Date: Friday, September 11, 2020 5:22:07 PM

Print

Close Application IRB00119815 Romanus Faigle

1 - General Information

ID: IRB00119815

* Principal Investigator: Click Select to choose Pl

Romanus Faigle

* Will the PI obtain consent for this study ?

O Yes No

* Is the PI a JHHS RN?

O Yes No

* Indicate the Pl's primary affiliation: (Select "Other (Affiliation Not Listed)" if the Pl's primary affiliation is not listed):

* Title of Study:

Presence and implication of an unconscious racial bias among speech-language pathologists involved in clinical decision-making regarding gastrostomy tube placement

* Provide a BRIEF statement of your research question and plan:

Gastrostomy tubes (for enteral feeding) are overutilized in ethnic minority stroke patients despite similar incidence of swallowing dysfunction, stroke severity, and other clinical and sociodemographic variables. Gastrostomy tubes are associated with morbidity and mortality, low quality of life, and additional costs. Speech language pathologists (SLPs) play an intricate role in the clinical decision-making process resulting in placement of gastrostomy tubes.

The present study seeks to determine whether SLP providers have an implicit racial bias and whether an potential implicit bias, if present, affects decision-making regarding gastrostomy tube placement. This will be accomplished via a web-based survey administered to SLP providers registered with the American Speech-Language Hearing Association. Participants will be presented with case vignettes presenting patients with varying degrees of swallowing difficulty after stroke, and will then be asked to determine the likelihood of swallow recovery, and whether they recommend gastrostomy or not. The race of the "fictitious" patient in the vignette will be altered randomly (black vs white). In addition to questions on the vignettes, participants will complete the Race Implicit Association Test, and answer questions about their basic demographics. Analysis will determine whether SLPs have an implicit race bias, and whether a potential bias among SLPs results in higher likelihood of recommending gastrostomy tubes to black vs. white patients.

* Select the type of review requested:

Expedited

* Will an external IRB act as the IRB of record for this study?

O Yes No

What kind of study is this? 9.

Single-site study

* Does this project ONLY involve review of records?

Select "Yes" if this project will ONLY involve review of charts/medical records.

O Yes No

* Is this a quality improvement project?

O Yes No

17. * Is this a resubmission of an expired, terminated, withdrawn or disapproved application?

O Yes No

* Is this a conversion of an active study already approved by a Hopkins/Affiliates IRB (including the JHM All Children's Hospital IRB)?

* Estimated time to complete this study:

1.5 years

25. Study Team Members:

Click Add to add new Study Team members. Click Update to modify existing Study Team member information.

	Last	First	Degrees	JHED Dept	Primary Affiliation	Role	Consenting	Physician- Investigator/	Agree Consenting Physician- Investigator/ Mid-Level Provider	Receive Notifications	Agree To Participate
View	Chen	Bridget	n/a	SOM Neuro Cerebrovascular	Neurology - Broadway	Study Coordinator	yes			yes	yes
View	Cooper	Lisa	M.D., M.P.H.	SOM DOM General Internal Medicine	General Internal Medicine - Broadway	Co- Investigator	no			no	yes

	Last	First	Degrees	JHED Dept	Primary Affiliation	Role	Consenting Hopkins participants	Physician- Investigator/	Agree Consenting Physician- Investigator/ Mid-Level Provider	Receive Notifications	Agree To Participate
View	Gonzalez Fernandez	Marlis	MD, PhD	SOM PMR Physical Med and Rehabilitation	Physical Medicine & Rehabilitation - Broadway	Co- Investigator	no			yes	yes
View	Gottesman	n Rebecca	M.D., Ph.D.	SOM Neuro Cerebrovascular	Neurology - Bayview	Co- Investigator	, no			no	yes
View	Wang	Nae Yuh	Ph.D.	SOM DOM General Internal Medicine	Bloomberg School of Public Health	Co- Investigator	, no			yes	yes

IRB00119815 Romanus Faigle

2 - Study Team Compliance Training

All Study Team Members listed below must complete indicated training requirements

Pls of active IRB Protocols must complete the REWards training (Research Ethics Workshops) or equivalent. Pls have one year from the date of their first eIRB submission to complete the REWards requirement.

