

Recording Study Subject Data at The Research Center

Robin Conklin

Ayushi Gupta

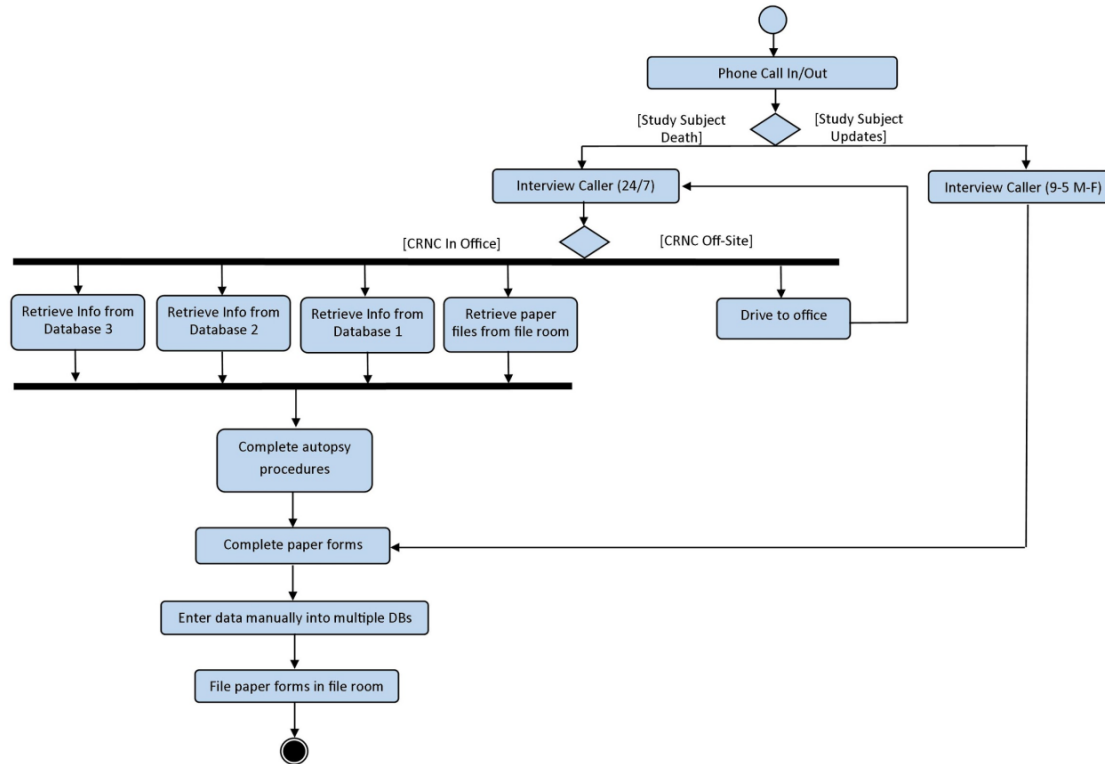
Kathryn Morbitzer

Background

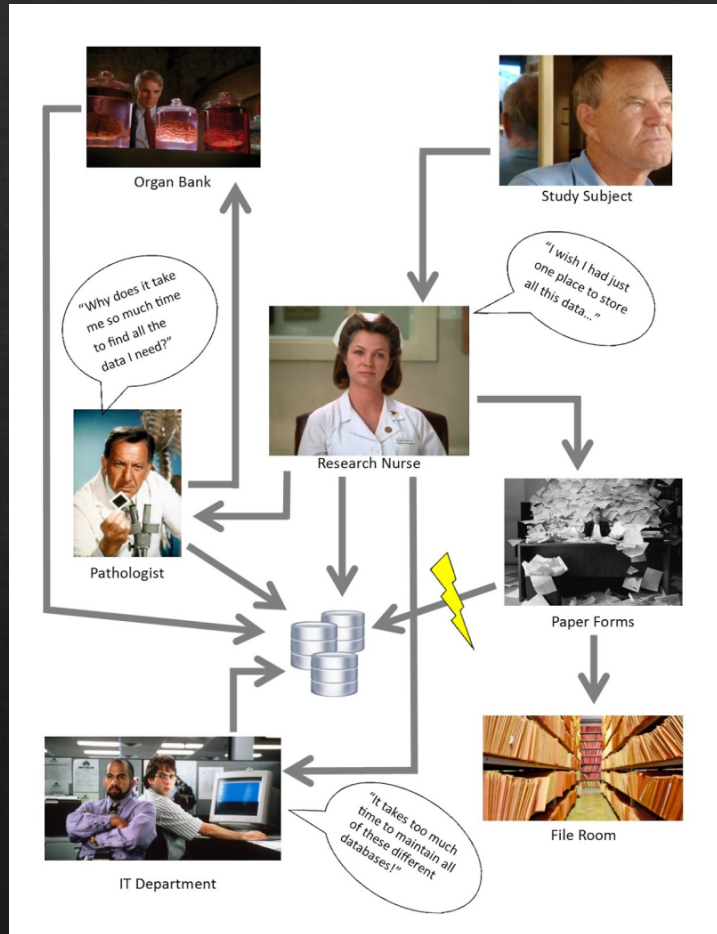
- ◆ The Research Center at the Major Academic Medical Center has an organ donation program that is coordinated by the Clinical Research Nurse Coordinator (CRNC)
- ◆ CRNC collects data annually on the cognition, health, and activities of daily living for each study participant
- ◆ Current system for collecting data is disorganized and decentralized, which causes issues for the CRNC

Current System

Activity Model—Current Process for Clinical Research Nurse Coordinator (CRNC)



Problem



Scope of Project

- ◆ Create new database for storage of research data
- ◆ Integrate three existing databases and paper forms into one database for easy access

Goal of Project: Make the retrieval of information by CRNC, pathologist, or organ bank manager possible from one source that can be accessed from anywhere

Examples from Current System

[Home](#) [Personal](#) [Protocols](#) [Tracking](#) [Status](#)

Bryan ADRC GlobalApp

[Clear All](#)

Last Name

First Name

[Search](#)

Global ID

Email

Global ID	Last Name	First Name	DOB	Address	City	State	Phone1	Phone2
