PI:
For IRB Use Only: **Assigned IRB #**

Application for Initial Review Submission Checklist
USF Institutional Review Board
OHRP Federalwide Assurance FWA-00001669

The following materials are required for IRB review. Please review your IRB submission for completeness of all required items. Complete submissions will ensure your submission is processed as efficiently as possible. ***Submissions must include one original packet and two copies of all applicable documents.*** ***Incomplete or handwritten submissions will be held for replacement for 30 days only.***

Document Checklist for PI		**For IRB Staff**
Complete, typed IRB application. ☐ PI signature of Assurance (Pg 16) ☐ Co-investigator signature of Assurance (Pg 16) ☐ Scientific / Scholarly review signature (pg 17) ☐ Departmental review signature (Pg 18) ☐ Application Addenda		
Full research protocol ☐ Student research – thesis/dissertation ☐ Grant Application / Contract (including budgetary information) ☐ DHHS-approved protocol ☐ Industry Sponsored Protocol ☐ Investigator's Brochure		
Informed consent forms ☐ Adult ☐ Parental ☐ Assent ☐ Proxy ☐ Non-English ☐ DHHS-approved sample consent documents ☐ Debriefing form or outline	☐ Addenda (Genetic, Summary of Consent & Interpreter Statement) ☐ Request for Waiver of Informed Consent (Process, Elements, Documentation) ☐ Research Authorization incorporated ☐ Separate HIPAA Authorization Document	
Supporting Documents ☐ Advertisement / Recruiting materials ☐ Study Instruments ☐ Scales ☐ Surveys ☐ Questionnaires ☐ Interview Scripts ☐ Other:_____ ☐ Affiliate approval letters (MCC, JAHVAH, TGH, Shriners) ☐ Off-site research approval (letters of support) ☐ Separate HIPAA Research Authorization / HIPAA Waiver ☐ Conflict of Interest Management Plan (with documentation that the management plan has been appropriately reviewed and approved, if any research personnel (and/or immediate family) associated with this project has a perceived or real conflict of interest) ☐ Investigators' CV (*PI and co-investigators*) ☐ Investigators' Responsibilities Certification (*PI and co-investigators*) http://www.research.usf.edu/cs/irb_forms/InvRespRev022002.doc ☐ On File at IRB Office ☐ Current Human Research Protections Training Certification ☐ On File at IRB Office ☐ Key Personnel Sheet (for all Personnel involved with participants) NEW!		
Additional Documents:		

NEW! **Date PI Completes Application:** [ ] NEW! **Date PI Submits Application:** [ ]

Application for Initial Review

Office of Research
Division of Research Integrity and Compliance
Social & Behavioral Institutional Review Board
OHRP Federalwide Assurance: FWA00001669

For IRB Staff only:

IRB #:_____

☐ **New Study**
☐ **Revision of** _____

If you believe your proposed human research activities qualifies for expedited review and all of your research procedures fall within one or more of the expedited review categories; complete ***Addendum 1 : Expedited Review*** *and submit it with this application.*

	IRB QUESTIONS	PRINCIPAL INVESTIGATOR RESPONSES *Please make sure all cells contain a response (even if it is "none" or "N/A"). Cells will expand to allow additional space for responses.*
Principal Investigator Information		
1	PI Name and Degree(s)	Stephanie Karidas
2	Indicate status	[X] Student [ ] Resident [ ] Fellow [ ] Staff [ ] Faculty [ ] Other
3	USF Employee or Student Number *(If not associated with USF, please provide an alpha numeric code consisting of the first 3 letters of your last name & the month and day of your birthdate [abcmmdd]).*	U15720860
4	USF Dep/College or other affiliation	USF Dept. of Communication Sciences and Disorders College of Arts and Sciences
5	Mailing Address *(for IRB correspondence)*	East Fowler Avenue, PCD 1017 Tampa, Florida 33620
6	E-mail Address	skaridas@mail.usf.edu
7	Telephone and Fax Numbers	Telephone #: 813 974 7468 Fax #: 813 974 0822
Contact Person (Person designated to serve as primary contact for all IRB communications). If PI, Skip to 15.		
8	Name and Degree(s)	[Please provide your full name - do not use nicknames]
9	USF Employee or Student Number *(See Item #3).*	
10	Primary Role in the Research	
11	Mailing Address *(for IRB correspondence)*	
12	E-mail Address	
13	Telephone and Fax Numbers	Telephone #: [Please specify] Fax #: [Please specify]
Co-investigator or Faculty Advisor Information		
14	Name and Degree(s)	Jacqueline Hinckley, Ph.D., CCC-SLP
15	Indicate Status	[ ] Co-Investigator [X] Faculty Advisor [ ] Student
16	Primary Role in Research	
17	USF Employee or Student Number *(See Item #3).*	U93953134
18	USF Dep/College or other affiliation	USF Dept. of Communication Sciences and Disorders College of Arts and Sciences
19	Mailing Address *(for IRB correspondence)*	East Fowler Avenue, PCD 1017 Tampa, Florida 33620
20	E-mail Address	jhinckley@chuma1.cas.usf.edu
21	Telephone and Fax Numbers	Telephone #: 813 974 7468 Fax #: 813 974 0822
Protocol Information		

