

# Research 102

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RESEARCH DEVELOPMENT

# Conflict of Interest Disclosure

## Conflicts of Interest

A Conflict of Interest occurs when an individual has an opportunity to affect educational content about healthcare products or services of a commercial interest with which she/he has a financial relationship.

There is no conflict of interest for this presentation.

## Commercial Support

No commercial support for this seminar

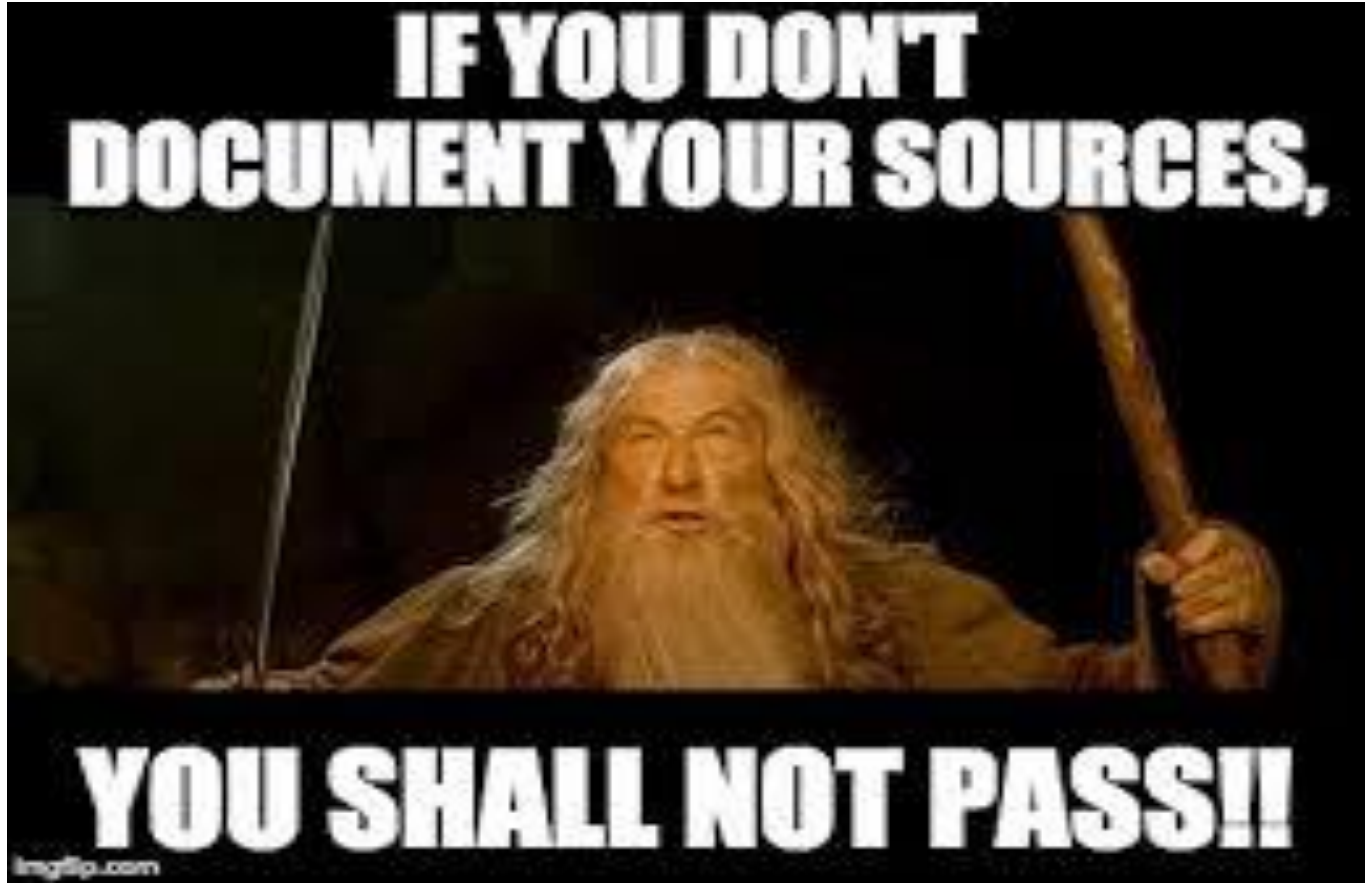
## Non-Endorsement of Products

Non-applicable

# Creating Site Worksheets/ Visit Checklists/Site Source Documents



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# Source Document



- ▶ 1<sup>st</sup> place information is documented is the source
- ▶ Original documents, data and records or certified copies of original records of clinical findings, and observations