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Data Management Section

[GO](#)

[Reports](#)

[Close](#)

[Home](#) [Personal](#) [Protocols](#) [Tracking](#) [Status](#)

Personal Information

Global ID

☐ Do Not Contact

CCRC

Prefix

Care Facility

First Name

Address 1

Middle Name

Address 2

Last Name

City

Suffix

State

Zip Code

Preferred Name

Phone 1

Date of Birth

☐ Deceased

Phone 2

Date of Death

Age at Death

Phone 3

Email

Race (check all that apply)

☐ White ☐ Hawaiian / Pacific Islander

☐ African-American ☐ Other, specify if possible

☐ American Indian ☐ Asian ☐ Unknown / Refused / Don't Know

Sex

☒ Male ☐ Female ☐ Unknown

Ethnicity

☐ Hispanic ☐ Not Hispanic ☐ Unknown

[Next](#)

Examples from Current System

[Home](#) [Personal](#) [Protocols](#) [Tracking](#) [Status](#)

Protocol Information

Study Name	ID Type	ID Value	Access Description	Access	Consent Date	Consent Type	IRB Number
Prepare AD	PTID	115324-2	Active/Enrolled	Allowed	2013-02-25	Written	Pro00028410
TOMMorrow	ThirdPartyID		Did Not Participate	Allowed			Pro00046510

Study Information

Study Name

Access Description

Consent Type

Date

By

Verbal

Written

Acknowledgement

Comment

ID Type

ID Value

Special Functions

New Study

Next

[Home](#) [Personal](#) [Protocols](#) [Tracking](#) [Status](#)

