The Michigan Stroke Transitions Trial (MISTT): Improving Care Transitions for Acute Stroke Patients Through a Patient-centered Home Based Case Management Program

NCT02653170

August 19, 2016

MICHIGAN STATE UNIVERSITY

Initial IRB Application Approval

October 12, 2015

To: Mathew Reeves
East Lansing, MI 48824

Re: **IRB#** 15-992M Category: EXPEDITED 5, 7
Approval Date: October 12, 2015
Expiration Date: October 11, 2016

Title: Michigan Stroke Transitions Trial (MISTT) Study [CGA#135457]

The Institutional Review Board has completed their review of your project. I am pleased to advise you that **your project has been approved**.

This protocol falls under the Reliance agreement between MSU and Sparrow Hospital. YOU MAY NOT BEGIN THIS PROJECT AT SPARROW UNTIL YOU RECEIVE AN ACCEPTANCE LETTER FROM THE SPARROW IRRC.

This protocol falls under the Reliance agreement between MSU and McLaren Healthcare System. This study will be conducted at the following McLaren sites: McLaren Greater Lansing.

This study is also conducted at University of Michigan Hospital and St. Joseph Mercy Hospital, Ann Arbor. These sites conducted separate IRB review.

The review level of this project has been changed from Full Review to Expedited categories 5 and 7. Please submit a revision to add the social workers as additional personnel to this project when they are hired.

The committee has found that your research project is appropriate in design, protects the rights and welfare of human subjects, and meets the requirements of MSU's Federal Wide Assurance and the Federal Guidelines (45 CFR 46 and 21 CFR Part 50). The protection of human subjects in research is a partnership between the IRB and the investigators. We look forward to working with you as we both fulfill our responsibilities.

Renewals: IRB approval is valid until the expiration date listed above. If you are continuing your project, you must submit an ***Application for Renewal*** application at least one month before expiration. If the project is completed, please submit an ***Application for Permanent Closure***.

Revisions: The IRB must review any changes in the project, prior to initiation of the change. Please submit an ***Application for Revision*** to have your changes reviewed. If changes are made at the time of renewal, please include an ***Application for Revision*** with the renewal application.

Problems: If issues should arise during the conduct of the research, such as unanticipated problems, adverse events, or any problem that may increase the risk to the human subjects, notify the IRB office promptly. Forms are available to report these issues.

Please use the IRB number listed above on any forms submitted which relate to this project, or on any correspondence with the IRB office.

Sincerely,

Ashir Kumar

Ashir Kumar, M.D.
BIRB Chair

c: Michele Fritz, Anne Hughes, Amanda Woodward, Paul Freddolino, Constantinos Coursaris

Office of Regulatory Affairs
Human Research Protection Programs

Biomedical & Health Institutional Review Board (BIRB)

Community Research Institutional Review Board (CRIRB)

Social Science Behavioral/Education Institutional Review Board (SIRB)

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APPLICATION FOR INITIAL REVIEW

APPROVAL OF A PROJECT INVOLVING HUMAN SUBJECTS

Biomedical, Health Sciences Institutional Review Board (BIRB)
Social Science, Behavioral, Education Institutional Review Board (SIRB)
207 Olds Hall, Michigan State University
East Lansing, MI 48824-1047
Phone: (517) 355-2180
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Office Hours: M-F (8:00 A.M.-5:00 P.M.)

IRB#: 15-992M
ID# i049657

1a.	**Responsible Project Investigator:** Name: **Mathew Reeves** ID#: Department: **EPIDEMIOLOGY** College: **HUMAN MED** Academic Rank: **Associate Professor** Mailing Address: **East Lansing, MI 48824** Phone: Fax: Email: **ReevesM@msu.edu**
1b.	**Secondary Investigator:** Name: **Michele Fritz** ID#: Department: **EPIDEMIOLOGY & BIOSTATISTICS** College: **HUMAN MEDICINE** Academic Rank: **Research Assistant** Mailing Address: Phone: Fax: Email: **fritzmi2@msu.edu**
1c.	**Additional Investigators and Key Personnel:** Anne Hughes Amanda Woodward

	Paul Freddolino Constantinos Coursaris **Other Personnel:**
1d.	**Person Preparing Document:** Mathew Reeves
2.	**Study Coordinator:** Name: **Michele Fritz** ID#: Department: **EPIDEMIOLOGY & BIOSTATISTICS** College: **HUMAN MEDICINE** Academic Rank: **Research Assistant** Mailing Address: Phone: Fax: Email: **fritzmi2@msu.edu**
3.	**Title of Project:** Michigan Stroke Transitions Trial (MISTT) Study
4.	**Have you ever received a 45 CFR 46.118 designation for this project?** NO
5.	**Category of Review** FULL REVIEW **(a) Subcategory:** ☐ 1. Clinical studies of drugs and medical devices when neither an IND or IDE is required. ☐ 2. Collection of blood samples from healthy, non-pregnant adults or other adults. ☐ 3. Prospective collection of biological specimens for research purposes by noninvasive means. ☐ 4. Collection of data through noninvasive procedures routinely employed in clinical practice.

	☐ 5. Research involving materials that have been collected, or will be collected for nonresearch purposes. ☐ 6. Collection of data from voice, video, digital, or image recordings made for research purposes. ☐ 7. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, or quality assurance methodologies. **(b) Please describe why your project is minimal risk.**	
6.	**Is this project being conducted to fulfill the requirements of an education/training program?**	Project Is Not Primarily An Education/Training Activity
7a.	**Funding:** **(1) Select appropriate funding source(s). Multiple funding sources may be selected. If a funding source is selected, list the name(s) of the funding source(s) and the CGA number.**	YES

	Funding Source Type	If funding source is selected, list the name(s) of the funding source	OSP/CGA Number
YES	**U.S. Federal Government (e.g. Department, Agency)**	Patient Centered Outcomes Research Institute (PCORI)	IHS-1310-07420 Transitions Trial (MISTT) Study
	U.S. State Government (e.g. Department, Agency)		
	Foreign Government		
	Industry Sponsored		
	Foundation or Non-Profit		
	Internal Funds (e.g. MSU department)		

(2) Are any of the funding sources pending?

NO

(i) Describe pending funding source(s):

(ii) If the project is not funded will you do the research?