For studies with a Prospective Reimbursement Analysis document (PRA), Clinical Research Billing Orientation (CRBO) training is required for study team members who have a role in the consenting process. Clinical Research Support Services will notify those members by email. The IRB cannot take final action until all training is complete.

Principal Investigator

HSR H&R COI **Date REWards** CRBO Date CRBO Last Name First Name Date Date Date Required Required Required Completed Required Completed 10/25/2016 7/18/2016 Faigle Romanus Yes 11/15/2019 Yes 4/5/2012 Yes 9/10/2015

Local Site PI

HSR H&R COI **Date REWards** CRBO Date CRBO Last Name First Name Date Date Date Required Required Required Completed Required Completed

Study Team:

	Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REWards Completed	CRBO Required	Date CRBO Completed
View	Chen	Bridget	yes	6/2/2018	yes	6/2/2018	yes	6/2/2018			
View	Cooper	Lisa	yes	5/29/2017	yes	4/12/2003	yes	11/14/2016	10/20/2006		
View	Gonzalez Fernandez	Marlis	yes	1/10/2018	yes	5/27/2016	yes	9/14/2016	1/25/2005		7/22/2008
View	Gottesman	Rebecca	yes	1/30/2017	yes	4/18/2005	yes	12/19/2016	3/22/2006		3/30/2009
View	Wang	Nae Yuh	yes	1/12/2020	yes	4/9/2003	yes	12/16/2016	1/5/2011		1/13/2020

If the dates above are blank or incorrect, upload copies of training certificates or myLearning Report and the JHM IRB staff will enter 2.0 the dates for you.

Click Add to upload a new document. Click Update to upload a revised version of the existing document. (Click History to see all uploaded versions of an existing document.)

Title Date Modified Version Status

There are no items to display

Application IRB00119815

6 - Protocol Information

1.0	* Type	of pr	otocol:

JHM-IRB eForm A

☐ JHM-IRB eForm B

Outside Sponsor

Investigator-Initiated

* Clean Protocol:

Click Add to upload a new clean document. Click Update to upload a clean revised version of the existing document. (Click History to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
View JHM IRB eFormA_Faigle_implicit_bias(4)	3/5/2018 12:14 PM	4	Submitted

Track Changes Protocol or Summary of Changes

Click **Add** to upload a new track change document. Click **Update** to upload a track change revised version of the existing document. (Click History to see all uploaded versions of an existing document.)

Title	Date Modified	Version	Status
View Tracked Changes(0.02)	3/5/2018 12:13 PM	0.02	Submitted