# Regulations/Guidance

- ▶ **21 CFR 312.62: Case histories.** An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study.
- ▶ **ICH GCP E6, section 1.51**, defines source data as "All information in original records and certified copies of original records or clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies)."
- ▶ **ICH GCP E6, section 1.52**, defines source documents as "Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries of evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial)."
- ▶ ***The data trail MUST lead back to the original source. No piece of data may be included in the body of research that cannot be found elsewhere***

Your site source document can serve as the original source!

# Purpose of Study Documentation

- ▶ Documents the rights, safety, and well-being of the subject was protected
- ▶ Ensure integrity of the data
- ▶ Show compliance with the protocol, regulations, guidance, policies, and procedures
  - ▶ Reconstruct the events of the trial
  - ▶ Tell the story of the subject's participation
  - ▶ Reconfirm data
  - ▶ Provide an audit trail
  - ▶ Subject's record of study participation
  - ▶ Confirms eligibility
  - ▶ Documents progress throughout the study
  - ▶ Records events (IP accountability, consenting)

# Examples of Source Documents

Medical records

Lab results

Test results (X-ray, CT)

Subject  
Diaries/Questionnaires

Informed Consent  
Process Documentation

Vital signs/Study  
Procedures

Physical Exam

\*Research notes/SSD/  
Visit worksheets\*



# Source Documentation vs SSDs

- ▶ Not all source docs are research visit notes
- ▶ But ALL research visit notes that you create are source documents!
- ▶ **SITE Source Documents reflect research activity at your SITE**
  - ▶ Research Visit Procedure documentation / Work Sheets / Checklists / Logs
  - ▶ ICP Documentation
  - ▶ Subject instruction sheets
  - ▶ Progress Notes
  - ▶ Eligibility Criteria Worksheet / Inclusion & Exclusion Checklist
  - ▶ Concomitant Medication Log
  - ▶ Adverse Event log
  - ▶ Communication log



Site Source Documents

Research Visit Note

Source Doc

Worksheets

Visit Checklist

# How Do I Know What to Include?

Schedule of Events

Trial Period	PK session											
	2						3		4	5		
Visit number	2						3		4	5		
Timing of visit	Day 1						Day 2		Day 3	Day 4		
Time point	-1 h	0	15 min	30 min	1 h	3 h	6 h	9 h	24 h	28 h	48 h	72 h
Visit window	+55 min		±5 min	±5 min	±15 min	±15 min	±30 min	±30 min	±60 min	±60 min	±120 min	±120 min
<b>SUBJECT RELATED INFO/ASSESSMENTS</b>												
In exclusion criteria	X											
Rescheduling criteria				X					X		X	
Withdrawal criteria	X								X		X	X
Concomitant medication	X								X		X	X
Body weight	X								X <sup>a</sup>		X <sup>a</sup>	X <sup>a</sup>
Vital signs												X
Physical examination												X
Bleeding episodes	X	X	X	X	X	X	X	X	X	X	X	X
Adverse events	X	X	X	X	X	X	X	X	X	X	X	X
Body composition									X <sup>b</sup>		X <sup>b</sup>	X <sup>b</sup>
<b>LABORATORY ASSESSMENTS</b>												
FVIII activity	X		X	X	X	X	X	X	X	X	X	X
FVIII inhibitors	X											X
Anti-FVIII antibodies	X											
Biochemistry												X
Haematology												X
Coagulation parameters	X											
<b>TRIAL MATERIAL</b>												
Administration of trial product		X										
Drug accountability					X							

- ▶ Know the protocol, study the Schedule of Events table
- ▶ Request worksheets, CRFs/e-CRF screenshots as soon as possible
- ▶ Determine what can be found in other source documents
- ▶ What data points can ONLY be created by your interaction with subject?

\*Early in the study set up process, use worksheets and CRFs to guide you:

- understand what data to collect
- realize what data may be hard to find
- make a plan for how to capture it all

# Components for SSDs

Header of the document:

- ▶ Study Information, as applicable for your particular study
  - ▶ Protocol Name, descriptor or identifying number
  - ▶ IRB#
  - ▶ PI
  - ▶ Sponsor
- ▶ Subject's Study Identifier (ie, initials, study ID #)
- ▶ Visit Type
  - ▶ Type of Visit
  - ▶ Visit #

Department / Institution Logo or Name

STUDY: Wonder-Drug - Randomized, Double Blind.....