22	Protocol Title	Aphasia Talk Bank
23	Additional Study Title (if requesting one) Provide a brief rationale for the additional study title and indicate how this will be used	
24	Sponsor/Funding Source, if applicable	[X] Not receiving any funding or support for this research. Go to Question 25 [ ] Yes. Identify the funding source and answer items **(a)** – (d):
	(a) USF Account Number for study	
	(b) Is this research funded by a training grant, Center grant, core grant, industry, DHHS or other	[ ] Yes. Identify the type of project. [ ] No.
	(c) Provide the complete grant/funding including budget proposal (Note: Salary info can be redacted)	[ ] Attached, including budget - [ ] Not attached. Explain why this is not provided.
	(d) PI listed on the grant / contract	
25	Anticipated Start and End Dates for the proposed research	Anticipated Start Date: March 15th, 2008 (depending on IRB approval) Anticipated End Date: March 14th, 2009
26	If this research is being conducted to fulfill an educational requirement (such as a Dissertation or Thesis) provide two copies of the approved proposal.	[X] Not being conducted as part of an educational requirement [ ] Yes – Please provide the date you dissertation/thesis committee approved the proposal [indicate date]. You must provide a copy of the dissertation/thesis proposal
Sites Involved		
27	Please indicate the sites at which this study is being conducted (please mark all that apply)	[X] A single site [ ] Multiple LOCAL sites (e.g., Hillsborough Schools) [ ] Multiple NATIONAL sites. Please indicate the number of sites: Name the primary national site: [ ] INTERNATIONAL sites. Please indicate the number of sites: Name the international site(s)
	Documentation required from research sites: • *Research conducted at **AFFILIATED SITE(S)** (column 2 below): a letter of approval from the appropriate facility's review committee.* • *Research carried out at a **NON-AFFILIATED SITE(S)** (column 3 below): a letter of support from an authorized person at the site giving permission to conduct the research at the site. If the site has an ethics review committee, please provide documentation of review and approval by that committee. For information about what to include in a **LETTER OF SUPPORT,** please refer to the information guide for "Off-Site Research" on our web site at **http://www.research.usf.edu/cs/irb_docs/off-siteresearch.doc*** • *Research conducted at **INTERNATIONAL SITES**: Documentation from appropriate authorities that you have permission to go into the country to conduct the research. Also please provide the name, telephone number and e-mail address of the contact person at the non-affiliated site, and indicate whether the site has an ethics review committee or IRB. If the site does have such a committee then please provide documentation of review and approval by the committee.*	
28	Please indicate the study sites involved by placing an "X" in front of all of the location(s) where you plan to collect data or implement your research. Provide the name of the site when choosing "Other":	

	USF Sites: [ ] FMHI [X] College of Arts & Sciences [ ] College of Business [ ] College of Education [ ] College of Medicine [ ] College of Nursing [ ] College of Public Health [ ] Harborside Medical Tower [ ] USF Ambulatory Clinics [ ] USF Medical Clinics North [ ] USF Medical Clinics South [ ] Other (Please list)	**Affiliated Sites:** [ ] All Children's Hospital (FWA 00000977) [ ] J. A. Haley VA Hospital (FWA 00000505) [ ] Moffitt Cancer Center (FWA 00001464) [ ] Moffitt Cancer Ctr South (FWA 00001464) [ ] Shriners Hospital (FWA 00001441) [ ] Tampa General Hospital (FWA 00001442) **Non-Affiliated Sites** [ ] Health Department [ ] DCF Agencies/Clinics [ ] Florida Orthopaedic [ ] LifeLink [ ] FDOH [ ] Other (Please list)
29	If USF or an Affiliate Site is the lead site for a Multi-center study, describe the plan for sharing information obtained in this multi-site research that may be relevant to the protection of research participants (reporting unanticipated problems, interim results, and protocol modifications).	[Please describe] [X] USF or an Affiliate is not the lead site.
30	If this research is being carried out at a non-affiliated site(s), provide a letter of support from an authorized person at the site. Provide the following:	N/A
	(a) Name of contact person at the site:	
	(b) Telephone number of contact person:	
	(c) E-mail address of contact person:	
	(d) Indicate whether the site has an IRB that will review the research or will rely on the USF IRB.	N/A
31	If you research will be conducted in another State (other than Florida), please identify the State(s).	N/A
	Describe how you will make yourself aware of the state laws that apply to your research (e.g., who under state law meets the federal definitions of "children", "legally authorized representative", and "guardian" and what are the reporting requirements, in that state)..	N/A
Research Plan		
32	Briefly describe any previous literature, research, etc. that provides a rationale or reason for conducting this study. Provide 2 to 3 most recent citations if available.	The data from this study will be submitted on a shared database of multimedia interactions for the study of communication in aphasia. "The overarching goal of this work is the construction of methods for improving patient-oriented treatments in aphasia. To reach this goal we must solidify the empirical database supporting our understanding of communication in aphasia" (AphasiaBank Proposal/ Whinney&James, 2007). "AphasiaBank is modeled after the Child Language Data Exchange System (CHILDES) […]. Most new empirical studies of child language production rely primarily on the analysis of data from the CHILDES database and the majority of theoretical

		papers on language that make reference to production data are now based on the use of the CHILDES database" (AphasiaBank Proposal/ Whinney&James, 2007). The AphasiaBank is an extended model of this database in order to study aphasic communication. It was established in 2005, sponsored by the National Science Foundation (NSF) TalkBank Project.
33	Concisely state the objectives and/or the hypotheses of your proposed project. This must be presented in lay language.	Our project will provide data to expand the shared database of multimedia interactions for the study of communication in aphasia. According to NINDS website, aphasia affects one quarter of the 4.7 million stroke victims in the United States. Our data will help to develop treatments that can help patients to improve their communicative use of language, and to understand the nature of the communication impairment – including conversational limitations – in aphasia.
34	Identify the type of design (e.g., experimental, correlational, cross-over, qualitative)	This is a qualitative study in which various linguistic and communicative aspects of aphasia will be analyzed in detail across multiple participants.
35	a) Concisely describe all of the research procedures that you will use to collect research data (e.g., interviews, observational studies, ethnographic studies, experiments, focus groups, review of records).	Each participant of this study will administered to the following: 1. Demographic data a. Aphasia classification type b. Classification basis c. Severity of aphasia d. Test scores e. Lesion location f. Lesion etiology g. Time post onset, course of recovery h. Physical status, handedness i. Gender, ages, SES (source), education, and occupations j. Ethnicity, including AAVE status, immigrant status, and relation to the immigrant community k. Language status: monolingual, childhood bilingual, late bilingual, and second language learner l. Additional language details: language loss, time since arrival 2. Free Speech Samples a. Stroke story and coping b. Describing of personal experienced scary event 3. Picture Descriptions a. Flood rescue b. Cat rescue c. Broken window d. Refused umbrella 4. Story Narrative a. Cinderella 5. Procedural Discourse Peanut Butter and Jelly Sandwich or other simple sandwich 6. Tests a. Aphasia Bank Repetition Test (2007) b. Boston Naming Test, 2nd Edition (2001)