5.0	Appendices/Sub-study protocol/Letter of Amendment Click Add to upload a new document. Click Update to upload a	revised version of the existing document.	(Click History to see all uploaded
	versions of an existing document.)	-	
	Title Date Modified	Version	Status
	There are no items to display		
6.0	* Did this study receive a non-IRB scientific review? ■ Yes ○ No		
7.0	* Who conducted the review? NIH K23 study section.		
8.0	Upload a copy of the scientific review, and related documer Click Add to upload a new document. Click Update to upload a versions of an existing document.)		(Click History to see all uploaded
	Title Date Modified	Version	Status
	There are no items to display		
9.0	Additional pilot data or relevant publications Click Add to upload a new document. Click Update to upload a versions of an existing document.)	revised version of the existing document.	(Click History to see all uploaded
	Title Date Modified	Version	Status
	There are no items to display		
10.0	* If your study is occurring at JHH or JHBMC, check all of	the below that apply:	
	☐ There are research activities or drugs administered in participants, such as: procedures to provoke an allergic re	-	
	 Research participants will undergo high risk, invasive participant. Examples include bronchoscopy, cardiac cath puncture is not considered high risk.) 		
	☐ There are drugs administered as part of the protocol to could require the use of rescue medications.	hat have a likelihood of causing an alle	rgic reaction, or side effects, which
	☐ This is the first time you have been listed as PI on a m	ore than minimal risk application.	
	None of the above		
11.0	* Does your study involve organ transplantation from an log Yes ■ No	HIV positive donor (living or deceased)	to an HIV positive recipient?
			Application IRB00119815 Romanus Falgle
7 - 0	linical Trials Information		
1.	Is this a clinical trial? ○ Yes ● No		
n	egistration on ClinicalTrials.gov is strongly encouraged or require ledical journal guidelines, in the terms and conditions of Foundati linicalTrials.gov, please enter the National Clinical Trials (NCT) n	ion or other sponsored research). If your p	
9.	* ClinicalTrials.gov identifier (NCT Number): Please enter only the eight digits of the registration number (with	out "NCT").	
			Application
			IRB00119815 Romanus Faigle
8 - 0	conflict of Interest		
1.0	* Does the PI or any study team member (or their spouse, d relationship that	omestic partner, or dependent children	n) have a financial interest or fiduciary
	1) could be affected by the research, or 2) is in an entity that could be affected by the research?		
	* This applies to current interests/relationships and those of Yes No	within the past 12 months.	
	All conflicted individuals must disclose potential conflicts of can be approved.	of interest to the Office of Policy Coord	ination (OPC) before this application
	* To the best of your knowledge, does Johns Hopkins have	a financial interest that 1) could be aff	
5.0	entity whose financial interest could be affected by the rese ○ Yes ■ No		ected by the research or 2) is in an

9 - Support Information

2.0	Does the sponsor red Standards (ICH GCP) O Yes No		B review process	s to comply with In	ternational Conference on	Harmonization / Good Clinical	Practice
3.0	* Will data from this	study be su	bmitted to a fede	eral genomic datab	ease or repository (e.g., db	GaP)?	
4.0	* MONETARY SUPPO	RT:					
	Click Add/Update to s Source		ary support source) :			
	View NIH K 23 Grant	Pending					
5.0	* Will Johns Hopkins ○ Yes ● No	s receive fu	nds through a su	b-contract or sub-	award?		
7.0	* Does this research ○ Yes ● No	have COMI	MERCIAL FUNDII	NG?			
9.0	* Will you apply to the or JHH ICTR-CRU (in O Yes • No				nal Research - Clinical Res	search Unit (ICTR-CRU) (forme	rly GCRC)
10.0	complete grant, incl	luding the fa	ace page but exc ent. Click Update	luding the append	ices:	Cell Research Fund, submit a ment. (Click History to see all up	
		Date Modifi			Version	Status	
11.0	Do you have or do y ● Yes ○ No Study Location	ou anticipa	te receiving fede	ral funding for this	s study?		Application IRB00119815 Romanus Faigle
1.0	Johns Hopkins Prima	-	me PI Email PI PI	hone Notes			
	View Johns Hopkins He	ospital					
	Johns Hopkins ICTR	-CRU Sites:					
	Location PI Nam There are no items to	e PIEm		Notes			
	Other Johns Hopkins	Sites:					
	Location PI Nam There are no items to	e PIEma	ail PI Phone	Notes			
	Other Non-Hopkins S	ites:					
	Location PI Nam There are no items to		ail PI Phone	Notes			
ı	f using a JHCP locatio	n click on t	ne help link for g	uidance and to co	mplete the JHCP Research	Application.	
2.0	Is this study using a ○ Yes ● No	Johns Hopl	kins Clinical Reso	earch Network site	?		
3.0	Is this study using a Yes No	PCORI-Path	ı site?				
	ollowing sites were sel Hopkins Hospital	ected unde	r the legacy Stud	ly Location page:			Application

11 - Sample Size

Material □ None

1.0 * Will this research involve intervention/interaction with participants?

■ Yes ○ No

2.0 * How many participants will be consented (or enrolled with a waiver of consent) at Hopkins/Affiliates?

- individual(s) responsible for approaching participant(s)
- where and when recruitment will take place
- how privacy issues will be addressed in recruitment process

The study population will be drawn from speech-language pathologists (SLPs) registered with the American Speech-Language-Hearing Association (ASHA). SLP providers will be invited to participate in a web-based survey. A random sample of registered inpatient SLP providers is available from ASHA for 21 cents per member contact information. Prospective participants will be mailed a postcard containing basic information on the nature of the study, and are provided the study site URL.