PI: John Doe, MD

IRB#: 19-12345-FB

Visit 1 / Screening

Subject Initials: \_\_\_\_\_

Subject ID#: \_\_\_\_\_

# Components, cont'd

Department Logo or Name

Adverse Event Log / Concomitant Medication Log

STUDY: Wonder-Drug - Randomized, Double Blind.....

PI: John Doe, MD

IRB#: 19-12345-FB

Subject Initials:\_\_\_\_\_

Subject ID#:\_\_\_\_\_

Page \_\_\_\_\_ of \_\_\_\_\_

# Components, cont'd

Body of the document in checklist format:

- ❑ Date and Demographics
- ❑ Eligibility met
- ❑ Informed Consent Process
- ❑ Study Procedures, in sequential order to be performed
- ❑ Closing note / education / next visit
- ❑ Progress Note option
- ❑ Documentation of research staff and date of completion

# Study Procedures

- ▶ VS completed by research staff
- ▶ Details about specimen collections
- ▶ Randomization, IP administration or dispensation, stickers
- ▶ IP return/compliance documentation
- ▶ Teaching / education
- ▶ Research specific procedures or testing (MoCA, 6" walk test, etc)
- ▶ Specific procedure information to show protocol compliance
- ▶ Additional information for procedures not documented elsewhere

# Other Forms to Create

- ▶ Inclusion / Exclusion checklist
- ▶ Informed Consent Process documentation / checklist
- ▶ Specimen Logs
- ▶ Concomitant Medications / flowsheet
- ▶ Adverse Event flowsheet
- ▶ Communication log (Interaction, communication, phone calls with participant)
- ▶ Blank progress notes





# Protocol Eligibility

## Inclusion criteria

1. Provision of informed consent prior to any study specific procedures
2. Men or women  $\geq 45$  years of age
3. Acute ischemic stroke with randomization occurring within 24 hours after onset of symptoms.
  - National Institute of Health Stroke Score  $\leq 10$
4. Head Computed Tomography (CT) or MRI ruling out hemorrhage or other pathology

## Exclusion criteria

1. Planned use of antithrombotic therapy including antiplatelets or heparin
2. Known hypersensitivity to Wonder-drug or ASA
3. Any history of atrial fibrillation
4. Receipt of any thrombolysis (such as tPA) within 24 hours prior to randomization
5. Known severe liver disease
6. Pregnancy

## Inclusion / Exclusion

### STUDY NAME

PI: John Doe, MD

IRB Number:

Subject Number: \_\_\_\_\_

Subject Initials: \_\_\_\_\_

### INCLUSION (All Answers Must Be Yes To Enroll)

Yes    No

- |                          |                          |   |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | 1. Provision of informed consent prior to any study specific procedures   |
| <input type="checkbox"/> | <input type="checkbox"/> | 2. Male or female $\geq$ 45 years of age  |
| <input type="checkbox"/> | <input type="checkbox"/> | 3. Either acute ischemic stroke or high-risk TIA and randomization occurring <u>within</u> 24 hours after onset of symptoms |
| <input type="checkbox"/> | <input type="checkbox"/> | 4. Head Computed Tomography (CT) or MRI ruling out hemorrhage or other pathology  |

### EXCLUSION (All Answers Must Be No To Enroll)

Yes    No

- |                          |                          |  |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | 1. Planned use of antithrombotic therapy in addition to study medication     |
| <input type="checkbox"/> | <input type="checkbox"/> | 2. Known hypersensitivity to wonder drug or ASA                              |
| <input type="checkbox"/> | <input type="checkbox"/> | 3. Any history of atrial fibrillation  |
| <input type="checkbox"/> | <input type="checkbox"/> | 4. Receipt of any thrombolysis <u>within</u> 24 hours prior to randomization |
| <input type="checkbox"/> | <input type="checkbox"/> | 5. Known severe liver disease  |
| <input type="checkbox"/> | <input type="checkbox"/> | 6. Pregnancy   |

---

Enrolling Investigator

Date

## Subject Eligibility Criteria Checklist

All subjects enrolled must meet eligibility criteria based on the inclusion/exclusion criteria detailed in the application and approved by the IRB.