		c. Verb Naming Test (Northwestern Assessment of Verbs and Sentences-Revised, Field Test Version) d. Western Aphasia Battery-Revised (2007)/AQ only (Measurements are described in nr. 36)
	b) Clearly indicate which procedures, if any, are new and might involve unforeseen risks to participants.	There are no new procedures and no unforeseen risks for participants. Fatigue might appear.
	c) Indicate whether deception will be involved (if deception is involved, be sure to attach your debriefing form and/or your outline for the debriefing process).	No deception will be involved.
36	Describe any testing materials and/or equipment you will use. Clearly indicate which, if any, are new and therefore might involve unforeseen risks to participants. Attach copies of all scales, survey instruments, questionnaires, interview scripts, etc.	1. AphasiaBank Repetition Test (2007) a. Word repetition b. Sentence repetition with increased length 2. Boston Naming Test, 2nd Edition, Short Form (2001) The Boston Naming Test (BNT) represents a measure of object naming from line drawings. It quantifies the severity of the word finding problem and can help the clinician determine whether and to what extent the patient can recognize the picture he/she has failed to name. 3. Verb Naming Test (VNT) Testing of verb retrieval in action naming from pictures presented to the client. 4. Western Aphasia Battery-Revised (2007) The Western Aphasia Battery WAB evaluates clinical aspects of language function/ linguistic skills, as well as reading, writing, calculation ability, and nonverbal skills.
37	Estimate, if applicable: *[b x c should = a]* (a) The total time each participant will be asked to volunteer. (b) The total number of contacts/visits for each participant. (c) The estimated time needed for each contact/visit.	(a) 1-3 hours (b) 1 (c) 1-3 hours
38	Describe past experience of the research team with the proposed research procedures and the targeted population, including a justification of how the research team includes adequate numbers of qualified staff.	Jacqueline Hinckley, Ph.D., CCC-SLP, has 20 years of professional clinical experiences, as well as research experience. She is knowledgeable in administering the above named tests and testing techniques. Stephanie Karidas has been trained (role-play) to administer these tests.
39	Provide justification that the facilities where the research is to be conducted are adequate to implement the research as approved by the IRB.	The department of Communication Sciences and Disorders (CSD) at USF offers clinical services for clients experiencing aphasia, and is therefore equipped with the necessary clinical facilities for administering and scoring tests for aphasia.
40	Describe whether additional facilities, equipment, or resources are necessary to adequately protect participants in the study.	The testing runs primarily in the clinical facilities of CSD. Participants will be asked to volunteer during normal business hours, and other faculty members will be present in case of emergencies.

	For example, is there access to counseling, educational or social services and is there a charge for that service, is there someone at school that the student call talk with if (s)he becomes upset, what is the availability of the research staff on weekends or 24/7 to answer questions or address unanticipated problems?	
Recruitment, Enrollment, Informed Consent		
41	Indicate the <u>total number of participants</u> (records, data sets, etc.) you **anticipate** enrolling in your study. *(Include drop-outs, withdrawals, etc., in that number.)* Indicate the rationale/justification for the number of participants to be enrolled (e.g., why was the number of anticipated participants chosen).	20 participants
42	Indicate the <u>age range</u> eligible for enrollment.	Youngest Age: 21 Oldest Age: 90
43	If your research involves **face-to-face visits with your participants**, indicate below the targeted/planned enrollment of the following members of ethnic and racial groups. *[Note: the IRB will expect this information to be reported with your Progress Report]*: <u>TO BE DETERMINED</u>	

Ethnic Category	**Females**	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category: Total of All Participants*			
Racial Categories			
American Indian / Alaskan Native			
Asian			
Native Hawaiian / Pacific Island			
Black or African American			
White			
Racial Categories: Total of all Participants*			

**The "Ethnic Category: Total of All Participants" must equal to the "Racial Categories: Total of all Participants"*

44	List the **<u>inclusion criteria</u>** (specify the characteristics that must be met for individuals to be enrolled in your study, e.g., physical/mental/health status, gender, occupation, diagnosis).	Participants will be individuals whose aphasia results from a stroke that can be verified through neuroimaging or a clear medical diagnosis. Co-existing apraxia and dysarthria are acceptable. Participants must be proficient in English (prior to stroke). Additional participants might include the spouses of clients.
45	List the **<u>exclusion criteria</u>** (specify the characteristics that will exclude individuals from your study, e.g., physical/mental/health status, gender, age, race, occupation, diagnosis) and justify why these persons will be excluded.	Participants with dementia or with co-morbidities associated with serious cognitive consequences will be excluded. Clients with aphasia who were not proficient in English prior to stroke will be excluded.
46	Describe any **<u>compensation</u>** (financial, stipends, etc.) or other **<u>incentives</u>** (tokens	[X] None is being offered.