7b.	**The protection of human subjects often requires resources be dedicated for things such as the consent process (space, personnel), the performance of the research (trained personnel**

	interacting with subjects, time, access to subjects, access to facilities) care of subject issues or injuries (counseling, medical care), confidentiality of data (space, equipment) and other monetary and non-monetary resources. Describe the resources that are available for this project for the protection of human subjects. The MISTT investigators understand that the protection of human subjects is absolutely essential to the successful implementation of the project. All study personnel involved in patient screening, consent, and enrollment, delivery of study interventions and collection of study data will be fully trained in all IRB relevant procedures and mechanisms. This includes trainings and certificates provided by the specific university or hospital IRBs, as well as study specific trainings and materials provided by the MISTT study investigators. All MISTT study personnel are employed either full time or part time by the study and thus these trainings are directly funded by the grant. Maintenance of human subjects protection during the course of the study is the responsibility of each study personnel who is directly funded by the MISTT study. Non-monetary resources used to ensure human subjects protection include secure computers and data servers, secure (lockable) office space and storage facilities which are provided by the Department of Epidemiology and Biostatistics, The School of Social Work and at the study sites (hospitals).	
8a.	**List all sites where this research will be conducted.** Patients will be recruited from 4 study sites: Sparrow Hospital, Lansing; McLaren Greater Lansing Hospital, Lansing; University of Michigan Hospital, Ann Arbor; and St. Joseph Mercy Hospital, Ann Arbor. This current application seeks approval to begin the study at the two Lansing area hospitals both of whom have reliance agreements with MSU. Once IRB approval has been obtained from the two Ann Arbor area hospitals these will be added to this application as a revision.	
8b.	**Do any of these sites have their own IRB?**	YES
8c.	**Will employees or agents of non-MSU organizations (e.g. schools, companies, hospitals) be involved in the research?** **(1) Explain how the employees or agents will be involved (e.g. will they perform research procedures, will they obtain informed consent from subjects).** Employees at each of the 4 hospital will be employed by the MISTT study to complete all patient screening, consent and enrollment, and collection of baseline study data	YES
8d.	**Will MSU units (e.g. Department of Radiology, Biomedical Research Informatics Core (BRIC), Department of Psychology) outside the control or supervision of the investigator be involved in the conduct of the research?** **(1) Identify the units.** Biomedical Research Informatics Core (BRIC) will be used to develop and maintain a REDCap database. LEARN Dat will develop and maintain a study website.	YES
8e.	**Are any of these sites international?**	NO
8f.	**Please indicate if you or your research team will be collaborating with any of the following organizations for this research project.** ☐ Allegiance Health ☐ Borgess ☐ Bronson ☐ Covenant HealthCare System ☐ Genesys Health System ☐ Hurley Medical Center ☐ Marquette General Health System	

	☑ McLaren Health Care ☐ Memorial Healthcare ☐ Mercy Health Saint Mary's ☐ Michigan Department of Health and Human Services ☐ Michigan Public Health Institute ☐ Munson Medical Center ☐ Pine Rest Christian Mental Health Services ☑ Sparrow Health Systems ☐ Spectrum Health System ☐ Van Andel Research Institute ☐ None	
9.	**Do you have any related project that were approved by an MSU IRB?** **(a) IRB Numbers:** 14-1112M	YES
10.	**Have you or will you submit this to any non-MSU IRBs?** **(a) Name of instititution(s):** University of Michigan Medical School IRB (IRBMED), and St. Joseph Mercy Health System IRB. **(b) Category of review submitted:** Full review **(c) Status of review (approved, not approved, pending):** Pending. Once approval has been obtained from these 2 hospitals we will add these sites to this current application as a revision.	YES
11.	**Is another institution(s) relying on MSU's IRB as the IRB of record?** **(a) Name of institution(s):** Sparrow Hospital, McLaren Greater Lansing Hospital.	YES
12.	**Are you using an FDA approved drug/device/diagnostic test?**	NO
13.	**Does this project involve the use of biological products, color additives, food additives, human drugs, medical devices, foods, infant formulas, dietary supplements, or nutritional supplements?**	NO
14.	**Has this protocol been submitted to the FDA or are there plans to submit it to the FDA?**	NO
15a.	**Does this project involve the use of materials of human origin (e.g. human blood, tissue, or cell lines)?**	NO
15b.	**Will there be any use of radioactive materials and/or use of radiation producing machines?**	NO
15c.	**Will this project involve human embryos?**	NO
15d.	**Has or will this study be registered with clinicaltrials.gov?**	YES
15e.	**Have you or will you be contractually obligated or otherwise obligated to comply with the E6 International Conference on Harmonisation - Good Clinical Practice Guidelines?**	NO
15f.	**Are you going to utilize any equipment from MSU Radiology (e.g. MRI, CT, PET)?**	NO

15g.	**Does your research study include any patient care services or items (e.g. clinic visits, EKGs, EEGs, blood draws, procedures, radiology, labs, etc.)? These events are typically associated with a CPT and/or HCPCS code.**	NO

16. Research Category

Education Research	☐ Yes	Gene Transfer Research	☐ Yes	Clinical Trial Type	
Survey/Interview	☑ Yes	Fetal Research	☐ Yes	☐ Surgical	
Audio/Video Recording	☐ Yes	Medical Records	☑ Yes	☐ Therapeutic	
Oral History	☐ Yes	Stem Cell Research	☐ Yes	☐ Prevention	
Internet-based	☐ Yes	Medical Imaging	☐ Yes	☐ Other	
Analysis of Existing Data	☐ Yes	Oncology	☐ Yes	☑ Investigator Initiated	
International Research	☐ Yes	Clinical Research	☑ Yes	Clinical Trial Phase	
		Other	☐ Yes	☐ Phase I	
				☐ Phase II	
				☑ Phase III	
				☐ Phase IV	

17. Project Description (Abstract)

Patients and caregivers often struggle to adjust to life after they leave the hospital following a stroke. Poor transitions in stroke patients can result in hospital readmissions, slow recovery, poor quality of life, dissatisfaction with care, and caregiver stress. Social workers play a vital role in healthcare by advocating for clients, providing counseling, and coordinating services. The Michigan Stroke Transitions Trial (MISTT) will implement a Social Work Case Management (SWCM) program, which through a combination of home visits and follow-up phone calls, will result in a personalized case management program designed to address unmet needs, increase patient engagement, decrease stress and improve quality of life. Access to accurate medical information during the transition period is also critical to patients and caregivers. The ideal information resource needs to be reliable, accessible, and responsive to the patient's changing needs. Therefore a second component to the MISTT study is the development of a study website that will serve as an information and support resource for patients and caregivers. The MISTT study will test the efficacy of these two complementary interventions in 480 acute stroke patients discharged from 4 Michigan hospitals. Patients will be randomly assigned to one of 3 groups: 1) usual care, 2) the SWCM program, or 3) the SWCM program plus the MISTT Study website. The intervention period will last 2 months and outcomes data (including quality of life) will be measured after 90-days.

18. Procedures

Baseline Clinical Data: For all subjects enrolled in the MISTT study, clinical data will be abstracted from the medical charts by the study coordinators at each hospital. Specific data elements are listed in Appendix 2a (Hospital baseline data) and will include demographic variables (age, race, sex, insurance status, pre-stroke residence), past medical history, comorbidities, pre-stroke function (mRS), and clinical stroke data (stroke type, stroke severity, tPA treatment, in-hospital complications, discharge mRS). All of these variables are collected as part of usual hospital care.
Baseline Patient-Reported data: Additional background data will be collected from all trial subjects at the first follow-up phone interview conducted at 7 days following discharge back to home. These variables include education level, marital status, family structure, in-home versus outside caregiver, patient function (dependence in activities of daily living [ADL] and instrumental activities of daily living [IADL]), CTM-15 (Care transition measures), Morisky scale (medication adherence), and technology related measures (Computer Self-efficacy, Attitudes to Technology, and Technology Utilization). These data elements are listed in Appendix 2b (Baseline Patient-reported data).