### I. Study Information

<b>Protocol Title:</b>	
<b>IRB #:</b>	
<b>Principal Investigator:</b>	
<b>Sponsor:</b>	

### II. Subject Information:

<b>Subject Initials/ID:</b>
Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female

### III. Inclusion/Exclusion Criteria

<b>Inclusion Criteria</b> (From IRB-approved protocol)	<b>Yes</b>	<b>No</b>	<b>Supporting Documentation*</b>
1.	<input type="checkbox"/>	<input type="checkbox"/>	
2.	<input type="checkbox"/>	<input type="checkbox"/>	
3.	<input type="checkbox"/>	<input type="checkbox"/>	
4.	<input type="checkbox"/>	<input type="checkbox"/>	
<b>Exclusion Criteria</b> (From IRB-approved protocol)			
1.	<input type="checkbox"/>	<input type="checkbox"/>	
2.	<input type="checkbox"/>	<input type="checkbox"/>	

\*All subject files must include supporting documentation to confirm subject eligibility. The method of confirmation can include, but is not limited to, laboratory test results, radiology test results, subject self-report, and medical record review.

### IV. Statement of Eligibility

This subject is [ **eligible** /  **ineligible**] for participation in the study.

<b>Signature:</b>	<b>Date:</b>
<b>Printed Name:</b>	

INVESTIGATION



PCP?



Lab Results?



IP Packages?



Medical Records?

# Protocol Eligibility

## Inclusion criteria

1. Provision of *informed consent prior to any study specific procedures*
2. Men or women *≥45 years of age*
3. Acute ischemic stroke with *randomization occurring within 24 hours after onset of symptoms.*
  - *National Institute of Health Stroke Score ≤10*
4. Head *CT or MRI* ruling out hemorrhage or other pathology

## Exclusion criteria

1. Planned use of antithrombotic therapy including *antiplatelets* or *heparin*
2. Known *hypersensitivity to Wonder-drug or ASA*
3. Any history of *atrial fibrillation*
4. Receipt of any *thrombolysis* (such as tPA) *within 24 hours* prior to randomization
5. Known severe *liver disease*
6. *Pregnancy*

ENROLLMENT VISIT

Visit 1 \_\_\_\_\_

Subject ID#: \_\_\_\_\_

Subject Initials: \_\_\_\_\_

**NAME OF STUDY**

“A Randomized, Double-Blind Study with WonderDrug Compared to Aspirin (ASA) in Patients with Acute Ischemic Stroke”

IRB#: \_\_\_\_\_

PI: John Doe, M.D.

Screening Date: \_\_\_\_\_

Symptom Event Date \_\_\_\_\_ Onset Time \_\_\_\_:\_\_\_\_ Duration: \_\_\_\_\_ (hrs and min)

Date of birth: \_\_\_\_\_ Gender: \_\_\_\_\_ Race: \_\_\_\_\_

- Hispanic or Latino             Not Hispanic or Latino
- Inclusion / Exclusion criteria reviewed per \_\_\_\_\_, MD, and deemed eligible to participate at this time.
- Informed Consent process completed using ICF version \_\_\_\_\_. See ICP documentation checklist attached.

Subject desires to participate in genetic sub-study:     Yes             No

*Informed Consent Form (version \_\_\_\_\_) given to subject / LAR. Subject/LAR was given ample time to read the Informed Consent Form. ICF explained and all questions answered to subject's/LAR's satisfaction. Voices understanding of intended purpose, subject requirements, possible risks, and benefits. Subject/LAR received a copy of the signed Informed Consent Form. Informed Consent Form completed per ICH GCP guidelines by: \_\_\_\_\_*

*Date: \_\_\_\_\_ Time: \_\_\_\_\_:\_\_\_\_\_.*

- History and Physical completed per \_\_\_\_\_, MD (see medical records attached)  
Weight \_\_\_\_\_lb    kg    Height: \_\_\_\_\_ cm    in    BMI: \_\_\_\_\_
- Pulse: \_\_\_\_\_ Blood Pressure \_\_\_\_\_ / \_\_\_\_\_ mm/Hg
- NIHSS per \_\_\_\_\_, MD (see attached)
- EQ-5D questionnaire completed per \_\_\_\_\_ (see attached)

- Employment status of subject and caregiver completed per \_\_\_\_\_.
- Concomitant medications documented (*See Concomitant Medication Flowsheet and MAR attached.*) Subject instructed to discontinue any medications listed as “restricted” per protocol as of today. Those medications include:  
\_\_\_\_\_

- Allergies: \_\_\_\_\_  NKA
- CT or MRI performed: Date \_\_\_\_\_ Time \_\_\_\_:\_\_\_\_
- Current lab values attached  ECG attached
- Serum Urine pregnancy test completed for women of childbearing potential: Result \_\_\_\_\_  NA

IVRS contacted to confirm enrollment, obtain randomization number and kit number for study drug administration during this visit.