	of appreciation**) <u>offered to investigators</u>**, research staff, or others for the identification, referral, recruitment, and/or enrollment of participants. (*Please Note: In the state of Florida it is unlawful for any health care provider to offer, pay, solicit, or receive remuneration for the referral of a patient. Florida Statutes: 456.054)*
47	Indicate the populations or data/materials/specimens targeted for this study - please check all that apply. [X] None of these groups apply (a) [ ] Neonates of uncertain viability [ ] Nonviable neonates [ ] Human embryo stem cells [ ] Human embryos [ ] Human fetal tissue [ ] Human fetuses
	(b) If the research targets any of the above populations, describe how and when you will obtain informed consent from both parents.
48	Indicate any of the populations below targeted for enrollment in this study. [ ] None of these groups apply [ ] Children (individuals who have not reached the legal age to consent to the treatment or procedures in this research.) [ ] Juvenile Offenders [ ] Patient Population [ ] Emergency Room Patients [ ] Prisoners [ ] Pregnant Women [ ] Decisionally Challenged [X] Elderly Persons (>65) w/potential for cognitive impairment [ ] Individuals w/potential for incarceration* ** Enrollment of prisoners requires that the IRB find that the seven conditions under federal regulations 45 CFR 46 Subpart C are met. If you plan to recruit individuals who are high risk of becoming incarcerated in a penal institution during the research (e.g., participants with substance abuse history, repeat offenders, etc.), please indicate above so that the IRB can address the Subpart C requirements at the time of initial review. If a participant becomes incarcerated during the course of the research and the IRB has not previously reviewed and approved your research for enrollment of prisoners, all research activity must immediately cease for that individual until review and application of Subpart C regulations occurs by the IRB.*
49	Indicate other populations or data/materials/specimens involved in this study - please check all that apply. [X] Normal, healthy volunteers [X] Elderly Persons (>65) not cognitively impaired [ ] Umbilical Cord Blood [ ] Placenta, placental material [ ] Persons with acute or severe mental or cognitive disabilities [ ] Persons with a likelihood to develop acute or severe mental or cognitive disabilities [ ] Individuals in a sedated, traumatized, or crisis state including those who present to the Emergency Room for treatment [ ] Persons who do not understand English fluently. Please attach a translated Informed Consent document for each language targeted. *(Note: The PI is responsible for the accuracy of translations)* [ ] Persons with social, economic, or educational disadvantages (illiterate, poor literacy, migratory populations, or illegal aliens) [ ] Existing data, specimens, biological materials (indicate whether there are identifiers or links to identifiers): [Please specify] [ ] Secondary data sets, public data sets *(indicate whether there are identifiers or links to identifiers)*: [Please specify] [ ] Medical Students *(must attach approval letter from COM Medical Student Affairs Committee)* [ ] Medical Residents *(must attach approval letter from COM Graduate Medical Education Committee*)

50	Provide the following information for each population or data/material/specimen checked in Items 47 – 49	
	a) Provide a description of how you will protect the rights and welfare of potential participants from coercion or undue influence.	Participants of the community study have been referred prior to this project in order to receive therapy at USF/CSD. Each participant will be verbally informed about the procedures of the study and its content. Each participant will additional be provided with a consent form where he/she is being asked to be a subject in this research study. Each participant will be able to take the consent form home. The therapist will then contact the participants within 2 to 3 business days. Identifiable information will not be included in the research data.
	b) Describe additional protections that will be utilized to respect individuals' rights when identifying and recruiting them into the study (e.g. respect for privacy).	The principal investigator and faculty advisor have absolved the HIPPA training and the Human Research Protection Program: Foundations in Human Subject Protections at the University of South Florida.
	c) Include your plan for initial and continuing assessment of each participant's capacity to provide informed consent. Describe how the consent process will be implemented and documented throughout the research (other than documentation on the informed consent form).	Each potential participant will be seated in a quiet, comfortable room –either a video-equipped research room or a clinic room within the PCD building on the Tampa campus of USF. The participant will be provided a written copy of the consent form. The investigator will read the consent form aloud to the potential participant in a slow, steady rate. Periodically, the examiner will ask the participant if he/she has any questions, concerns, or difficulty in understanding the preceding information. When the participant indicates understanding of the consent form, the potential participant will be asked if they agree to these conditions, and if so, to sign the consent form. All signed consent forms will be kept separate from other collected data in a secure file cabinet located in a locked lab space (PCD3017). Data will only be collected from individuals who have signed the consent form. As an additional check, participants who initially signed the consent form will be asked to indicate their agreement, again, after data have been collected. This will ensure that participants have an opportunity to re-affirm their consent once they fully understand the nature of the data that will be shared in the video data base. A final check is included in the data sharing agreement with the CHILDES Aphasia Talk Bank. A form must be signed by the investigator indicating that all participants have consented to participate and to have their audio and/or video images shared on the secure database.
	d) Include your plan for obtaining assent from adults unable to provide consent. Address whether assent will be a condition of taking part in the research. If assent is not to be obtained from these individuals, provide a rationale for not seeking participants' assent.	All individual who are potential participants in this project will be able to provide informed consent. Only individuals who have sufficient language abilities to provide informed consent are eligible to participate in the project.