	Intervention-related Process data: Data relevant to the SW case management intervention will be collected by the SWs during the home visits and telephone follow-up calls. These data include the patient's bio-psycho-social assessment, details of the personalized case management treatment plan, progress toward goals, and details of any referrals made. These data elements are listed in Appendix 2c (Intervention-related process data). For those subjects who are given access to the MISTT Study website, data will be collected through Google Analytics concerning patient and caregiver use of the website. Data will include how often users log in, what pages they go to, how long they spend on those pages, the type of technology they use including type of browser, operating system, and use of mobile technology. Outcome data: Outcomes data will be collected on all enrolled trial subjects (patients and caregivers) by telephone interviews conducted at 7-days and 90-days after the patient returns home. Patient related data elements are listed in Appendix 2d (Patient Outcomes), caregiver specific outcomes are listed in Appendix 2e (Caregiver Outcomes). The final choice of outcome measures will be decided upon by the research team after pilot testing of the candidate measures is completed. The following list includes the universe of candidate measures we are considering: 1) END Outcomes (Collected at 90-days): NIH PROMIS quality of life instruments including PROMIS Global QOL (Q10), and PROMIS self-efficacy (social interaction, medications, emotions and daily activities). NeuroQOL quality of life instruments including depression, anxiety, and satisfaction with social roles and activities, patient activation measure (PAM), hospital and ED visits since discharge, stroke recurrence, and 90-day home time (number of days at home during 90-day period). 2) Mediating Outcomes (Collected at 90-days): NIH PROMIS support measures including informational, instrumental, and emotional support. Dyad relationship scale, stroke knowledge test, stroke action test. 3) Effect modifier variables (collected at baseline, 7-days and/or 90-days): Demographics, stroke severity/stroke type, disability measures (mRS, Barthel Index (BI), ADL, IADL, cognitive function, social and living arrangements. CTM-15, technology use (Computer Self-efficacy, Attitudes to Technology, and Technology Utilization), medication adherence measures (Morisky scale), NeuroQOL quality of life instruments including communication, positive affect and well-being, emotional and behavioral dyscontrol. 4) Caregiver Specific Outcomes (collected at 7days and 90-days): Caregiver Strain index, Preparedness for Caregiving, mood, stroke knowledge, satisfaction, and function/disability (ADLs and IADLs). For enrolled patient-caregiver dyads we will also collect information from both parties on the Dyadic Relationship Scale, patient ADLs/IADLs, patient quality of life, patient depressive symptoms, and patient social support. All baseline, process, and outcomes data will be entered into the Study's REDCap database. The management and protection of REDCap data is described in sections 22B and 22D.	
19.	**Does your investigation involve incomplete disclosure of the research purpose or deception of the subjects?**	NO
20a.	**Subject Population** Adult stroke patients who are discharged from the hospital to their home or patients discharged to a rehabilitation facility with the expectation that they will return home within 4 weeks. The subject population will also include the primary caregiver of enrolled patients if available.	
20b.	**Age range of subjects**	18 to no limit
20c1.	**The following study populations will be purposely included in the research:** ☐ Minors ☐ Pregnant Women ☐ Women of Childbearing Age ☐ Institutionalized Persons ☐ Students ☐ Low Income Persons	

	☐ Minorities ☐ Prisoners ☐ HIV/AIDS Individuals ☐ Psychiatric Patients ☐ Individuals with Diminished Capacity ☐ Wards ☑ None of These	
20c2.	**Will some or all of the subjects likely be vulnerable to coercion or undue influence?**	NO
20c3.	**Will some or all of the subjects be prisoners (i.e. involuntarily confined or detained in a penal institution)?**	NO
20c4.	**Will the research be conducted in the Federal Bureau of Prisons (i.e. Federal Prison System)?**	NO
20d.	**Total expected number of subjects (including controls) for the entire project period**	500 (20 for the pilot test, 480 for the final study)
20e.	**Provide the rationale for your sample size.** Sample size estimates were based on 2 outcome measures: Stroke-specific QOL (SS-QOL), and the Patient Activation Measure (PAM). Anticipated differences in the summary SS-QOL measure were obtained from a previous registry study of the PI (Reeves) (Ref: Gargano et al, 2007) which found significant differences of 0.5 with a standard deviation of 1.9. Validation work on the PAM measure has shown that an average PAM score is 56 with a standard deviation of 13 (Ref: Hibbard et al, 2005), and that increases of 4.6 are clinically meaningful (Ref: Fowles et al, 2009). In all simulations, power was set to 80% with alpha= 0.05. All estimates were generated in SAS using the overall F test for a one-way ANOVA model based on the 3 group RCT design. To detect a 0.5 unit difference in mean SS-QOL scores with an assumed standard deviation of 1.9, a total sample size of 213 is required. To detect a 5 unit difference in mean PAM score with an assumed standard deviation of 13, a total sample size of 102 is required. When these baseline estimates were subjected to plausible changes in the effect size (through changes in detectable difference or the standard deviation) we obtained estimates between 63 or as high as 366. Our goal total sample size of 480 is therefore more than sufficient to detect clinically meaningful differences in these two outcomes.	
20f.	**Describe the criteria for the inclusion of subjects.** Patient Inclusion Criteria: All of the following inclusion criteria need to be met for a patient to be included in the trial. i) A final confirmed hospital diagnosis of acute stroke (ischemic or hemorrhagic). ii) Patient living at home pre-stroke. iii) Presence of stroke-related deficits at admission (defined as a National Institute of Health Stroke Severity score of >=1). iv) Presence of functional limitations at discharge (defined as a modified Rankin score [mRS] score of >=1). v) Discharged directly home (includes patient's residence or that of a family member), or discharged to a rehabilitation facility with the expectation of return to home within 4 weeks Caregiver Inclusion Criteria: All of the following inclusion criteria need to be met for a caregiver to be included in the trial. i) Any person identified by the stroke patient as the primary caregiver (individual who has primary responsibility for assisting with the patient's care). ii) Age 18 or over.	
20g.	**Describe the criteria for the exclusion of subjects.**	

