not replaced, then the procedure is listed as a craniectomy, whether or not the bone is replaced at a later time during the episode of care for SAH.
- Hematoma evacuation: Craniotomy for removal of an acute intraparenchymal, subdural, or epidural hematoma caused by the index aneurysm, for the purpose of reducing mass effect on the brain, with or without definitive open aneurysm treatment at the same episode of care.
- Temporary vessel occlusion: Placement of a temporary clip at any time during microsurgical aneurysm clipping; the temporary clip must be removed at some point during the microsurgical clipping.

SAH Surgical/Procedural Interventions (New for Stroke)
CRF Module Instructions

[Study Name/ID pre-filled] Site Name:

Subject ID:

- Number of temporary occlusions: Total number of temporary clip applications during the microsurgical clipping procedure; each time a clip is placed and then removed, on any vessel either in sequence or simultaneously, counts as a “temporary clip occlusion.”
- Temporary occlusion maximum duration: The maximum duration of any one temporary clip application from the time of placement until removal, in minutes.
- Temporary occlusion total duration: The sum of all temporary clip occlusion durations during the microsurgical clipping procedure. If clips are placed on more than one vessel simultaneously, the time of clip occlusion is considered overlapping and not summed.
- Endovascular repair: Type of endovascular repair described in detail including all endovascular devices utilized, alone or in combination. Flow diverters include all stent technology intended to alter flow into the aneurysm sac. Stent in this context means a non-flow diverting stent.
- Intraoperative endovascular rupture: Any evidence of intraoperative rupture, defined as contrast extravasation on angiographic imaging.
- Endovascular intraprocedural complication: Procedure-related complication, directly attributable to the endovascular procedure and identified during the procedure.
- Endovascular postprocedural complication: Procedure-related complication, directly attributable to the endovascular procedure and identified after the procedure.
- Endovascular procedure duration: From initiation of vascular access to access closure or equivalent during the procedure for treatment of the aneurysm.
- Endovascular intervention result: Degree of occlusion of aneurysm following endovascular repair, as confirmed with post-procedure angiography using Raymond-Roy grading.

Stroke Surgical and Procedural Interventions

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Surgical or Therapeutic Procedures Data Table

Surgical or Therapeutic Procedure	Inpatient or Outpatient?	Start Date	End Date
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)

Stroke Surgical and Procedural Interventions

[Study Name/ID pre-filled]

Site Name:

Subject ID:

Surgical or Therapeutic Procedure	Inpatient or Outpatient?	Start Date	End Date
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)
(data to be entered by site)	☐ Inpatient ☐ Outpatient	(mm/dd/yyyy)	(mm/dd/yyyy)

The interview questions that follow are provided to make certain all important surgical/procedural interventions are recorded in the preceding table.

Stroke Surgical and Procedural Interventions

[Study Name/ID pre-filled]

Site Name:

Subject ID:

In-Hospital Surgeries/ Procedures

Indicate whether or not the participant/ subject received any of the following interventions while being treated in the hospital for the index stroke event.

~~1. Intubated and placed on a mechanical ventilator: ☐ Yes ☐ No~~

2. Cervical carotid revascularization: ☐ Yes ☐ No
   IF YES, type(s) of carotid revascularization: (choose all that apply)
   - ☐ Carotid endarterectomy (CEA)
   - ☐ Carotid artery stenting (CAS)
   - ☐ Other, specify:
3. Vertebral artery revascularization: ☐ Yes ☐ No
   IF YES, type(s) of vertebral artery revascularization: (choose all that apply)
   - ☐ Angioplasty
   - ☐ Stenting
   - ☐ Surgical reimplantation
   - ☐ Other, specify:
4. Intracranial revascularization: ☐ Yes ☐ No
   IF YES, type(s) of intracranial revascularization: (choose all that apply)
   - ☐ Angioplasty
   - ☐ Stenting
   - ☐ Bypass
   - ☐ Other, specify:
5. Ventricular drainage placed: ☐ Yes ☐ No
   IF YES, type(s) of ventricular drainage placed: (choose all that apply)
   - ☐ Temporary extraventricular drain
   - ☐ Permanent shunt
   - ☐ Other, specify:
6. Thrombectomy: ☐ Yes ☐ No
   IF YES, which artery(ies): (choose all that apply)
   - ☐ MCA:
     - ☐ M1
     - ☐ M2
   - ☐ ICA