Tracking History by Study

Study Name

TOMMorrow

Display Entire Tracking History

Date	Time	Staff Name	Event	Result	Study Stage	Outcome
2016-10-25	4:00 PM	Conklin, Robin	Email - Out	Questions Resolved		
2016-10-19	6:00 PM	Conklin, Robin	Phone Call - Out	Scheduled		
2016-10-19	3:00 PM	Conklin, Robin	Appointment - ScheduleApp	Interviewed	Year 3, Month 3 - Phone Call	
2016-07-13	9:30 AM	Chip	Z-Scores Received	Z Scores - Pass		
2016-07-08	12:00 PM	Chip	Appointment - ScheduleApp	Interviewed	Year 2, Month 12 - In Person	
2016-07-08	12:00 PM	Candace	Appointment - ScheduleApp	Interviewed	Year 2, Month 12 - In Person	
2016-06-06	2:30 PM	Jessica	Phone Call - Out	Scheduled		
2016-04-20	4:30 PM	Conklin, Robin	Phone Call - Out	Scheduled		
2016-04-20	2:45 PM	Conklin, Robin	Appointment - ScheduleApp	Interviewed	Year 2, Month 9 - Phone Call	

Tracking Information

Date/Time

By

Event

Result

Outcome

Comments

Follow-up

Specific Date

Specific Time

Days

Months

Date Calculated

Special Functions

New Tracking

Next

Examples from Current System

ProdAppADRC.adp - v2014.07.11 - Build 1 - Prod

File Home Create External Data Database Tools Add-Ins Acrobat

Clinical Autopsy Brain Bank Tissue Samples Tissue Requests Doctors Researchers

Search Fields

Last Name:

First Name:

Neuro Psych Tests?: ☐

Doctor: Clinic Group:

Visit Date Between: and Date of Birth Between: and

Diagnosis Type: Race:

Diagnosis Category: Gender:

Diagnosis: Duke History Number:

Other Neuro Conditions: First Visit Date Between: and

Study: Tagged/Untagged:

Find Now
New Search
Show All
Print...
Export...

Match...
Any search field
All search fields
Negate Search: ☐

Person	Duke History Number	Date of Birth	Last Visit	Consented

New Person Edit Person Delete Person Tag/Untag Person

Go To:

The screenshot displays the 'Person' form in the NeuroPath software. The form is organized into tabs, with 'Personal Info' currently selected. The form contains various fields for personal and medical information, including names, dates, and identifiers. The 'Autopsy Pgm' tab is also visible, indicating the form's use in forensic pathology. The interface includes a menu bar at the top with options like 'File', 'Home', 'Create', 'External Data', 'Database Tools', 'Add-Ins', and 'Acrobat'. A sidebar on the left shows a list of 'Person' records, with the first record highlighted. The main form area has a 'Person' dropdown menu and a 'Commitment' status indicator. The 'Personal Info' tab contains fields for 'Consent', 'Prefix', 'First Name', 'Middle Name', 'Last Name', 'Suffix', 'Preferred Name', 'Date of Birth', 'Home Phone', 'Street', 'City', 'State' (set to 'NC'), 'Zip', 'IOSP' (set to '14056'), 'Race' (set to 'Caucasian'), 'Gender' (set to 'Male'), 'Marital Status' (set to 'Married'), 'Nursing Home', 'Care Level' (set to 'Private Home'), 'Date Admitted', 'Years of Education', 'Year of Onset', 'Age of Onset', 'Initial Contact Date', 'First Visit', 'Last Visit', 'MDC Doctor', 'Primary Language' (set to 'English'), 'Groups' (set to 'Autopsy Pgm Groups'), 'Autopsy UDS', 'DNA' (set to 'blood'), 'PTID' (set to '16057'), 'In UDS' (set to 'Yes'), and 'In MDS' (set to 'No'). At the bottom of the form, there are buttons for 'Add to Group', 'Remove from Group', 'Referred by' (set to 'Other'), 'Print Clinical Contact Form', 'View Neuro-Path Record', and 'Close'.