	Patient Exclusion Criteria: Patients will be excluded from the trial if they meet any of these criteria: i) Patients who live more than 50 miles from the hospital (for reasons related to the home visits). ii) Patients discharged to hospice care, nursing home for long term care, or long term care hospital (LTCH). iii) Patients who fail the Abbreviated Mental Test Score (AMTS) screening for cognitive function and for whom a proxy respondent is not available. iv) Patients enrolled in another acute stroke intervention trial that has a significant impact on the post-acute period (i.e., intensive data collection required of patient during follow-up). v) Limited life expectancy (< 6 months) or significant medical comorbidity likely to impact completion of the study (e.g., severe mental illness, drug or alcohol abuse, metastatic cancer). vi) Does not speak English. Caregiver Exclusion Criteria: The following caregivers would be excluded from the trial. i) Does not speak English.
20h (1).	**How will the subjects be identified, recruited and enrolled? Include who will make initial contact with the subjects, who will recruit the subjects, and who will enroll the subjects.** Potential study subjects are patients hospitalized due to acute stroke at one of the 4 participating institutions. Hospital personnel (clinical stroke nurses or site coordinators) who are employed by the MISTT study will screen stroke patients during their hospital stay and will be responsible for contacting, consenting and enrolling all eligible patients. Procedures for approaching and consenting stroke subjects into clinical studies are well established at the participating hospitals, having been built on the experience of prior clinical research studies including the MASCOTS stroke registry that was conducted by PI (Reeves). In brief, study personnel will introduce the study to the patient, assess the patient's eligibility (including AMTS screening for cognitive function), seek their consent, and ask them to identify the primary caregiver who will also be invited to participate. Stroke patients will be identified by reviewing the hospital's daily census logs. At a suitable time during the hospital stay, preferably when family members are present, the study coordinator will approach the patient to introduce the study. If the patient and family express interest and eligibility is confirmed, the coordinator will complete the consent process. When the patient agrees to participate, he/she will read and sign the written consent and HIPPA approval forms. The informed consent process will explain the potential risks and include appropriate HIPAA language that will not prohibit data from being shared with the research team. A copy of the informed consent instrument and HIPPA form will be provided to each participant. Study personnel will query the patient for the name of the person most likely to provide the majority of care for them when they return home (i.e., the primary caregiver). Study personnel will then approach this identified caregiver to assess eligibility, attempt recruitment, and obtain informed consent from the caregiver. If the primary caregiver declines to participate in the study, this will not affect the inclusion of the patient. If a patient is unable to give consent because they fail the AMTS screening then a proxy respondent will be sought (e.g., see section 24B1 for further details). We believe that the use of proxy respondents is critically important for stroke studies to avoid study bias from exclusion of the most severely affected patients. Enrollment of caregivers will most likely occur in the hospital setting (when they visit the patient) but may occur by phone (if study personnel are unable to meet with them in person).

20h (2).	**Will an advertisement be used?**	NO
20i.	**Are you associated with the subjects?**	NO
20j.	**Will someone receive payment for recruiting the subjects?**	NO
20k.	**Will the research subjects be compensated?** **(1) Details concerning payment, including the amount and schedule of payments including any conditions:** Subjects will received a one time $25 payment after completing the 90-day data collection follow-up call.	YES

20l.	**Will the subjects incur additional financial costs as a result of their participation in this study?**	NO
20m.	**Will this research be conducted with subjects in another country?**	NO
20n.	**Will this research be conducted with subjects in the U.S. from an ethnic group of sub-group or other non-mainstream minorities (including non-English speakers)?**	NO
20o.	**Will student education records that directly relate to a student be accessed?**	NO
20p.	**Will any subjects be recruited from MSU Health Team clinics?**	NO
20q.	**Will any subjects' insurance be billed as part of this project?**	NO

21a.	**Risks and Benefits for subjects: Describe and assess any potential risks (physical, psychological, social, legal, economic) and assess the likelihood and seriousness of such risks.** This RCT study is designed to ameliorate stress and burden associated with the transition back to the home that occurs under current usual care environments. The two interventions used in this study include: 1) home based case management services provided by the social worker (SW), and 2) training and use of the MISTT study website (a purpose-built, patient-centered, online information and support resource). Both interventions have limited risk for participants. The most substantial of these is loss of confidentiality. There is also a possibility that identifying and addressing unmet needs with the social worker may raise difficult and emotional issues for both the patient and the caregiver that would have otherwise gone unaddressed. It is also possible that medical emergencies or other adverse situations might arise when study personnel are interacting with the subjects. Social workers are trained to identify such problems and provide crisis intervention; the social workers will be able to refer patients for additional services if needed. They will have regular meetings with and receive ongoing supervision from Co-Investigator Dr. Hughes to address potential problems and a protocol will be in place for emergencies (see section 21B for further details).
21b.	**Describe procedures for protecting against or minimizing potential risks and provide an assessment of their likely effectiveness.** There are two study related potential risks to participants in this study: 1) loss of confidentiality, and 2) increased stress as a result of the social work intervention addressing unmet needs and other bio-psycho-social stressors. It is also possible that a medical emergency or other adverse situation might arise when study personnel are interacting with the subjects. Section 22A and 22D provide a description of the extensive protections put in place to mitigate the risk of loss of confidentiality. Here we address the protections put in place to protect subjects against increased stress or unexpected medical emergencies: If, during the trial, a serious non-medical situation arises that suggests the patient is in crisis, the SW will refer the patient to local crisis support services and ensure that the patient is connected to the appropriate services. In these situations the SW will contact Co-Investigator Dr. Hughes to develop an emergency care and follow-up plan to ensure patient safety. Dr. Hughes has considerable prior experience in practical community-based social work including home visits. The SW will also inform the hospital study coordinator about any serious issues. The SWs will have bi-weekly meetings with Dr. Hughes where they will discuss strategies to manage high-needs cases. Also, these situations will be discussed at the bi-weekly research team meetings (including the PI, Project Manager, Co-I Hughes and other team members) where strategies can be discussed and refined to ensure that patients receive necessary services. It is also possible that medical emergencies or adverse conditions may be identified by either the SW (during their home visits or the follow-up calls) or by the research assistants who are conducting the telephone follow-up data collection calls. All personnel will be instructed on the appropriate use of 9-1-1 services should any situation arise that could represent a medical emergency (examples could include recurrence of stroke symptoms, a serious fall, acute cognitive change). If other serious but

	non-emergent medical problems arise (for example, ran out of medications, symptoms suggestive of a new medical problem or condition) the SW or research assistants will contact the patient's primary care provider to set up an appointment and will follow-up to insure that treatment is received.
21c.	**Assess the potential benefits (if any) to be gained by the subjects in this study, as well as benefits which may accrue to society in general as a result of the planned work.** Patients enrolled in the two intervention groups (the SW case management program, or the SW case management program plus access to the study website) may directly benefit from the case management services delivered by the SWs, and/or may benefit from the information and support services provided by the study website. The risks associated with this study are reasonable considering that the study interventions may improve the transition experience (by decreasing stress/anxiety and improving overall quality of life). Other benefits include the fact that the knowledge gained from this study may benefit future stroke patients and caregivers. All study subjects will be given access to the study website after completing their final 90-day telephone interview.
22a.	**How will the subject's privacy be protected? Include a description of who will be interacting with the subjects or accessing and abstracting data from the subject's records (academic, medical, etc.) and where the study will take place. For example, will individuals not associated with the research study be present during the consent process and the conduct of the study?** All interviewers and study staff will follow study specific procedures for maintaining respondent confidentiality. All of our study staff will receive training in the proper method of conducting interviews that contain personal information, including mandatory HIPAA training. Consent processes will occur within the hospital inpatient setting and will be conducted by the hospital study coordinators. In the hospital setting, study related bedside interactions and conversation with patients will be conducted by the hospital personnel using their usual protections against loss of patient confidentiality. Procedures for approaching and consenting stroke subjects into clinical studies are well established at the participating hospitals, having been built on the experience of prior clinical research studies. Study identification numbers, rather than written names or other personal identifying information, will be used to identify and track hard copy data forms containing patient information. The Social Work Case Management intervention will occur in the privacy of the patient's home, and so threats to patient privacy are minimal. The MISTT web site will be structured to require strong passwords for all subjects, and no identifiable data will be retained on the site.
22b.	**Where will the data be stored and for how long?** All electronic data collected in REDCAP will be stored on the secure BRIC server (hosted at the MSU-Health Information Technology computer data center). All hard copy files that pertain to patient or caregiver data (e.g., signed consent forms, patient contact information) will be kept in lockable file drawers within secure offices located in either the Department of Epidemiology or the MSU School of Social Work. Study forms maintained by the hospitals will be stored using equivalent security procedures. All study related data will be maintained for at least 3 years after the completion of the research.
22c.	**Who will have access to the research data?** Only members of the research team will have access to the data. No identifiable data will be shared outside the research team.
22d.	**How will you ensure the confidentiality and/or anonymity of the research data? Include a description of the procedures and safeguards you will use, including if identifying information will be stored with the data.** Patient specific clinical data will be entered remotely by hospital study coordinators into a REDCap database using secure web-based data entry screens. Similarly, remote data entry in REDCap will also be used by the social workers (SW) to record data collected during home visits and telephone follow-up calls. Contact information required to find the patient's home be stored on secure password protected study laptop computers and cell phones – no hard copy forms that contain patient information will be maintain by the SWs. The outcomes data for this trial will be collected by phone by