5. * Are you submitting recruitment materials and/or telephone screening scripts for review?

6.	* Check the recruitment materials that you are submitting for review	r:		
	□ Brochures			
	☐ Letters ☐ Flyers			
	□ Newspaper Advertisements			
	☐ Radio Advertisements			
	□ TV Advertisements			
	✓ Postcards ✓ Website postings			
	□ Posters			
	☐ Telephone screening scripts			
	Other			
7.	Recruitment materials and/or telephone screening scripts (Leave a	1.5" margin at top of the doc	ument for IRB approv	al stamn)
	Click Add to upload a new document. Click Update to upload a revised v	-		
	versions of an existing document.)	ordinary and anothing addamen	ni (enek riieter) to eek	o an aproduod
	Title	Date Modified	Version	Status
	View FINAL_Faigle_00119815_Postcard.pdf(3)	12/4/2019 9:21 AM	3	Submitted
8.	* Data Sources:			
0.		al databases		
	JHM Clinical Data (including EPIC, Casemix, CCDA, Department)	ai databases)		
	Non-Hopkins/Affiliates clinical databases or medical charts/reco	ords		
	 ☐ JHM IRB approved studies or research databases ☐ Non-Hopkins IRB approved studies 			
	Public databases/registries/repositories			
	$\hfill \Box$ Administrative/claims data from Johns Hopkins Healthcare LLC			
	☐ Cancer registry data elements			
	☐ Imaging Data collected for research			
	♥ Other * Please Specify:			
	The study population will be drawn from speech-language pathologists (S			
	Association (ASHA). SLP providers will be invited to participate in a web- available from ASHA for 21 cents per member contact information. Prosp			
	on the nature of the study, and are provided the study site URL.			
10.	Provide any additional information about your recruitment process:			
11.	JHM-IRB waiver of privacy authorization (HIPAA Form 4)			
	Required for:			
	Chart/record review without participant consent/authorization Receiving PHI from a referring Clinician not on the study team Conducting telephone screening prior to obtaining written consent	t		
	Click Add to upload a new document. Click Update to upload a revised v	version of the existing documen	nt. (Click History to see	e all uploaded
	versions of an existing document.)			
	Title Date Modified	Version	Status	
	There are no items to display			
				Application
				IRB00119815 Romanus Faigle
14 -	Consent and Waivers			
1.	* Check the type(s) of consent planned for this study:			
	☐ Written Consent			
	□ Oral Consent □ Consent Waiver			
	☑ Survey/questionnaire research			
	The following text should be added to your questionnaire:			
	Your completion of the survey or questionnaire will serve as your consent t	to be in this research study.		
	☐ In vitro diagnostics			
	□ None of the above			

20 - Supplemental Study Documents

14

1.

● Yes ○ No

You are not required to submit standard and recognized questionnaires or tests if they have not been altered for specific use in this study.