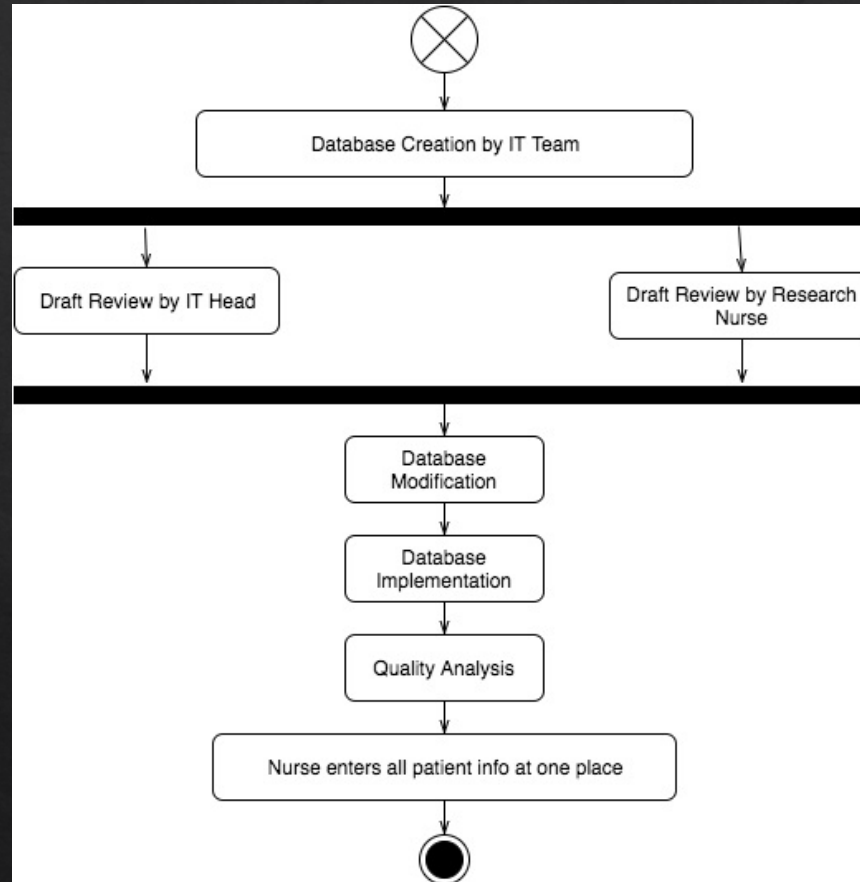
Examples from Current System

ADL INVENTORY (impaired)	
(S) = Subject	Participant's Name:
1. Regarding eating , which best describes (S) usual performance during the past 4 weeks?	<input type="checkbox"/> 3 Ate without physical help and used a knife <input type="checkbox"/> 2 Used a fork or spoon, but not a knife, to eat <input type="checkbox"/> 1 Used fingers to eat <input type="checkbox"/> 0 Usually or always was fed by someone else
2. Regarding walking (or getting around in a wheelchair), in the past 4 weeks, which best describes (S) optimal performance?	<input type="checkbox"/> 3 Mobile outside of home without physical help <input type="checkbox"/> 2 Mobile across a room without physical help <input type="checkbox"/> 1 Transferred from bed to chair without help <input type="checkbox"/> 0 Required physical help to walk or transfer
3. Regarding bowel and bladder function at the toilet , which best describes (S) usual performance in the past 4 weeks?	<input type="checkbox"/> 3 Did everything necessary without supervision or help <input type="checkbox"/> 2 Needed supervision, but no physical help <input type="checkbox"/> 1 Needed physical help, and was usually continent <input type="checkbox"/> 0 Needed physical help, and was usually incontinent
4. Regarding bathing , in the past 4 weeks, which best describes his/her usual performance?	<input type="checkbox"/> 3 Bathed without reminding or physical help <input type="checkbox"/> 2 No physical help, but supervision/reminders <input type="checkbox"/> 1 Needed minor physical help (eg washing hair) <input type="checkbox"/> 0 Needed to be bathed completely
5. Regarding grooming , in the past 4 weeks, which best describes his/her optimal performance?	<input type="checkbox"/> 3 Cleaned & cut fingernails without physical help <input type="checkbox"/> 2 Brushed or combed hair without physical help <input type="checkbox"/> 1 Kept face & hands clean without physical help <input type="checkbox"/> 0 Needed help for grooming of hair, face, hands and fingernails