	e) Describe how you will accommodate for participants disadvantaged by low literacy levels, socio-economic and cultural factors, language barriers, etc., during recruitment, informed consent, participant questions, early withdrawal and implementing the research procedures. Address how you will minimize coercion or undue influence.	Two consent forms are available, and both formats will be offered to potential participants. One format is typical narrative, checked for readability at the sixth grade level. The alternative format is in pictographic form, for those individuals with aphasia who have severe difficultly understanding written language. All communications with the participants will use supported conversation techniques, an established communication support system for facilitating comprehension and participation by adults with aphasia.
51	Describe your **recruitment procedures**. Include how you will identify potential participants. Describe the steps for recruitment of participants. Identify who will have responsibility for recruitment. Attach copies of any recruiting materials, e.g., flyers, brochures, advertisements.	Potential participants are clients that are attending therapy at USF/CSD. In addition, their spouse might be asked to participate as well. Potential participants are asked to be a subject in our project. Content of the consent form will be verbally explained to the participant by the investigators. Thereupon, consent forms will be handed out.
52	Describe how these recruitment procedures have been constructed to ensure that potential individuals' **privacy is not breached** during identification and recruitment (e.g., agency initiates contact w/potential participant).	Every participant will be informed verbally and in their consent from that identifiable information is excluded from the research data. Each participant will be given 2 to 3 business days in order to make his/ her decision.
53	Please describe how the individual being recruited will be provided ample time to consider whether or not they choose to participate in the study.	The participant will be contacted by one of the investigators after 2 to 3 business days. If the participant has not been able to make a decision during that time, he/ she will be given additional time.
54	Describe the **compensation** that will be offered to participants for their time in the study and the schedule for payment of this compensation. Address how payment will be disbursed, including for participants who may choose to withdraw from the study. *Payment cannot be based on completing the study but rather should be paid in full or pro-rated on the time volunteered.*	Each participant will be able to receive their test scores to be personal kept as part of their personal medical record.
55	Describe any **costs participants will incur** because of participation (e.g., travel costs, parking fees, purchase of special materials, etc.) and explain, if applicable, how those costs will be reimbursed.	No costs except for personal transportation costs to the USF Tampa campus.
The following items require you describe the informed consent process to allow the IRB to adequately assess the information being provided and the process that will occur during the study. ***Written informed consent is required if the participants can be identified, even in minimal risk studies.*** *Certain populations may be vulnerable to coercion or unable to give valid informed consent.* ***Additional safeguards*** *must be included, as appropriate, e.g., participant assent with consent obtained from a legally authorized representative, parental permission, consent from both the participant and a care-giver or family member, independent monitors, waiting periods, or continuing assessment of capacity to give valid consent.*		
Questions 56 – 60 ask about the use of vulnerable populations or individuals with limited autonomy. Read through the questions and if you are not planning to enroll any of these populations, skip to Question 61. [ ] Will not be utilizing a vulnerable population		
56	If using vulnerable populations, describe	Verbal and written information will be delivered in simple

	how you will accommodate for participants who are disadvantaged by low literacy levels, socio-economic and cultural factors, language barriers, etc. during recruitment, informed consent, participant questions, and implementing the research. .	language. The investigator will read the consent form aloud. Written and verbal information will be given periodically, which will maximize the informational input for the participant.
57	If using a vulnerable population with diminishing cognitive capacity, include your plan for initial and continuing assessment of each participant's capacity to give informed consent.	The interview procedure will be explained verbally. Two consent forms will be handed out: One written/ orthographic form, and one pictographic form.
58	For any populations who might be <u>specially vulnerable to coercion or undue influence or have reduced capacity</u> to consent, please describe:	
	a) Additional protections that will be utilized to respect these individuals' rights, given the potential for limited autonomy. Also include under what circumstances and how you will obtain consent from a legally authorized representative *(in the State of Florida, will be a health surrogate or a proxy).*	Consent forms will only be handed out to participants that are mentally capable of understanding its content. Participants unable to provide consent are not eligible for this study.
	b) Your plan for initial and continuing assessment of each participant's capacity to provide informed consent.	
	c) Your plan for obtaining assent from adults unable to consent. Indicate whether assent of the participant will be a condition of enrollment.	A consent from each client is obligatory in order to participate in this study. If the client is unable to consent, his/her legal authorized person will be included to provide assent for that person.
	d) What additional procedures will be used to ensure participants understand the consent process and are participating voluntarily.	The participant will be asked before the interview if he has understood the reason, procedure, and content of this study, and if he/she is still willing to participate.
59	Indicate how you will verify that a person giving consent for a potential participant has that authority (i.e., can serve as the legally authorized representative).	Prospective participants will be asked if he/ she have a legally authorized representative in order to fill out the consent form.
60	For participants who <u>do not understand English fluently</u>, address what additional procedures will be implemented during recruitment, the informed consent process, and the research procedures to overcome any language barriers. Please attach translated Informed Consent documents for each language. The PI will be responsible for ensuring the accuracy of each translation.	Participants, not fluent in English (prior the stroke), will not be part of this project.

***You may be asked to submit an electronic copy of the informed consent document(s). You may be contacted by an IRB Compliance Administrator once this study has been received and processed.**

An investigator can request either a waiver of documentation of consent or waiver of the consent process for studies that involve no greater than minimal risk. However, waivers can only be granted when they meet certain federally mandated criteria and when obtaining or documenting consent would be impractical or would increase risks for the participants. In cases where documentation of informed consent is waived, the IRB may still require that the participant be provided a written statement explaining the study. Please note: for FDA regulated research, parental consent cannot be waived.

61	Will full written and signed informed consent be obtained from all participants?	[X] Yes. Attach **2** copies of the consent documents, including any translated consent documents, and skip to question 62 [ ] No. Skip to (a) or (b), as applicable
	a) Are you requesting a waiver of the consent process?	[ ] Yes. Complete and submit Addendum 2. [X] No.
	b) Are you requesting a waiver of documentation of consent?	[ ] Yes. Complete and submit Addendum 2. [X] No.
62	Describe the informed consent process, not only at the beginning of the study, but the efforts that will be made throughout the study to ensure the participant understands and wants to continue the research procedures.	The client will be informed before each session what he/she will be administered for. The investigators will also explain the procedures and why they are included in this project.
63	Describe the steps that will be taken to discuss the research study in terms that are understandable to the participant.	
64	From whom will consent be obtained?	[X] Participant [ ] Parental Permission [ ] Health Surrogate/Proxy [ ] Child
65	Who will be authorized to provide research information to this individual?	Jacqueline Hinckley, Ph.D., CCC-SLP Stephanie Karidas
66	For individuals authorized to obtain informed consent, provide a description of the training the individual has received that qualify him/her for this responsibility.	Both investigators have completed the IRB-training and practiced role-play in session.
67	After information about the research has been provided to the individual, describe how sufficient opportunity will be provided to the individual for consideration of whether to take part in the research	Participants will be re-contacted in 2 to 3 business days. If individuals need more time in order to make their decision, the investigators will contact them again.