**Kit Number:** \_\_\_\_\_ **Batch No.:** \_\_\_\_\_ **Expiration Date:** \_\_\_\_\_

**Date:** \_\_\_\_\_ **Time:** \_\_\_\_\_ **RZ Code:** \_\_\_\_\_

IP dispensed per protocol. Subject given detailed instruction and educational materials regarding medication and dosing schedule. Trial Information Card given to subject. Verbalizes understanding of all instructions. Encouraged to call with questions or concerns. Return appointment made for \_\_\_\_\_ at \_\_\_\_:\_\_\_\_. Detailed instructions for return visit given to subject. Subject reminded not to take medication on the morning of next visit for PK level - verbalizes understanding. Will call subject prior to next visit for reminder of appointment and instructions.

Additional Comments:

\_\_\_\_\_

\_\_\_\_\_

Form Completed by: \_\_\_\_\_

Signature

Date



# ICP Initial Documentation

Screening Visit		
<b>I. INFORMED CONSENT PROCESS (ICP)</b>		
• The following persons were present for the IC process:		
• The consent form and study were explained by:		
• The cognitive ability of the subject was assessed by _____ and determined to the best of their ability to be capable of making decisions for him/herself.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• All pertinent aspects of the study were explained including all of the information contained in applicable subparagraphs of section 4.8.10 of the ICG GCP E6 Guidance.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• The PI was available to answer questions, if needed.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Did the subject request to speak to PI for additional information?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• The IC process was performed in a comfortable, quiet, private and closed-door location.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• The Subject was given ample time to read the consent form and opportunity to inquire about details of the research study.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• The Subject was offered the opportunity to take the ICF home and/or to discuss with others.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• The Subject chose to take the ICF home or to discuss with others before making a decision to participate.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• The Subject was encouraged to ask questions regarding the study throughout the Informed Consent Process.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• The randomization method was explained to the subject.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• The subject was asked direct questions regarding their participation, responsibilities during the study and risks. The subject verbalized understanding of all. The subject appears to have a clear understanding of the study procedures and risks.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• All questions were answered / addressed to the subject's satisfaction and understanding.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Subject voluntarily agrees to participate in the study without coercion or undue influence.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Version/Date _____ / _____ of the IRB approved ICF was signed/personally dated by the Subject and the person conducting the informed consent process today at _____ am / pm, before any study procedures were performed on this date.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Copy of the signed and dated ICF given to subject.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Was a witness utilized during the IC process? If yes, explain	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Subject states understanding of research procedures that will be performed at today's visit and all questions have been answered to the subject's satisfaction.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• Subject is able to read and write in the English language.	<input type="checkbox"/> YES	<input type="checkbox"/> NO
• The PI _____ is aware of enrollment today.	<input type="checkbox"/> YES	<input type="checkbox"/> NO

<b>TITLE:</b>	<b>SSD / Continued Participation/Informed Consent Process</b>
<b>PROTOCOL:</b>	
<b>IRB#:</b>	
<b>PI:</b>	

**Continuation participation: Visit #**

Subject ID#:	Date of visit:
--------------	----------------

<b>INFORMED CONSENT PROCESS (ICP)</b>		
The following person(s) were present for the IC process:		
The study procedure(s) to be performed at today's visit was/were explained by:		
The cognitive ability of the subject was assessed and determined to be capable of making decisions for him/herself	YES	NO
The study procedure(s) to be performed was/were discussed in a comfortable, quiet, private and closed-door location.	YES	NO
The subject was encouraged to ask questions regarding study procedures.	YES	NO
Did the subject request to speak to PI for additional information?	YES	NO
The PI was available to answer questions, if needed.	YES	NO
All questions were answered / addressed to the subject's satisfaction and understanding.	YES	NO
Subject voluntarily agrees to continue participation in the study without coercion or undue influence.	YES	NO