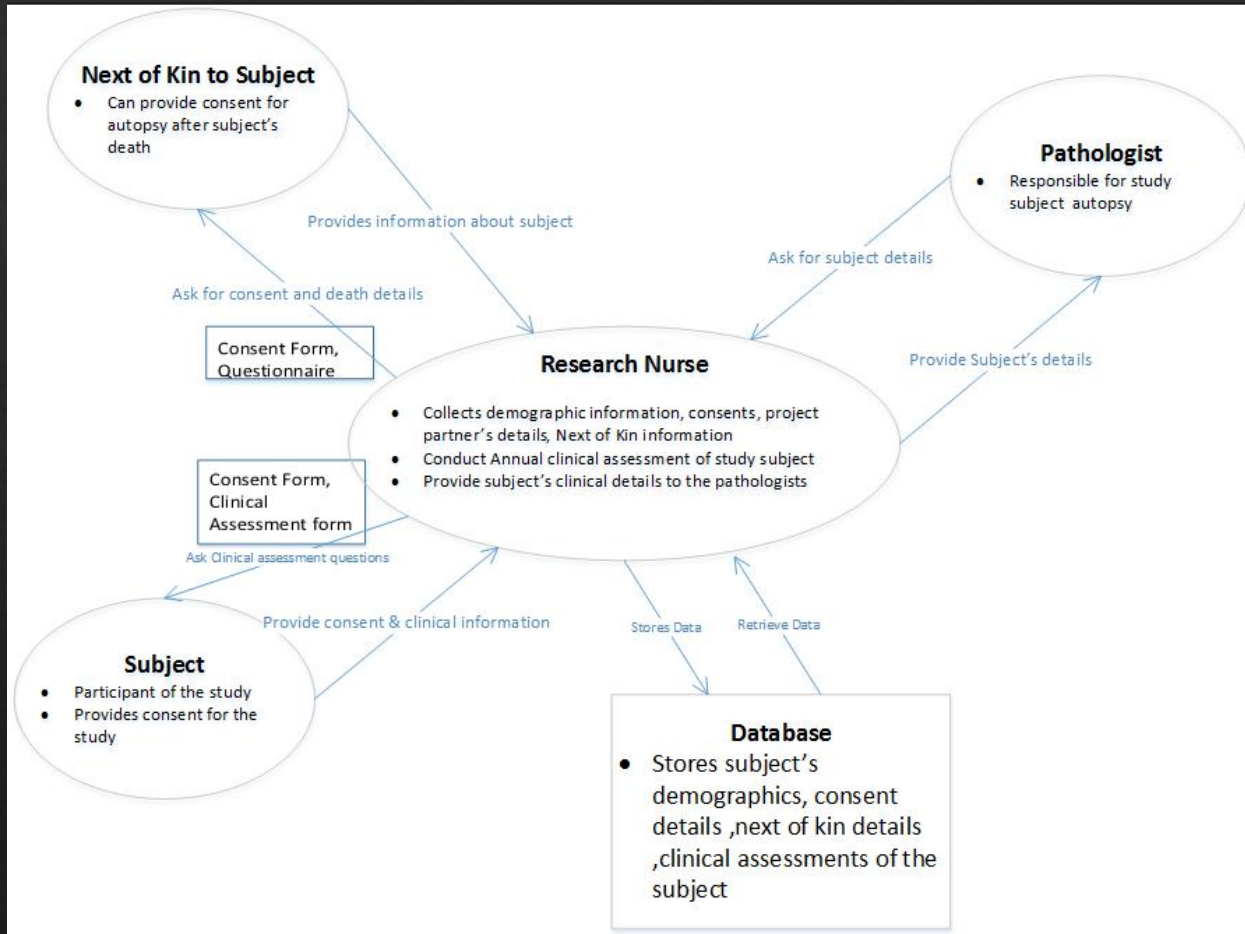
BRYAN ALZHEIMER'S DISEASE CENTER (ADC) <i>Brain Donation Program Participant Medical and Family History</i>	
Participant Information	
Participant Name:	Preferred Name:
Date of Birth:	Gender: Marital Status:
Address:	Type of residence:
Phone (home):	
Phone (cell):	
Phone (work):	
Email:	
Project Partner Information	
Project Partner Name:	Relationship:
Address:	
Phone (home):	
Phone (cell):	
Phone (work):	
Email:	
Funeral Home or Crematorium Information	
Name:	Notes:
Address:	
Phone Number:	