	trained research assistants working under the supervision of the PI (Reeves) and Project Manager (Fritz). Data will be collected at two time points: 7 days and 90-days after returning home. Separate interviews will be conducted for patients and caregivers. The Project Manager, social workers, and research assistants conducting the telephone follow-up calls will all use secure (password protected) study-specific laptop and desktop computers. Laptop computer bags will be locked during transport and will be stored in locked offices. Desktop machines will be kept in a locked designated interview room in the Department of Epidemiology at MSU. During this research project, MSU-BRIC personnel will have no contact with human subjects and will play no role in the collection of patient data. Only the PI and Project Manager (both located at MSU) will have global privileges that permit viewing and editing of the total database. The PI will be responsible for authorizing users and permissions for access to the database via read and write privileges. Study field personnel (i.e., hospital study coordinators and the SW) will be allowed to view only the patient data from their study site. Audit logs, created automatically within REDCap, will capture the complete user history of database activity. REDCap variables designated as 'personally identifying' will be excluded from export by using REDCap user-defined permissions. In addition, BRIC tracks the certification of IRB training for all REDCap users and will suspend access to REDCap in the unlikely event that current IRB training certification lapses for any of the study personnel. Study data will be stored and managed using the REDCap application hosted on servers at the MSU-Health Information Technology computer data center in a HIPPA-class compliant server room with climate-control and swipe-card entry. Daily and monthly backups of the database will be made and retained on the server and backups will be moved to a separate site on a monthly basis. All subjects using the MISTT study website will be required to use strong passwords, and no identifiable data will be retained on the site. MISTT website utilization data collected through Google Analytics (e.g., how often users log in, what pages they go to, how long they spend on those pages) will be stored on Google servers. Google will not have access to any data that identifies an individual user (such as name, Email or address). The utilization data will be linked to the project-specific subject ID numbers and not subject names or other identifiers. The key to link the utilization data to a specific individual will be stored in a Drupal database on secure MSU servers, and are not publicly available We believe that the combination of high level training of all study personnel with respect to confidentiality and data security, in combination with state-of-the art security features implemented by MSU-BRIC on its REDCAP databased minimize any risk of a breach in subject confidentiality.	
22e.	**Is it appropriate for your research to have a monitoring plan to periodically assess the data to ensure the safety of subjects or to ensure negative outcomes do not occur (e.g., ongoing study of domestic abuse, clinical trial, full board projects)?** **Describe the steps that you will be taking to assure that subjects are protected. If appropriate, attach a copy of the plan.** The safety of the subjects participating in this study is of paramount concern to the investigators. The PI (Reeves) is ultimately responsible for the overall safety monitoring of the study. Because there is no drug or investigational device being tested in this trial, participation has no more than minimal risk to the subjects. Commensurate with the very low risk associated with study participation and the lack of any tangible Adverse Events to monitor, the study team (PI, Co-I's, Project Manager, SWs) plans to directly oversee all safety monitoring. Thus no formal data safety monitoring board is planned. All patient safety concerns identified by the SWs will be discussed at their weekly meetings, and at the bi-weekly research team meetings. Summaries of these issues and the approaches used by the project team to address them will be shared with a Patient-Professional Advisory Panel who will meet every 6 months during Years 2 and 3 to provide oversight on the trial's implementation. These data will also be	YES

	shared with the funding agency (PCORI) as part of the regular biannual reports submitted to them. With respect to monitoring the integrity of the REDCap database, Dr. Nicole Jones will work closely with the BRIC Unit Information Systems Manager to oversee and ensure implementation and monitoring of the data management plan. She will ensure that the informatics configuration, testing, and production processes are conducted appropriately to ensure security and confidentiality of data in the Study's REDCap database. **Is there a data safety monitoring committee or data safety monitoring board?** NO	
23.	**Does this project involve protected health information as defined by HIPAA?**	YES
24.	**(a) Select appropriate consent option.**	Approval of a consent form and process
	(b) Consent Procedures: Hospital personnel (clinical stroke nurses or study site coordinators) who are employed by the MISTT study will be responsible for consenting eligible patients. Procedures for approaching and consenting stroke subjects into clinical studies are well established at the participating hospitals; all study personnel have experience in enrolling patients into clinical research studies. Hospital study personnel will first assess the patient's eligibility and will screen each patient using the Abbreviated Mental Test Score (AMTS) to determine if a proxy consent is required (see below for further details). If a patient is deemed potentially eligible at a suitable time study personnel will approach the patient to introduce the study (preferably when other family members are present). If the patient and family express interest and eligibility is confirmed, the coordinator will provide further details of the study. This discussion will follow the information on the consent form including a description of the study's purpose, the use of randomization, the study procedures involved (including the use of home visits), the expectations of participating subjects with respect to providing information via follow-up telephone calls. Risks and potential benefits as well as compensation will also be discussed. If the patient agrees to participate, he/she will read and sign the written consent and HIPPA forms. A copy of these forms will be provided to each participant. Study personnel will query enrolled patients for the name of the person most likely to provide the majority of care for them when they return home (i.e., the primary caregiver). Study personnel will then approach this identified caregiver to assess eligibility, attempt recruitment, and obtain informed consent from the caregiver. Enrollment of caregivers will most often occur either in the hospital setting (if they visit the patient) or may occur by phone (if study personnel are unable to meet with them in person). Whether the caregiver chooses to participate in the study or not, will not affect the inclusion of the patient. We will seek to enroll any patient who fails the Abbreviated Mental Test Score (AMTS) screening – a 10-item screening tool that identified subjects with confusion or disorientation. If a patient scores ≤7 or has aphasia and is not able to complete the test then a proxy respondent will be sought. We will follow the rules as outlined in the MSU HRPP manual (Section 6-8-D) for determining the most appropriate person to act as a surrogate decision maker. In the absence of an advanced care directive that addresses consent for	