Stroke Surgical and Procedural Interventions

[Study Name/ID pre-filled] Site Name:

Subject ID:

- ☐ Basilar artery
- ☐ Posterior cerebral artery
- ☐ Vertebral artery

7. Therapy for increased intracranial pressure: ☐ Yes ☐ No
   IF YES, type(s) of therapy for increased intracranial pressure: (choose all that apply)
   - ☐ Hemicraniectomy
   - ☐ Osmotic therapy
     - ☐ Hypertonic saline
     - ☐ Mannitol
   - ☐ Decompressive craniectomy
   - ☐ Hypothermia
   - ☐ Shunt placement
   - ☐ ~~Inter~~ V~~v~~entricular catheter
   - ☐ Other, specify:

Surgeries/ Procedures after Initial Discharge

Indicate whether or not the participant/ subject received or was evaluated and scheduled for a surgical/ operative procedure as a preventative therapy for stroke after initial hospital discharge for the index stroke/ TIA.

8. Surgical/ Operative preventive treatment: ☐ Yes ☐ No ☐ Unknown
   IF YES, type(s) of surgical/ operative preventive treatment: (choose all that apply)
   - ☐ Cardiac, specify:

   Neurosurgical:
   - ☐ Encephaloduroarteriosynangiosis (EDAS)
   - ☐ Obliteration of vascular malformation
   - ☐ Other, specify:

Stroke Surgical and Procedural Interventions CRF Module Instructions

General Instructions

This case report form (CRF) contains data elements related to surgical and other procedure interventions the participant/ subject is treated with while in the hospital for the index stroke event or after initial discharge from the hospital.

Important note: None of the data elements included on this CRF Module is considered Core (i.e., strongly recommended for all stroke clinical studies to collect). Rather, all of the data elements are Supplemental and should only be collected if the research team considers them appropriate for their study.

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

- Surgical or therapeutic procedure – Choose all that apply. Recommend collection during acute hospital care. In previous studies, information on surgical procedures has typically been documented in free text format, thus often precluding any meaningful analysis. We therefore propose the use of ICD-10 coding
- Inpatient or outpatient status - Choose one.
- Surgical or therapeutic procedure start date and time – Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).
- Surgical or therapeutic procedure end date and time - Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.).

UIA Management (New for Stroke)

[Study Name/ID pre-filled]

Site Name:

Subject ID:

1. ***Initial management plan for unruptured intracranial aneurysm (UIA):
   - ☐ Observation without follow-up imaging
   - ☐ Observation with follow-up imaging
   - ☐ Microsurgical clipping
   - ☐ Endovascular intervention
   - ☐ Undetermined
2. ***Reason for observation of UIA:
   - ☐ Patient's age
   - ☐ Health status
   - ☐ Risk of treatment
   - ☐ Size of UIA
   - ☐ Location of UIA
   - ☐ Protocol
   - ☐ Other
3. ***Reason for treatment of UIA:
   - ☐ Patient's age
   - ☐ Health status
   - ☐ Risk of rupture
   - ☐ Size of UIA
   - ☐ Location of UIA
   - ☐ Aneurysm growth on serial imaging
   - ☐ Protocol
   - ☐ Other
4. ***Subject/participant following advice?
   - ☐ Yes
   - ☐ No, specify:
5. PHASES aneurysm risk score:
6. UIATS (UIA treatment score)
   Treatment:
   Observation:

UIA Management Instructions (New for Stroke)

[Study Name/ID pre-filled]

Site Name:

Subject ID:

General Instructions

This CRF contains data on the management of UIA for SAH studies.

Important note: Some data elements included on this CRF Module are considered Supplemental and should only be collected if the research team considers them appropriate for their study. The remaining elements are Exploratory and are indicated by asterisks as specified below:

***Element is classified as Exploratory

Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.