Questions 68-75 deal with the enrollment of children. The DHHS provides this definition: "*Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402(a) and 21 CFR 50.3(o)]

If your research does not include children, indicate here that children are not involved and go to Question 76

[X] My research does not involve children.

Parental permission/consent must be obtained in order to enroll a child (an individual who has not reached the legal age to consent to the treatments or procedures in research) in this research, unless explicitly waived by the board. To enroll children who are under guardianship, the PI must obtain documentation from the guardian that demonstrates the person is authorized to consent on behalf of the child to general medical care [45 CFR 46.402(e)]. USF Policy 306 and Policy 603 set forth the requirements for "Assent" from the child.

- **Written documentation of that assent (a separate assent form) is required for children 12 or older.**
- **Children 7 to 11 should be given the opportunity to verbally assent and their agreement should be noted**

in the research record.

- **For children under the age of 7 the investigator should inform the IRB what information, if any, will be given to the child and whether that will be noted in the research record.**

***Permission from both parents (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child) is required to enroll children in research in all cases. However, unless one of the following is true, the IRB may determine that the permission of one parent is sufficient even when the other parent is alive, known, competent, reasonably available, and share legal responsibility for the care and custody of the child":**

- **The research does not present direct benefit to the child, but is likely to yield generalizable knowledge about the participant's disorder or condition.**
- **The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.**

68	If children (individuals who have not reached the legal age to consent to the treatment or procedures in this research) are to be enrolled in the study, please attach **2 copies** of the parental permission form and **2 copies** of the child assent form (templates are available at www.research.usf.edu/cs/).	[ ] Parental Permission and Assent documents are attached [ ] I am requesting a waiver of parental permission. Complete Addendum 2 - Waiver or Alteration of Informed Consent and submit with this application. ***Please note: for FDA regulated research, parental consent cannot be waived.*** [ ] I am requesting a waiver of documented assent. Complete **Addendum 2** - Waiver or Alteration of Informed Consent and submit with this application
69	If children are to be enrolled in the study and this study involves greater than minimal risk please indicate which of the following is true (only one can be chosen) and provide justification for your decision.	[ ] The research presents the potential for direct benefit to the child [ ] The research does not present direct benefit to the child but is likely to yield generalizable knowledge about the child's disorder or condition [ ] The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children..
70	Unless the IRB determines that the permission of one parent is sufficient (even when the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child), permission from both parents is required to enroll children in the research unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. **Describe the procedures that will be followed to obtain permission from both parents.**	**[Description of parental consent process]**
71	Will assent be obtained from:	[ ] All children [ ] Some children [ ] None of the children
72	If assent will be obtained from some children, which children will be asked for assent?	N/A

73	If assent will be obtained from some or none of the children, provide the rationale.	
74	If assent will be obtained from some or all of the children, attach a transcript of what will be said during the assent process and indicate how assent will be documented.	[ ] Transcript attached Assent will be documented by
75	If the child does not live with his/her parents, how will you determine that the person with whom the child does live, has authority to provide consent for participation in research? *(Note: Guardians are defined as individuals who are not parents but have authority to provide consent on behalf of the child to general medical care. **However**, in the State of Florida specific authority must be given to the Guardian before he/she can consent for the ward to participate in research [See Policy 306])*	Describe how you will determine that the person has the authority to provide consent for the child's participation.
Anticipated Risks and Benefits		
DHHS [45 CFR 46.102(i)] and FDA [21 CFR 50.3(k)] define minimal risk as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."		
76	Provide a description of the risks associated with the research.	The only potential risk is fatigue. The likelihood of any psychological distress is extremely small since these are routine tabletop activities, however there is an unlikely possibility that a participant could become overly frustrated or distressed.
77	Based on the definition above, indicate the level of risk to participants. Please check the appropriate box (**check only one** from a, b, c, or d) and provide the information requested:	
	[X] **a. Minimal risk** to participants. Please briefly explain why you believe this is a minimal risk study	The magnitude and probability of harms or discomfort anticipated in this research are no greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Participants might experience fatigue and psychological stress due to the testing situation.
	[ ] **b. Greater than minimal risk** and the study **presents the prospect of direct benefit** to the participant. Please briefly explain why you believe this study holds the prospect of direct benefit to the participant.	
	[ ] **c. Greater than minimal risk** and the study presents **no prospect of direct benefit** to the participant, but will likely **yield generalizable knowledge** about the study topic. Briefly explain why you believe this research will contribute to the body of knowledge about this topic.	