Signature/Date: \_\_\_\_\_

# Return Visit

## FLOW CHART

Investigations/Tests and Procedures	SCREENING	RANDOMIZATION	TREATMENT PERIOD <sup>4</sup>													FOLLOW UP PERIOD
	1	2	3	4	5	6	7 <sup>2</sup>	8	9 <sup>2</sup>	10	11 <sup>2</sup>	12	13 <sup>2</sup>	EOT <sub>3</sub>	FINAL VISIT <sub>3,5</sub>	PHONE CALL <sup>6</sup>
Months since Randomization			3	6	9	12	15	18	21	24	27	30	33			
Time Window (days) <sup>4</sup>	Up to -14 days	0 <sup>1</sup>	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14	+/- 14		+/- 14	+/- 14
Informed Consent	X															
Check Eligibility	X	X														
Medical History	X															
Demographics	X															
Confirm Inclusion/Exclusion		X														
Randomization via IRT		X														
Physical Exam	X														X	
Vital Signs (BP, sitting heart rate) <sup>7</sup>	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
ECG <sup>8</sup>	X	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)
Documentation of Cardiac Monitoring <sup>8</sup>	X	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)	(X)
Pregnancy Test <sup>9</sup> for WOCBP	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
Safety Laboratory Tests <sup>10</sup>	X	(X) <sup>10</sup>		X	X	X	X	X	X	X	X	X	X	X	X	X
Weight	X			X	X	X	X	X	X	X	X	X	X	X	X	X
Height	X															
PK sample <sup>11</sup>	X	(X) <sup>11</sup>	X			X										
Biomarker (substudy) <sup>12</sup>	X			X												
Plasma sample for assay validation (substudy) <sup>13</sup>	X		X			X										
The Montreal Cognitive Assessment (MoCA) <sup>14</sup>	X														X <sup>15</sup>	

## RETURN VISIT

Visit 4 (6 month)

Subject Initials: \_\_\_\_\_

Subject Number: \_\_\_\_\_

NAME OF STUDY

Study: Full Description

PI: John Doe, M.D.

IRB#:

Visit Date: \_\_\_\_\_

Subject desires to continue participation in study.

### **INFORMED CONSENT PROCESS (ICP)**

The following person(s) were present for the IC process:

The study procedure(s) to be performed at today's visit was/were explained by:

The cognitive ability of the subject was assessed and determined to be capable of making decisions for him/herself	YES	NO
The study procedure(s) to be performed was/were discussed in a comfortable, quiet, private and closed-door location.	YES	NO
The subject was encouraged to ask questions regarding study procedures.	YES	NO
Did the subject request to speak to PI for additional information?	YES	NO
The PI was available to answer questions, if needed.	YES	NO
All questions were answered / addressed to the subject's satisfaction and understanding.	YES	NO
Subject voluntarily agrees to continue participation in the study without coercion or undue influence.	YES	NO

ICF current  Yes  No

If No: Updated Informed Consent Form (version \_\_\_\_\_) given to subject / LAR. See attached ICP documentation checklist.

Subject desires to continue participation in biomarkers sub-study:  Yes  No  NA

Study procedures completed per protocol:

Pulse: \_\_\_\_\_ (sitting, palpated w/finger x 60 seconds)     Regular     Irregular

Per Subject, have there been any noticeable irregularities in pulse since last visit?     Yes     No

Blood Pressure assessed per protocol (seated, resting for 5”), machine # \_\_\_\_\_

R    L    Arm; \_\_\_\_\_ / \_\_\_\_\_ mm/Hg        Weight: \_\_\_\_\_ kg    lb

Concomitant medications updated (see con med log). Subject reminded not to take any medications listed as “restricted” per protocol. Encouraged to call with questions should new medications or supplements be prescribed.

Subject interviewed / assessed for any adverse events. Subject encouraged to call should any invasive procedures be scheduled or adverse events occur before next visit.

Study medication compliance assessed.

Study Drug or Placebo: \_\_\_\_\_%    ASA or Placebo: \_\_\_\_\_%

Was compliance for both medications between 80-120%?         Yes     No

If no, compliance issues must be addressed and reinforced. Document below.

Has Subject missed any study medications in the last 3 days?     Yes     No

If yes, please detail missed study medication: \_\_\_\_\_

Protocol Safety Laboratory tests drawn per \_\_\_\_\_, at \_\_\_\_:\_\_\_\_ Location\_\_\_\_\_

Biomarkers drawn: Yes  No  NA

Processed & shipped / stored according to protocol. See specimen logs for details.