SELF-REPORT COGNITIVE SCREENING MEASURE Telephone Interview for Cognitive Status-modified (TICS-m)	
Question by Question Specifications	
<p>NOTE: If the subject is hard of hearing, it is important to enunciate clearly and slowly. Speak in a normal tone of voice. Diction is much more important than volume. Do NOT speak too loudly or yell as this distorts sound over the phone.</p>	
<p>What is the highest grade of school or year of college or trade school [NAME] completed?</p>	
01 = grade 1 02 = grade 2 03 = grade 3 ... etc ... 10 = grade 10 11 = grade 11 or grade 12 & no diploma	12 = HS diploma or GED 13 = some college (1 yr or some courses & no degree) 14 = 2 yrs or Associates degree 15 = 3 yrs or 4 yrs & no degree
16 = College Degree (B.A., B.S.) 17 = Some post-graduate 18 = M.A., M.S. 19 = Some Doctoral work 20 = Doctoral Degree	<div style="border: 1px solid black; width: 30px; height: 30px; margin: 0 auto;"></div> (99=DK / 88=Refused)
SPECIFICATIONS:	
<p>Years of completed education are used to adjust the TICS-m score. It is important to capture 'completed' years of education. For example, if an individual began 10th grade, but did not complete it, then the number of completed years of education is 9. If the individual reports having completed the 11th grade, ask if s/he received a H.S. diploma at the end of 11th grade. If needed, explain that several decades ago in some schools that 11th grade was the highest grade and students graduated with a H.S. diploma at the end of 11th grade. If s/he obtained a GED and that was his/her highest level of education, code 12 years of education regardless of many years s/he actually attended school. If participant reports s/he never attended school, code 1 year of education. For options above 12 years, probe to be sure the number of years of education match the degree options. For 16, 18 and 20 years of education, be sure the participant has the degree stated. For trade or technical school, years of education would generally be 13 or 14. We generally do not count continuing education in the estimate of completed education.</p>	

Implementation Plan



Proposed Future State



Examples of Future System

AutopsyAppDev-v01.30: [Navigation Icons] [Window Controls]

Demographics	Memory	Connections	Contacts	Autopsy	Status
Home	ADCS_ADL	TICS	Medications	Medical Hx	Family Hx

Autopsy Protocol

Global ID Clear

Protocol IRB Number

Protocol Group Name

Protocol Stage Name Find

Close

Data Manager

Validate

Finalize

UnFinalize

Examples of Future System

AutopsyAppDev-v01.30: [REDACTED]

Demographics Memory Connections Contacts Autopsy Status

Home ADCS_ADL TICS Medications Medical Hx Family Hx

ADL Inventory (impaired)

Global ID: [REDACTED] Last Name: [REDACTED] Visit Date: 10/24/2016 15

Entry 1 Entry 2 Data Entry: 10/24/2016 15 By: Lawrence

1. Regarding eating, which best describes (S) usual performance during the past 4 weeks?

- ☐ 3. Ate without physical help and used a knife
- ☐ 2. Used a fork or spoon, but not a knife, to eat
- ☐ 1. Used fingers to eat
- ☐ 0. Usually or always was fed by someone else

2. Regarding walking (or getting around in a wheelchair), in the past 4 weeks, which best describes (S) optimal performance?

- ☐ 3. Mobile outside of home without physical help
- ☐ 2. Mobile across a room without physical help
- ☐ 1. Transferred from bed to chair without help
- ☐ 0. Required physical help to walk or transfer

3. Regarding bowel and bladder function at the toilet, which best describes (S) usual performance in the past 4 week

- ☐ 3. Did everything necessary without supervision or help
- ☐ 2. Needed supervision, but no physical help
- ☐ 1. Needed physical help, and was usually continent
- ☐ 0. Needed physical help, and was usually incontinent

Examples of Future System

AutopsyAppDev-v01.30: [REDACTED]

DemographicsMemoryConnectionsContactsAutopsyStatus

HomeADCS_ADLTICSMedicationsMedical HxFamily Hx

Telephone Interview for Cognitive Status - modified

Global ID: [REDACTED]Last Name: [REDACTED]Visit Date: 10/24/2016 15

Entry 1Entry 2Data Entry: 10/24/2016 15By: [REDACTED]

Now I would like to ask you some questions to check your memory and concentration. Some of the questions may be easy and some will be harder. Take your time if you need to. We can skip over questions if you don't understand them. Skip Test

Please tell me your full name
(Record only if different from ... whatever is given ...)