	research studies, or power of attorney, or health care guardian, we will be next defer to the patient's spouse or family member as available. **(b)(2)Will the subject or legally authorized representative sign a consent document(s)?** YES	
25a.	**Does any person responsible for the design, conduct, or reporting of findings of this protocol have a Significant Financial Interest (as defined for the MSU Faculty Conflict of Interest Policy) or other opportunity for tangible personal benefit related to the conduct of the research that might compromise, or reasonably appear to compromise, the independence of judgment with which their responsibilities would be completed under this research protocol? A reportable financial interest includes, but is not limited to, a financial interest in the sponsor, product, or service being tested, or in a competitor of the sponsor or product or service being tested.**	NO
25b.	**Has any financial arrangement, including compensation, ownership interest, stock options, or other ownership interest, (e.g., compensation that is: explicitly greater for a favorable result; in the form of an equity interest in the sponsor of a covered study; or in the form of compensation tied to sales of the product, such as a royalty interest) been established whereby the value of compensation or ownership interest to investigators conducting the study could be influenced by the outcome of the study?**	NO
25c.	**Is this a clinical study where the results may be used to support marketing applications for new human drugs and biological products and marketing applications and reclassification petitions for medical devices to the FDA, as required by law?**	NO
25d.	**Are you aware of any individual who has a financial interest which may create an organizational conflict of interest?**	NO
26a.	**When would you prefer to begin this project?**	11/1/2015
26b.	**Estimated duration of project (including identifiable data analysis):**	2 years

ADDITIONAL DOCUMENTS/ATTACHMENTS

01. 9/18/2015 **Grant Application Materials** (i049657_9-18-2015_PCORI Grant References-FINAL.docx)

02. 9/18/2015 **Abstract** (i049657_9-18-2015_PCORI Public Abstract FINAL.docx)

03. 9/22/2015 **Specific Aims** (i049657_9-18-2015_PCORI Specific Aims FINAL.docx)

04. 9/18/2015 **Appendix contents** (i049657_9-18-2015_PCORI_Appendix FINAL.docx)

05. 9/18/2015 **Research Strategy** (i049657_9-18-2015_PCORI_Stroke Research Strategy FINAL.docx)

06. 9/18/2015 **Caregiver consent Form** (i049657_9-18-2015_MISTT Caregiver consent form_V2.docx)

07. 9/18/2015 **Patient Consent Form** (i049657_9-18-2015_MISTT Patient consent form_V2.docx)

08. 9/18/2015 **Hospital baseline data** (i049657_9-18-2015_MISTT MSU IRB appendix 2a_V2_FINAL.DOCX)

09. 9/18/2015 **patient baseline data** (i049657_9-18-2015_MISTT MSU IRB appendix 2b_V3_FINAL.DOCX)

10. 9/18/2015 **Data collection form** (i049657_9-18-2015_MISTT MSU IRB appendix 2c_V2_FINAL.DOCX)

11. 9/18/2015 **Patient Outcome Measures** (i049657_9-18-2015_MISTT MSU IRB appendix 2d_V4_FINAL.DOCX)

12. 9/18/2015 **Caregiver Outcome Measures** (i049657_9-18-2015_MISTT MSU IRB appendix 2e_V1_FINAL.DOCX)

13. 9/18/2015 **use of PHI appendix p. 2** (i049657_9-18-2015_MISTT Use of Protected Health Information Application_Sept 2015_REEVES S....pdf)

14. 9/18/2015 **use of PHI appendix p.1** (i049657_9-18-2015_MISTT Use of Protected Health Information Application_Sept 2015_V1_FINAL....docx)

15. 9/21/2015 **Signature Page** (i049657_9-18-15_Signature Page.pdf)

16. 9/24/2015 **Revised Consent** (i049657_9-24-15_MISTT Caregiver consent form_V2_FINAL2.docx)

17. 9/24/2015 **Revised Consent** (i049657_9-24-15_MISTT Patient consent form_V2_FINAL2.docx)

MICHIGAN STATE UNIVERSITY

Revision Application Approval

March 16, 2016

To: Mathew Reeves
B614 W Fee Hall
East Lansing, MI 48824

Re: **IRB# 15-992M** Category: EXPEDITED 5, 7
Revision Approval Date: March 16, 2016
Project Expiration Date: October 11, 2016

Title: Michigan Stroke Transitions Trial (MISTT) Study [CGA#135457][IRRC# 1500-13M]

The Institutional Review Board has completed their review of your project. I am pleased to advise you that **the revision has been approved**.

This revision includes changes to the consent form, research instruments, receipt of DUA from the U of M IRB, registration of the project with ClinicalTrails.gov and the addition of Dr. [redacted] the project. In addition to other personnel being added [redacted] to the project.

The review by the committee has found that your revision is consistent with the continued protection of the rights and welfare of human subjects, and meets the requirements of MSU's Federal Wide Assurance and the Federal Guidelines (45 CFR 46 and 21 CFR Part 50). The protection of human subjects in research is a partnership between the IRB and the investigators. We look forward to working with you as we both fulfill our responsibilities.

Renewals: IRB approval is valid until the expiration date listed above. If you are continuing your project, you must submit an ***Application for Renewal*** application at least one month before expiration. If the project is completed, please submit an ***Application for Permanent Closure***.

Revisions: The IRB must review any changes in the project, prior to initiation of the change. Please submit an ***Application for Revision*** to have your changes reviewed. If changes are made at the time of renewal, please include an ***Application for Revision*** with the renewal application.

Problems: If issues should arise during the conduct of the research, such as unanticipated problems, adverse events, or any problem that may increase the risk to the human subjects, notify the IRB office promptly. Forms are available to report these issues.

Please use the IRB number listed above on any forms submitted which relate to this project, or on any correspondence with the IRB office.

Good luck in your research. If we can be of further assistance, please contact us at 517-355-2180 or via email at IRB@msu.edu. Thank you for your cooperation.

Sincerely,

Ashir Kumar

Ashir Kumar, M.D.
BIRB Chair

c: Michele Fritz, Anne Hughes, Amanda Woodward, Paul Freddolino, Constantinos Coursaris, Kristen Boeskool, Debra Montgomery, Danielle Steplowski, Taylor Seaton, Shyamali Mukerjee, Anmar Razak, Ann Ripberger

Office of Regulatory Affairs
Human Research Protection Programs

Biomedical & Health Institutional Review Board (BIRB)

Community Research Institutional Review Board (CRIRB)

Social Science Behavioral/Education Institutional Review Board (SIRB)

Olds Hall
408 West Circle Drive, #207
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www.hrpp.msu.edu

APPLICATION FOR RENEWAL or REVISION

APPROVAL OF A PROJECT INVOLVING HUMAN SUBJECTS

Biomedical, Health Sciences Institutional Review Board (BIRB)
Community Research Institutional Review Board (CRIRB)
Social Science, Behavioral, Education Institutional Review Board (SIRB)
207 Olds Hall, Michigan State University
East Lansing, MI 48824-1047
Phone: (517) 355-2180
Fax: (517) 432-4503
E-mail: irb@msu.edu

Office Hours: M-F (8:00 A.M.-5:00 P.M.)