Urine pregnancy test completed for women of childbearing potential: Result\_\_\_\_\_  NA

Serial #\_\_\_\_\_ Expiration Date:\_\_\_\_\_

IVRS contacted to confirm visit, obtain randomization number and kit number for study drug administration during this visit. See attached notification. See stickers below:

██████ ██████

██████████

Optional ██████████

IP dispensed per protocol; dose taken at \_\_\_\_:\_\_\_\_. Subject given detailed reminders regarding medication, proper storage and dosing schedule. Verbalizes understanding of all instructions. Encouraged to call with questions or concerns. Return appointment made for \_\_\_\_\_at \_\_\_\_:\_\_\_\_. Detailed instructions for return visit given to subject.

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Form Completed by:\_\_\_\_\_Date:\_\_\_\_\_



# Concomitant Medication Log

Study: Wonder-Drug  
 IRB#: 19-12345-FB  
 PI: John Doe, MD

Subject Initials: \_\_\_\_\_  
 Subject ID#: \_\_\_\_\_

Drug Name (Trade name preferred)	Unit Dose	Units	Frequency	Route	Reason for Medication (Indication)	Start Date	Taken Prior to Study?	Ongoing?
						__/__/__	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No End Date: __/__/__
						__/__/__	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No End Date: __/__/__
						__/__/__	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No End Date: __/__/__
						__/__/__	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No End Date: __/__/__
						__/__/__	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No End Date: __/__/__
						__/__/__	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No End Date: __/__/__
						__/__/__	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No End Date: __/__/__
						__/__/__	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No End Date: __/__/__
						__/__/__	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No End Date: __/__/__
						__/__/__	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No End Date: __/__/__

Comments: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_



# Assessment Tool Flowsheet

## NIHSS Flowsheet

Study: Wonder-Drug  
 PI: John Doe, MD  
 IRB #: 19-12345-FB

Subject Number: \_\_\_\_\_

Subject Initials: \_\_\_\_\_



NIH STROKE SCALE ITEM	Screening	2-6 hours	20-36 hours	Unscheduled	5 days or DC	30 days
	Date:	Date:	Date:	Date:	Date:	Date:
	Time:	Time:	Time:	Time:	Time:	Time:
1a. Level of Consciousness (0-3)						
1b. LOC Questions (0-2)						
1c. LOC Commands (0-2)						
2. Best Gaze (0-2)						
3. Visual (0-3)						
4. Facial Palsy (0-3)						
5&6 Motor Arm and Leg:						
5a. Motor Left Arm (0-4 or UN)						
5b. Motor Right Arm (0-4 or UN)						
6a. Motor Left Leg (0-4 or UN)						
6b. Motor Right Leg (0-4 or UN)						
7. Limb Ataxia (0-2 or UN)						
8. Sensory (0-2)						
9. Best Language (0-3)						
10. Dysarthria (0-2 or UN)						
11. Extinction & Inattention (0-2)						
<b>Other neurological findings:</b>	<b>TOTAL SCORE:</b>	<b>TOTAL SCORE:</b>	<b>TOTAL SCORE:</b>	<b>TOTAL SCORE:</b>	<b>TOTAL SCORE:</b>	<b>TOTAL SCORE:</b>
<b>Assessment performed by:</b>						



# Your Documentation Matters!

The research visit note is one piece of the research puzzle.



Your documentation is the “glue” that pulls the research pieces together!



# Common Findings Related to Documentation

- ▶ Eligibility criteria could not be confirmed
- ▶ Informed Consent Process documentation missing or incomplete
- ▶ Discrepancies within records
- ▶ Missing information/visits not documented
- ▶ AE/SAEs not documented/captured
- ▶ ALCOA-C not followed

# Benefits of Complete Documentation

- ▶ Documents subject safety and well-being
- ▶ Demonstrates understanding of documentation requirements
- ▶ Provides confidence in site and study staff by others
- ▶ Ensures integrity and credibility of the site/staff/data
- ▶ Prepares for favorable monitoring or audit outcomes

# Takeaways

“If it wasn’t documented, it wasn’t done”

Running, handwritten progress notes leave room for omissions and human errors

The Site Source Doc can serve as a visit checklist

Make sure that you tell the entire story

Your SSDs/source should mirror your protocol and CRFs



*Thank  
You*

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