FirstMiddleLast

First name is exactly as shownLast name is exactly as shown

First name is very different from above nameLast name is very different from above name

OtherOther

What is your age?

77CorrectIncorrectOther

Without looking at a calendar or watch, what is today's date?

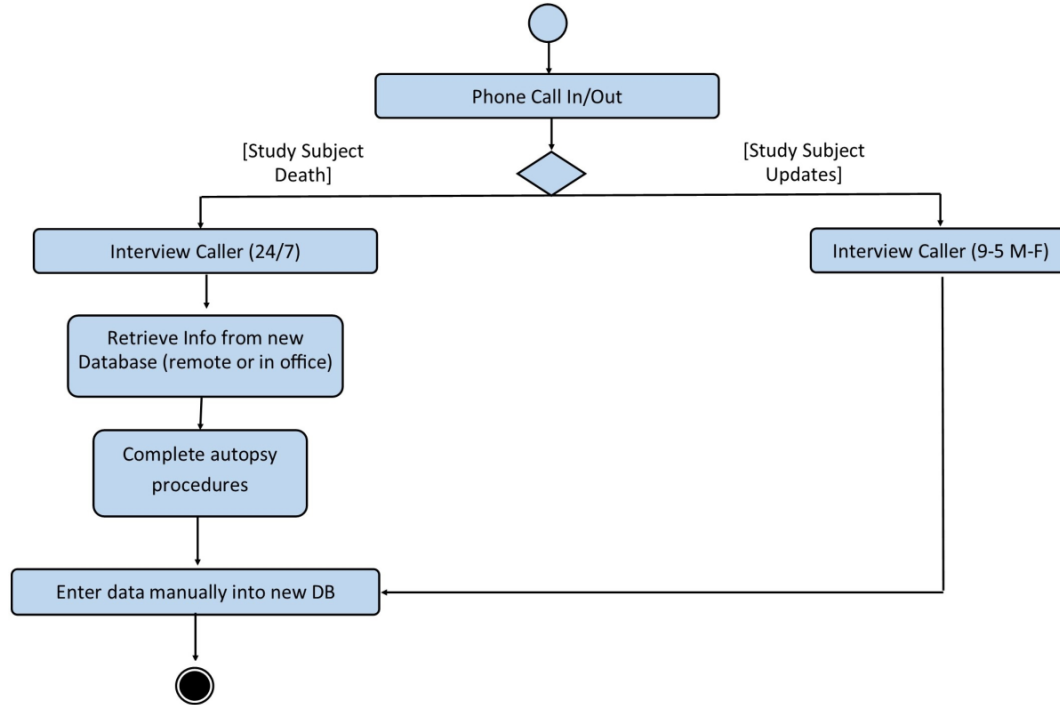
Nov 21, 2016Month: CorrectIncorrectOtherDay: CorrectIncorrectOtherYear: CorrectIncorrectOther

What day of the week is it?

MondayCorrectIncorrectOther

Recommendations

Activity Model—Recommended Process for Clinical Research Nurse Coordinator (CRNC) calls



Project Takeaways

Strengths:

- ◆ Our medical backgrounds helped efficiently understand and brainstorm our way out
- ◆ Had a subject matter expert within our group itself

Challenges:

- ◆ Experienced some delays due to unavailability of concerned IT personnel
- ◆ Kept the scope of the project limited due to lack of availability of time

Lessons Learned:

- ◆ Concepts of informal interview techniques, artifact models, big picture, sequence diagrams, flow diagrams, activity models and wireframes helped building this project and provided an understanding to manage other projects in future