	[ ] **d. Greater than minimal risk** and the study would otherwise be unapprovable, but presents an **opportunity to understand, prevent, or alleviate a serious problem** affecting people's health or welfare. Briefly explain why you believe this research will promote a better understanding, will help prevent, or otherwise alleviate this serious problem.	
78	Provide a description of the potential benefits of participation in this study	Participants will be offered the results of their testing in order to share these data with other rehabilitation centers/ institutions.
	a) Describe the measures that will be used to determine that the potential benefits of participation outweigh the known and potential risks.	The potential risk is no greater than the risk of any typical or table top testing situation. The benefits to the participant are small but potentially highly useful, as results may inform the participant's therapy program or the rehabilitation service.
	b) For individual participants, describe the measure(s) that will be used to decide when a participant should be withdrawn from the study (that is, the study no longer provides the prospect of a potential benefit or the benefits are outweighed by the risks).	A participant will be withdrawn from this single-session study if he/she shows undue fatigue on psychological distress during the one-time, 1-3 hours appointment.
	c) For the study, describe the measures that will be used to determine that the safety of the study is outweighed by the risks to participants. Indicate at what point the study would be considered unsafe to continue.	If 20% or more (at least 2 participants in the first 10 consecutive participants) show acute signs of fatigue or distress during their appointment, the study will be disconfirmed and the testing procedure re-examined and analyzed.
Data Safety and Monitoring		
For research involving greater than minimal risk, a plan to monitor the data for the safety of participants is required. This plan is not intended to address reporting of adverse events / unanticipated events but rather how you plan to monitor those events and the outcome measures that will be used to ensure that participants are not being subjected to risks that outweigh the benefits or that the events are not of a greater severity or frequency than was originally recognized.		
79	Does this study involve greater than minimal risk or harm to participants?	[X] No. Provide an answer to 79a. [ ] Yes. Please complete **Addendum 3** – Data and Safety Monitoring and attach. If the human research is funded and the sponsor has a formal data and safety monitoring plan, please include that with your submission.
	a) Every research project should include a plan for monitoring the integrity of the data. Describe your plan for ensuring the integrity of the data you collect. Include how often you plan to monitor the data.	The data will monitor every five enrolled participants. The investigator will ensure protocol compliance including IRB procedures and documentation.
Privacy, Confidentiality, and HIPAA Compliance		
PLEASE NOTE: Principal Investigators are required to maintain all IRB related research records, including original documentation of informed consent and research authorization (if using PHI), for a minimum of six years after the final IRB approval period has expired.		

80	Will you use, receive, and/or disclose protected health information (PHI) in the course of conducting this research? *If you are not sure whether your research involves PHI, please refer to the "Decision Tree for HIPAA in Research" and/or the Information Guide, "Does HIPAA Apply to Social/Behavioral Research?" available at http://www.research.usf.edu/cs/hipaa.htmF or questions regarding HIPAA, please contact Vinita Witanachchi, J.D., USF DRIC Privacy Officer at (813) 974-5478.*	[ ] No. Please proceed to next question. [X] Yes. Complete **Addendum 5** – Use, Disclosure, or Receipt of PHI and submit with this Application.
81	Please describe: a) the steps that will be taken to protect the privacy of participants during the conduct of the research.	(a) Identifiable information will not be included in the data.
	b) how the data (including informed consent documents) will be kept confidential during **collection**, **analysis**, **and storage. Address both physical and electronic records.**	(b) Code numbers will be assigned and used on all materials. signed IRB forms will be kept in a separate file from all coded materials (including videos).
	c) the format of the data that will be recorded, how and where it will be stored; how long it will be kept (note 3-year policy above), and how it will be destroyed at the end of the 3-year period.	(c) The video data will be kept on DVDs in files with coded protocols so that electronic video information can not be assigned otherwise. The electronic videos and test scores will be uploaded to the Aphasia TalkBank database. At the end of three years the DVDs and paper material will be shredded/ destroyed.
82	Do you plan to share the confidential data with anyone other than members of your research group?	[ ] No. [X] Yes. Please describe who you will share the confidential data with and under what circumstances this will occur. Explain how participants will be informed that this data will be shared: Only members of the Aphasia TalkBank will have access through a password-protected system. Participants are told of this through the informed consent process. Data will be kept in a separate file from all coded material (including videos).
83	Will the participants be providing private, identifiable information about individuals other than themselves (e.g., family, friends)?	[X] No. [ ] Yes. Please describe who these other individuals are and how the privacy or confidentiality of these individuals will be protected (in some instances, it may be necessary to obtain informed consent from such individuals): [Please specify]

Disclosure of Investigator Interests

The USF *Policies and Procedures Manual* states that "any University employee who is responsible for the design, conduct, or reporting of a sponsored research project which is conducted under the auspices of the University must disclose financial or other interests that are, or may be perceived to be, related to the project." However, **the IRB is required to consider all real or potential conflicts of interest, regardless of funding, type of conflict, or level of financial conflict**.

Significant financial or other interests, as defined in USF's Policies and Procedures Manual, may include (but are not limited to) the following:

1. *Income (e.g., salary, fees, honoraria, reimbursements, dividends, or other payments or considerations) for the investigator and the investigator's spouse and dependent children;*
2. *Equity interests (e.g., stock, stock options, or other ownership interests) exceeding for the investigator and the*

investigator's spouse and dependent children; *3. A position (e.g., director, officer, partner, trustee, or member of the board of directors); and/or* *4. Intellectual property rights (e.g., patents, copyrights, or royalties) of the investigator and the investigator's spouse and dependent children.*		
84	Do you, your spouse or dependent children, or any of the study personnel (and/or their families) have financial or other interests related to this project or may be perceived to be related to this project?	[X] No. Please proceed to the next section. [ ] Yes. Describe the real or perceived conflict. If the conflict involves financial or other interests (listed above), complete **Addendum 4 – Disclosure of Investigator, Key Personnel (or their Immediate Family) Conflicting Interests**
All potential financial conflicts of interest must be reviewed by USF's HSC Conflict of Interest Committee (HSC COIC) or your institution's conflict of interest review committee. A Conflict of Interest Management Plan and documentation that the plan has been approved by the COIC or your institutions' COI Committee must accompany this application. Please attach a copy of the approved management plan. IRB approval cannot be granted until a management plan has received review and approval by such a COI committee.		