- Drugs - Drugs - Drugs - Property - Proper	-	ns of an existing document)			
Click Add to upload a new document. Click Update to upload a revised version of the existing document. Click History to see all uploaded versions of an existing document. Title Date Modified Version Status Vew Conset page(1) 1/82017 12:28 PM 1 Submitted Vew Conset page(2) 1/82017 12:28 PM 2 Submitted Vew Consetionnaire A(0.01) 11/25/2019 10:32 AM 0.01 Submitted Vew Consetionnaire B(0.01) 11/25/2019 10:33 AM 0.01 Submitted Vew Consetionnaire B(0.01) 11/25/2019 10:33 AM 0.01 Submitted Vew Vigneties(0.01) 11/25/2019 10:33 AM 0.01 Submitted **Vigneties(0.01) 11/25/2019 10:33 AM 0.01 Submitted **Vigneties(0.01) 11/25/2019 10:33 AM 0.01 Submitted **Provides One of the provided of the prov			Version	Sta	tus
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Title Date Modified Version Status vew conset page(1)			ate to upload a revised version of the existing	document. (Click H	story to see all
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Very Vignettes(0.01) 11/25/2019 10:33 AM 0.01 Submitted Agriculture of Romanus Fa - Drugs - Portugs - Will participants receive any drugs, substances, or biologicals that are specified by name in the protocol (FDA approved or investigational)? ○ Yes ■ No - Devices - Will any devices be studied in this research (including devices which are FDA-approved for marketing)? ○ Yes ■ No 2. *Will any investigational devices (non-FDA-approved for marketing or used according to non-FDA-approved indications) be used in this research? ○ Yes ■ No - Institutional Biological Samples - Institutional Biosafety Committee 1. *Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research? ○ Yes ■ No - Recombinant or synthetic nucleic acid molecules ○ Potential infectious agents or viral-based vectors	View Questionnai	re A(0.01)	11/25/2019 10:32 AM	0.01	Submitted
Application of Recessors Fa - Drugs - Will participants receive any drugs, substances, or biologicals that are specified by name in the protocol (FDA approved or investigational)? O Yes No Application of Recessors Fa - Devices - Will any devices be studied in this research (including devices which are FDA-approved for marketing)? O Yes No - Will any investigational devices (non-FDA-approved for marketing or used according to non-FDA-approved indications) be used in this research? O Yes No - No Application of Recessors Fa - Institutional Biosafety Committee 1. Will any of the following be used in this research? Recessors Fa - Recombinant or synthetic nucleic acid molecules Potential infectious agents or viral-based vectors	View Questionnai	re B(0.01)	11/25/2019 10:33 AM	0.01	Submitted
Browning Face	View Vignettes(0.0	01)	11/25/2019 10:33 AM	0.01	Submitted
- Drugs * Will participants receive any drugs, substances, or biologicals that are specified by name in the protocol (FDA approved or investigational)? ② Yes ■ No Applicationally and devices be studied in this research (including devices which are FDA-approved for marketing)? ② Yes ■ No 2. * Will any investigational devices (non-FDA-approved for marketing or used according to non-FDA-approved indications) be used in this research? ③ Yes ■ No Applications Recombination Applications Applica					Applicati
Will participants receive any drugs, substances, or biologicals that are specified by name in the protocol (FDA approved or investigational)? ○ Yes ● No Applications 7s Devices 1. * Will any devices be studied in this research (including devices which are FDA-approved for marketing)? ○ Yes ● No 2. * Will any investigational devices (non-FDA-approved for marketing or used according to non-FDA-approved indications) be used in this research? ○ Yes ● No Applications Pa Applications Pa Applications Pa I. * Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research? ○ Yes ● No Applications Pa Application					IRB001198 Romanus Fai
investigational? O Yes ● No Applicating Romanus Fa - Devices 1. * Will any devices be studied in this research (including devices which are FDA-approved for marketing)? O Yes ● No 2. * Will any investigational devices (non-FDA-approved for marketing or used according to non-FDA-approved indications) be used in this research? O Yes ● No Applicating Romanus Fa - Human Biological Samples 1. * Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research? O Yes ● No Applicating Romanus Fa - Institutional Biosafety Committee 1. * Will any of the following be used in this research? Recombinant or synthetic nucleic acid molecules Potential infectious agents or viral-based vectors	- Drugs				