IRB#: 15-992M
ID# r049818

Title: Michigan Stroke Transitions Trial (MISTT) Study [CGA#135457][IRRC# 1500-13M]

Review Category: EXPEDITED 5, 7

Expiration Date: 9/14/2018

Responsible Project Investigator:

Name: **Mathew Reeves**
ID#:
Department: **EPIDEMIOLOGY & BIOSTATISTICS**
College: **HUMAN MEDICINE**
Academic Rank: **Professor**
Mailing Address:
East Lansing, MI 48824
Phone:
Fax:
Email: **ReevesM@msu.edu**

REVISION

1. Categories: Mark all categories of proposed changes below.

Administrative Changes

Funding	NO
Project Title	NO
Study Investigator(s)	NO
Data Analysis Only	NO

Study Changes / Amendments

Advertisement/Recruitment	NO

Consent	YES
Eligibility Criteria	NO
Instrument(s)	YES
Protocol/Design/Analysis	NO
Subject Incentive	NO
Target Population	NO
Protected Health Information	NO
Other	YES

2. Briefly describe the proposed revision(s) and rationale:

We request the following revisions:

1) OTHER - Add Dr. [redacted] as study personnel. [redacted] is the study Investigator at Sparrow and [redacted] is a social worker who will be providing our Stroke Case Management intervention. The following approved personnel only need to be listed as "additional personnel" and not identified as "investigators and key personnel"
[redacted]

2) CONSENT - Approval for a waiver of documentation to obtain Caregiver Consent verbally over the phone. This will occur if the Caregiver is unavailable at the time of patient consent. A script is included in the supporting documentation. Hospital site coordinators, Social Work Stroke Case Managers (SWSCMs), and student research assistants will all be trained to conduct informed consent for both in-person and over-the-phone processes.

3) INSTRUMENTS - The finalized Patient and Caregiver 7 day Phone Interview instruments have been submitted for approval. The Caregiver Instrument contains two scales that were not previously approved: the Oberst Caregiving Burden Scale and the Bakas Caregiving Outcomes Scale.

4) OTHER - Approval for University of Michigan as a study site. The U-M IRB approval letter has been included with our supporting documentation which includes the executed Data Use Agreement (DUA) and their approved consent forms.

5) OTHER - The ClinicalTrials.gov ID is: NCT02653170

6) OTHER - We have included letters and educational materials for the first and second mailings. For the first mailing, enrolled patients will receive a letter and, depending on their randomized group assignment, two National Stroke Association (NSA) brochures and an interview response option sheet (attached). The second mailing is sent only to the usual care group and includes two American Stroke Association (ASA) brochures (previously approved). The second letter has been attached. The "Mailing Supply List" document summarizes the timeline and specifics for each mailing.

3.	**Does the proposed revision(s) add or increase the level of risk for subjects (including any additional adverse effects)?**	NO
4.	**Does the proposed revision(s) require changes in the consent process and/or forms (e.g., parental permission, child assent, diminished cognitive capacity)?** **(a) The new consent, parental permission, or child assent document(s) is in addition to the current one(s).** YES **(b) The revised consent, parental permission, or child assent document(s) is to replace the current one(s).** NO **(c) Please describe changes to the consent process (e.g. who will obtain consent and inform/educate the subjects).**	YES
5.	**Have any new funding sources been added to the project?**	NO

6.	**If needed, provide any special name/number/language that should appear in this revision's approval letter.** please provide a list of the things that have been approved	
7.	**Is the approval period for this project two years (i.e. project was granted a two year approval as part of the demonstration project)?**	NO

ADDITIONAL DOCUMENTS/ATTACHMENTS

01. 3/7/2016 **Consent Form** (r049818_03-04-2016_MISTT verbal phone consent for caregiver_3.docx)

02. 3/7/2016 **Survey/Instrument** (r049818_03-04-2016_CAREGIVER 7d data collection v10.docx)

03. 3/7/2016 **Survey/Instrument** (r049818_03-04-2016_PATIENT 7d data collection_V9.docx)

04. 3/7/2016 **Data Use Agreement** (r049818_03-04-2016_AGR2016-00606 UM-MSU DUA_FINAL SIGNED.PDF)

05. 3/7/2016 **University of Michigan Approval** (r049818_03-04-2016_HUM00107251_initial approval letter_2-2016.docx)

06. 3/7/2016 **Consent Form** (r049818_03-04-2016_MISTT Informed consent patient final_U-M.PDF)

07. 3/7/2016 **Consent Form** (r049818_03-04-2016_MISTT Informed consent caregiver final_U-M.PDF)

08. 3/7/2016 **Protocol** (r049818_03-04-2016_mailing supply list_2.docx)

09. 3/7/2016 **Other** (r049818_03-04-2016_NSA_CaregiversAndStroke.pdf)

10. 3/7/2016 **Other** (r049818_03-04-2016_NSA_STARSBrochure.pdf)

11. 3/7/2016 **Survey/Instrument** (r049818_03-04-2016_PATIENT 7d interview response options SHEET_v2.docx)

12. 3/7/2016 **Other** (r049818_03-04-2016_UC mail 1_Adjusted WITH heading and logo_V3.docx)

13. 3/7/2016 **Other** (r049818_03-04-2016_UC mail 2_Adjusted WITH heading and logo_v2.docx)

14. 3/7/2016 **Survey/Instrument** (r049818_03-04-2016_CAREGIVER 7d interview response options SHEET_v2.docx)

15. 3/7/2016 **Other** (r049818_03-04-2016_Intervention mail 1_Adjusted WITH margin and logo_v3.docx)

16. 3/8/2016 **Oral Consent** (r049818_3-8-16_MISTT verbal phone consent for caregiver_4.docx)

17. 3/16/2016 **University of Michigan Approval** (r049818_03-16-2016_HUM00107251_Ame00059544_approval letter_3-2016.docx)

MICHIGAN STATE UNIVERSITY

Revision Application Approval

August 19, 2016

To: Mathew Reeves

East Lansing, MI 48824

Re: **IRB# 15-992M** Category: EXPEDITED 5, 7
Revision Approval Date: August 19, 2016
Project Expiration Date: October 11, 2016

Title: Michigan Stroke Transitions Trial (MISTT) Study [CGA#135457][IRRC# 1500-13M]

The Institutional Review Board has completed their review of your project. I am pleased to advise you that **the revision has been approved**.

This letter notes approval for the revised consent & recruitment, parent/caregiver phone interview & letters for the third and fourth mailings along with the post-intervention MISTT website registration e-mail.

The review by the committee has found that your revision is consistent with the continued protection of the rights and welfare of human subjects, and meets the requirements of MSU's Federal Wide Assurance and the Federal Guidelines (45 CFR 46 and 21 CFR Part 50). The protection of human subjects in research is a partnership between the IRB and the investigators. We look forward to working with you as we both fulfill our responsibilities.