85. Other Key Personnel NEW!

Please list all personnel in the table below (omit the PI & Co-Investigator listed in Items 1 & 8). Make as many copies of the table as needed. "Key personnel" are those individuals who have contact with participants or participants' private, identifiable information for research purposes.

***Retain** this completed **original form** in the Investigator's file. **Submit a copy** of this form with this application. When personnel are added or deleted, hand write in changes. These changes can be submitted to the IRB with your Progress Report. However, if your research is VA- regulated, signatures of each person listed must be submitted and changes must be presented to the IRB and R&D Office as a Modification Request*

Title of Study:

Personnel certify the following by signing this document:

a. I acknowledge my responsibilities in the conduct of this research study and have received adequate training to fulfill those responsibilities.
b. I agree to follow the procedures for the conduct of this study as described in the IRB approved application.
c. I agree to uphold the rights and welfare of all study participants.

Name	Degree, license, and/or certification	Employee or Student # (or first 3 ltrs of last name and mm/dd of birthdate	Responsibilities (Scope of Work) – select all that apply from list below	Date began service on this study	Date left service on this study	Date USF IRB Education requirements	% of work time available dedicated to this research (for VA purposes)	Signature

Responsibilities (Scope of Work):

a. Screens potential participants	e. Data management	i. Addresses Regulatory issues	m. Enters patient data into CPRS
b. Obtains Informed Consent	f. Collects specimens	j. Communicates with IRB	n. Educates participants, families, or staff
c. Conducts physical exams	g. Dispenses medications	k. Administers IV Meds	o. Other: List other applicable duties
d. Enters data on CRF	h. Administers P.O. medications	l. Prepares Study initiation activities	

***All personnel authorized to obtain informed consent must provide a copy of their CV**.

PRINCIPAL INVESTIGATOR'S STATEMENT OF ASSURANCE

This application, which describes my proposed investigation involving human participants, was prepared in accordance with the policies of University of South Florida (USF) and its affiliates for the protection of humans participating in research. I certify that I have read and will conduct this study in accordance with the terms of Ethical Principles set forth in the Belmont Report. and the USF IRB Policies and Procedures.

I understand USF's policies concerning research involving human participants and I agree to:

a. Obtain the voluntary informed consent of participants (or of participants' legally authorized representatives), in a language that is understandable to them, to the extent required by federal regulations and by the determinations of the IRB.
b. Report promptly to the IRB any problem that requires reporting (See "List of Problems that Require Prompt Reporting to the IRB") and submit an Information Report within the appropriate reporting period.
c. Cooperate with the IRB in the timely continuing review of this project (submit IRB progress reports in a manner consistent with USF policies).
d. Will not initiate any change in the approved research or consent(s) document(s) without prior IRB approval, except where necessary to eliminate apparent immediate hazards to participants. I will report this change to IRB within two (2) business days to enable the IRB to determine that the change was consistent with ensuring the participants' continued welfare and safety.
e. Maintain informed consent documents and progress reports as required by institutional and federal policies (for more information, see the Research Integrity and Compliance Web Site at www.research.usf.edu/cs/).
f. Accept responsibility for the conduct and supervision of this research and protect human participants as required by state and federal law and regulation, and as documented in all applicable Federalwide Assurances.
g. Ensure that research staff and students have been trained and are qualified to conduct this research and to protect human participants. I agree to provide supervision to research staff and students that will ensure the protection of human participants. I will keep records that prove that these requirements have been met.
h. Allow site visits for evaluation and monitoring by the FDA, the DHHS, the USF Division of Research Integrity and Compliance, and the USF IRBs.

With my signature below, I attest to conduct the research in accordance with the ethical principles of the Belmont Report, the requirements of the federal regulations, and the policies of the University of South Florida. I further attest I have read and understand HRPP Policy 701 regarding additional responsibility of investigators.

_____ _____

Signature of Principal Investigator **Date**

_____ _____

Signature of Co- Investigator or Faculty Advisor **Date**

SCIENTIFIC AND SCHOLARLY REVIEW

Principal Investigator: Stephanie Karidas

Study Title: Aphasia Talk Bank

Scientific or scholarly review must be conducted following the guidelines of the Principal Investigator's department or centrally by an affiliate's research administration branch. The Scientific / Scholarly Review must be someone other than the PI or Co-Investigator/Faculty Advisor

With my signature, I certify that:

- **the IRB application and study protocol have been reviewed for scientific or scholarly merit;**
- **the research design is appropriate to answer the research question;**
- **the sample size is statistically appropriate to answer the research question;**
- **the data collection and analysis methods are appropriate to answer the research question;**
- **there are adequate data and safety monitoring measures to protect participants; and**
- **the information provided meets the mission of the department / affiliate and is designed to meet departmental/affiliate professional standards.**

The following concerns were raised during the scientific and scholarly review of this proposed research:

_____

_____

_____

_____

_____ _____

Signature of Scientific or Scholarly Reviewer **Date**

Print or Type Name: _____

Department/Affiliate: _____ /
_____

DEPARTMENT CHAIRPERSON'S SIGNATURE

Principal Investigator: [Principal Investigator Name]

Faculty Advisor (if student research): [Faculty Advisor's Name]

I certify that this study application and protocol have been reviewed and meet departmental standards.

I certify that there are adequate resources, including space and support personnel, available to the Principal Investigator to conduct this study in the manner proposed and that this Principal Investigator has the appropriate expertise and/or experience to conduct this research or, if the research is being conducted by a USF Student, he/she will be provided the appropriate mentoring and oversight from a USF Faculty member.

_____ _____

Signature of Department Chairperson **Date**

Print or Type Name: _____

Print or Type Department: _____