Power of the following be used in this research? - Devices 1. *Will any devices be studied in this research (including devices which are FDA-approved for marketing)? O Yes ● No 2. *Will any investigational devices (non-FDA-approved for marketing or used according to non-FDA-approved indications) be used in this research? O Yes ● No Applicating Romanus Fa 1. *Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research? O Yes ● No Applicating Romanus Fa Institutional Biosafety Committee 1. *Will any of the following be used in this research? O Recombinant or synthetic nucleic acid molecules O Potential infectious agents or viral-based vectors					Applica
1. * Will any devices be studied in this research (including devices which are FDA-approved for marketing)? ② Yes ■ No 2. * Will any investigational devices (non-FDA-approved for marketing or used according to non-FDA-approved indications) be used in this research? ③ Yes ■ No Applicating 1880019 Romanus Fa 3. * Human Biological Samples 1. * Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research? ④ Yes ■ No Applicating 1880019 Romanus Fa 4. * Institutional Biosafety Committee 1. * Will any of the following be used in this research? □ Recombinant or synthetic nucleic acid molecules □ Potential infectious agents or viral-based vectors					Applicat IRB001198 Romanus Fai
O Yes ● No 2. *Will any investigational devices (non-FDA-approved for marketing or used according to non-FDA-approved indications) be used in this research? O Yes ● No Applicating Romanus Fa 3 Human Biological Samples 1. *Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research? O Yes ● No Applicating Romanus Fa 4 Institutional Biosafety Committee 1. *Will any of the following be used in this research? O Recombinant or synthetic nucleic acid molecules O Potential infectious agents or viral-based vectors	? - Devices				
research?	-	s be studied in this research (in	cluding devices which are FDA-approved for n	narketing)?	
RB80119 8 - Human Biological Samples 1. * Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research? ○ Yes ● No Applicat IRB0119 Applicat IRB0119 Applicat IRB0119 Applicat IRB0119 Committee 1. * Will any of the following be used in this research? □ Recombinant or synthetic nucleic acid molecules □ Potential infectious agents or viral-based vectors	research?	igational devices (non-FDA-appr	roved for marketing or used according to non-	FDA-approved indic	ations) be used in this
Romanus Fa 1. * Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research? ○ Yes ■ No Applicat IRB00119 Romanus Fa - Institutional Biosafety Committee 1. * Will any of the following be used in this research? ○ Recombinant or synthetic nucleic acid molecules ○ Potential infectious agents or viral-based vectors					Applicati
1. * Will human biological samples (e.g., blood, cells, tissue, urine) be used in this research? ○ Yes ● No Applicat IRB00119 Romanus Fa - Institutional Biosafety Committee 1. * Will any of the following be used in this research? ○ Recombinant or synthetic nucleic acid molecules ○ Potential infectious agents or viral-based vectors					Romanus Fai
O Yes ■ No Applicating Booting Romanus Fa - Institutional Biosafety Committee 1. * Will any of the following be used in this research? □ Recombinant or synthetic nucleic acid molecules □ Potential infectious agents or viral-based vectors	- Human Biolo	ogical Samples			
Institutional Biosafety Committee 1. * Will any of the following be used in this research? Recombinant or synthetic nucleic acid molecules Potential infectious agents or viral-based vectors		logical samples (e.g., blood, cell	ls, tissue, urine) be used in this research?		
- Institutional Biosafety Committee 1. * Will any of the following be used in this research? □ Recombinant or synthetic nucleic acid molecules □ Potential infectious agents or viral-based vectors					Applicati
□ Recombinant or synthetic nucleic acid molecules □ Potential infectious agents or viral-based vectors	- Institutional	Biosafety Committee			Romanus Fal
☐ Potential infectious agents or viral-based vectors	1. * Will any of the	following be used in this researd	ch?		
_	☐ Recombinan	t or synthetic nucleic acid mole	cules		
☐ Biological toxins	☐ Potential infe	ectious agents or viral-based ve	ctors		
	☐ Biological to	xins			