Renewals: IRB approval is valid until the expiration date listed above. If you are continuing your project, you must submit an ***Application for Renewal*** application at least one month before expiration. If the project is completed, please submit an ***Application for Permanent Closure***.

Revisions: The IRB must review any changes in the project, prior to initiation of the change. Please submit an ***Application for Revision*** to have your changes reviewed. If changes are made at the time of renewal, please include an ***Application for Revision*** with the renewal application.

Problems: If issues should arise during the conduct of the research, such as unanticipated problems, adverse events, or any problem that may increase the risk to the human subjects, notify the IRB office promptly. Forms are available to report these issues.

Please use the IRB number listed above on any forms submitted which relate to this project, or on any correspondence with the IRB office.

Good luck in your research. If we can be of further assistance, please contact us at 517-355-2180 or via email at IRB@msu.edu. Thank you for your cooperation.

Sincerely,

Ashir Kumar

Ashir Kumar, M.D.
BIRB Chair

c: Michele Fritz, Anne Hughes, Amanda Woodward, Paul Freddolino, Constantinos Coursaris, Kristen Boeskool, Debra Montgomery, Danielle Steplowski, Taylor Seaton, Shyamali Mukerjee, Anmar Razak, Alina Farah, Amy Nagaj, Lindsay Ross, Garrett Reichle

Office of Regulatory Affairs
Human Research Protection Programs

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www.hrpp.msu.edu

APPLICATION FOR RENEWAL or REVISION

APPROVAL OF A PROJECT INVOLVING HUMAN SUBJECTS

Biomedical, Health Sciences Institutional Review Board (BIRB)
Community Research Institutional Review Board (CRIRB)
Social Science, Behavioral, Education Institutional Review Board (SIRB)
207 Olds Hall, Michigan State University
East Lansing, MI 48824-1047
Phone: (517) 355-2180
Fax: (517) 432-4503
E-mail: irb@msu.edu

Office Hours: M-F (8:00 A.M.-5:00 P.M.)

IRB#: 15-992M
ID# r050607

Title: Michigan Stroke Transitions Trial (MISTT) Study [CGA#135457][IRRC# 1500-13M]

Review Category: EXPEDITED 5, 7

Expiration Date: 9/14/2018

Responsible Project Investigator:

Name: **Mathew Reeves**
ID#:
Department: **EPIDEMIOLOGY & BIOSTATISTICS**
College: **HUMAN MEDICINE**
Academic Rank: **Professor**
Mailing Address:
East Lansing, MI 48824
Phone:
Fax:
Email: **ReevesM@msu.edu**

REVISION

1. Categories: Mark all categories of proposed changes below.

Administrative Changes

Funding	NO
Project Title	NO
Study Investigator(s)	NO
Data Analysis Only	NO

Study Changes / Amendments

Advertisement/Recruitment	YES

Consent	YES
Eligibility Criteria	NO
Instrument(s)	YES
Protocol/Design/Analysis	NO
Subject Incentive	NO
Target Population	NO
Protected Health Information	NO
Other	YES

2. Briefly describe the proposed revision(s) and rationale:

PROPOSED REVISIONS:
We request the following revisions and have submitted supporting documentation via e-mail:

1) Advertisement/Recruitment: The MISTT study timeline will be used during recruitment to help explain the study.

2) CONSENT: Patient and Caregiver consent forms (both in-person and verbal) have been revised to include language explaining that participant usage of the MISTT website will be tracked. Tracking will occur for participants randomized to the Social Work Case Management + MISTT website group as well as for any participant that requests access to the website after completing their 90 day intervention period. Following the completion of the 3-month intervention phase of the study we are making the website available to all participants who request access via e-mail. This access will be maintained for a minimum of six months, and we will continue to track website usage during this post-intervention period, which is addressed in the consent forms.

3) INSTRUMENTS: The finalized Patient and Caregiver 90 day Phone Interview instruments have been submitted for approval.

4) OTHER: Letters for the third and fourth mailings along with the post-intervention MISTT website registration e-mail have been submitted.
-The third letter is sent to patients in all intervention groups and serves as a reminder for the 90d Phone Interview. It includes a copy of the interview response options.
-The fourth letter, along with a $25 gift card, is sent to both patients and caregivers who have completed the study. It also contains an invitation to e-mail us if interested in registering for MISTT website access.
-The post-intervention MISTT website registration e-mail contains information for interested participants to register and access the MISTT website after their 90d intervention period is complete.

3.	**Does the proposed revision(s) add or increase the level of risk for subjects (including any additional adverse effects)?**	NO
4.	**Does the proposed revision(s) require changes in the consent process and/or forms (e.g., parental permission, child assent, diminished cognitive capacity)?** **(a) The new consent, parental permission, or child assent document(s) is in addition to the current one(s).** NO **(b) The revised consent, parental permission, or child assent document(s) is to replace the current one(s).** YES **(c) Please describe changes to the consent process (e.g. who will obtain consent and inform/educate the subjects).**	YES
5.	**Have any new funding sources been added to the project?**	NO

6. If needed, provide any special name/number/language that should appear in this revision's approval letter.

please list the approved content

7.	**Is the approval period for this project two years (i.e. project was granted a two year approval as part of the demonstration project)?**	NO

ADDITIONAL DOCUMENTS/ATTACHMENTS

01. 8/8/2016 **Data collection form** (r050607_8-8-16_CAREGIVER 90d data collection_V8.docx)

02. 8/8/2016 **Other** (r050607_8-8-16_CAREGIVER 90d interview response options SHEET_v2.docx)

03. 8/8/2016 **Email** (r050607_8-8-16_e-mail for post-study VSSP access_v3.docx)

04. 8/8/2016 **Other** (r050607_8-8-16_Gift Card Mailing_All groups_adjusted WITH margin and logo_v4.docx)

05. 8/8/2016 **Other** (r050607_8-8-16_mail 3_All groups_adjusted WITH margin and logo_v1.docx)

06. 8/8/2016 **Consent Form** (r050607_8-8-16_MISTT Caregiver consent form_FINAL_level 9_v2.docx)

07. 8/8/2016 **Consent Form** (r050607_8-8-16_MISTT Patient consent form_FINAL_level 9_v2.docx)

08. 8/8/2016 **Consent Form** (r050607_8-8-16_MISTT verbal consent form for patient_v4 FINAL_v2.docx)

09. 8/8/2016 **Consent Form** (r050607_8-8-16_MISTT verbal phone consent for caregiver_4 FINAL_v2.docx)

10. 8/8/2016 **Data collection form** (r050607_8-8-16_PATIENT 90d data collection_V12.docx)

11. 8/8/2016 **Other** (r050607_8-8-16_PATIENT 90d interview response options SHEET_v1.docx)

12. 8/8/2016 **Other** (r050607_8-8-16_timelineINFOGRAPHIC DRAFT1.7 FINAL3 with 0.125 bleed.pdf)

13. 8/19/2016 **Consent Form** (r050607_08-19-2016_MISTT Patient consent form_FINAL_level 9_v3.docx)

14. 8/19/2016 **Consent Form** (r050607_08-19-2016_MISTT Caregiver consent form_FINAL_level 9_v3.docx)