1.	* Does the study involve any of the following where an individual's results will be disclosed?
	No

26 - Imaging/Radiation

1. * Does this study involve imaging (e.g., MRI, CT, PET, x-rays, ultrasound, fluoroscopy or nuclear medicine)?

O Yes No

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32

32 -	Data and Safety Monitoring Plan				
	Is the Data and Safety Monitoring Plan described Yes	in the protocol? (This is leg	acy data and is being displa	y as read only.)	
1.0	* Indicate the methods for data safety monitoring The principal investigator will have sole resp. A group of designated Hopkins/Affiliates facuprotocol events An independent individual or group of non-Homonitoring, oversight of adverse events and othe A designated medical monitor, or group of mesponsibility for monitoring, oversight of adverse The SKCCC CRO will have responsibility for a A formal Data and Safety Monitoring Board (I oversight of adverse events and other protocol events)	onsibility for monitoring an ulty/staff will have respons opkins/Affiliates individual or protocol events onitors for commercially o e events and other protoco monitoring, oversight of ac DSMB) or Data Monitoring	nd oversight of problem/ev ibility for monitoring, overs s (e.g., coordinating center r for not-for-profit sponsor of events dverse events and other pro	ight of adverse events and oth) will have responsibility for ed studies, will have otocol events	er
2.0	Describe the data and safety monitoring plan in the following in your plan:	he text box below or upload	d a document detailing this	plan. Please address the	
	procedures for analysis and interpretation of dat actions to be taken concerning specific events c time points for review and reporting procedures	or end points			
	Click Add to upload a new document. Click Update to versions of an existing document)	o upload a revised version o	f the existing document. (Cli	ck History to see all uploaded	
	Title Date Modified	Category	Version	Status	
	There are no items to display				
3.0	Provide data safety monitoring information, includes read only.): Click History to see all uploaded versions of an exist. Title Date Modified There are no items to display		m other study sites (This is	legacy data and is being displayed Status	ed.
				Appli IRB001 Romanus	19815
34 -	SKCCC CRO				
1.	* Is this study cancer related (e.g., cancer preventicenter facilities/resources? O Yes No	ion, screening, therapeutic	, diagnostic, etc.), involvin	g cancer patients, using cancer	
	* Does this study involve a drug that will be admin ○ Yes No	nistered/dispensed in the W	einberg IDS?		
				Appli IRB001 Romanus	19815
36 -	Data Confidentiality				
1.0	* I confirm that all the procedures listed below wiresearch purposes: Yes O No	ill be used to protect the co	onfidentiality of data and sa	imples collected and stored for	
	 Only authorized persons will be granted access Only authorized persons may enter and view s Passwords and system IDs will not be shared Physical security of the workstations/files will b Adequate back-up plan is in effect Staff trained on data entry system and importar Workstations with databases will not be left una 	etudy data ne maintained nce of security procedures			

* Will PHI or other confidential information be stored on laptops or other mobile devices (such as mobile phones, tablets, netbooks, flash drives and other portable storage devices) for this study?

O Yes
No

* Will a Certificate of Confidentiality be obtained for this study?

O Yes
No

3.0

Study Team member: 1.0 **Bridget Chen** * Study Team role: 2.0 Study Coordinator 3.0 * Primary Affiliation: Neurology - Broadway 4.0 * Will this study team member be consenting participants for this study? Yes O No Is this study team member a physician-investigator or mid-level provider who will be consenting participants for this study? 5.0 O Yes O No Will this person serve as a lead study coordinator? O Yes No **Study Team Information** 1.0 * Study Team member: Lisa Cooper * Study Team role: 2.0 3.0 * Primary Affiliation: General Internal Medicine - Broadway * Will this study team member be consenting participants for this study? 4.0 O Yes No Will this person serve as a lead study coordinator? 6.0 O Yes O No **Study Team Information** 1.0 * Study Team member: Marlis Gonzalez Fernandez * Study Team role: Co-Investigator 2.0 3.0 * Primary Affiliation: Physical Medicine & Rehabilitation - Broadway * Will this study team member be consenting participants for this study? 4.0 O Yes No 6.0 Will this person serve as a lead study coordinator? O Yes O No **Study Team Information** 1.0 * Study Team member: Rebecca Gottesman 2.0 * Study Team role: Co-Investigator * Primary Affiliation: Neurology - Bayview 3.0 * Will this study team member be consenting participants for this study? 4.0 6.0 Will this person serve as a lead study coordinator?

1.0 * Study Team member: Nae Yuh Wang

○ Yes ○ No

Study Team Information

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3.0	* Primary Affiliation: Bloomberg School of Public Health
4.0	* Will this study team member be consenting participants for this study? O Yes No

6.0 Will this person serve as a lead study coordinator?

○ Yes ○ No

* Study Team role: Co-Investigator

2.0