Title: Implementing a Family Caregiver Checklist in Primary Care: A Pilot Study

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TITLE: "Implementing a Family Caregiver Checklist in Primary Care: A Pilot Study"

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Participating Sites: N/A

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Confidentiality Statement

This document is confidential and is to be distributed for review only to investigators, potential investigators, consultants, study staff, and applicable independent ethics committees or institutional review boards. The contents of this document shall not be disclosed to others without written authorization from WCM.

List of Abbreviations

AE	Adverse Event
CFR	Code of Federal Regulations
CRF	Case Report Form
CTSC	Clinical Translational Science Center
DSMB	Data Safety Monitoring Board
DSMP	Data Safety Monitoring Plan
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act of 1996
HRBFA	Human Research Billing Analysis Form
HUD	Humanitarian Use Device
ICF	Informed Consent Form
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
PHI	Protected Health Information
PI	Principal Investigator
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
UIRTSO	Unanticipated Problem Involving Risks to Subjects or Others
WCM	Weill Cornell Medicine

1. Protocol Summary

Full Title:	Implementing a Family Caregiver Checklist in Primary Care: A Pilot Study
Short Title:	CHEC
Principal Investigator:	Catherine Riffin, PhD
Study Description:	The goal of this project is to pilot test CHEC (Collaborative Healthcare Encounters with Caregivers) in primary care. CHEC is brief intervention with two components: 1) a checklist to identify the needs and concerns of unpaid/family caregivers who accompany older patients (aged 65+) to their primary care visits and 2) accompanying Tip Sheet for clinicians.
Sample Size:	*N = 60 caregivers** *N = 60 patients** *N = 10 primary care clinicians* **Participants will be a part of a patient-caregiver dyad and will be recruited together.*
Enrollment:	This study will enroll 60 patient-caregiver dyads and 10 primary care clinicians. It will screen up to 200 patients, up to 200 caregivers, and up to 15 clinicians.
Study Population:	Patient participants will include individuals who have upcoming appointments at the Center on Aging (COA) and are identified by COA clinicians as typically attending appointments with a family caregiver. Patient participants will vary in age, gender, race/ethnicity, and health conditions. Family caregiver participants will include caregivers of patients receiving care at the COA. They will also vary in age, gender, and race/ethnicity. The clinician sample will include individuals who provide care at the COA. Clinicians will vary in age, be enrolled regardless of gender, and include those who have patient visits scheduled for June 2021 – August 2022.
Enrollment Period:	14 months
Study Design:	Two group single-blind randomized pilot RCT collecting: 1) survey data, 2) audio-recordings, and 3) electronic medical record data.
Description of Sites/ Facilities Enrolling Participants:	Participants will be recruited and enrolled at WCM/NYP offices, specifically the Center on Aging.
Study Duration:	August 31, 2024
Participant Duration:	**Providers – 14 months** **Caregivers – 6 months** **Patients – 1 month**
Primary Objective:	To examine the feasibility and acceptability of implementing CHEC in primary care practice.

Secondary Objectives:	To examine the preliminary impact of CHEC on primary care visit communication (discussion of family caregivers' needs).
Exploratory Objectives:	Not applicable
Primary Endpoints:	**Feasibility** will be assessed by accrual rates and rate of intervention completion. **Acceptability** will be assessed by surveys assessing perceived helpfulness, satisfaction, length, and impact on workflows. **Effectiveness** will be measured by the number of checklists that result in a conversation about caregivers' needs/concerns.
Secondary Endpoints:	Not applicable.

1.1 Study Objectives

1.1.1 Objectives

Objective 1: To demonstrate the feasibility and acceptability of CHEC in primary care practice.

Objective 2: To test the preliminary impact of CHEC on primary care visit communication (discussion of family caregivers' needs).

1.1.2 Hypotheses / Research Questions

Hypothesis 1*:* Greater than 70% of caregivers will perceive the checklist to be an acceptable length and easy to use.

Hypothesis 2: Greater than 70% of caregivers will report that the checklist is helpful in identifying their unmet needs and starting a discussion with providers.

Hypothesis 3: Greater than 70% of caregivers and providers will report that they desire to continue using the checklist in the future.

Hypothesis 4: The checklist will not significantly impact primary care workflow or visit duration.

Hypothesis 5: Discussion of caregivers' needs and concerns will occur more often in the intervention group than in the usual care group.

Hypothesis 6: Caregiver perceptions of visit communication will be more positive in the intervention group than in the usual care group.

2. Background and Significance

In the United States, nearly 8 million older adults rely on family and other unpaid caregivers (neighbors; friends) for assistance with their health care. These caregivers collectively provide 75-80% of the total care hours to community-dwelling older adults and fill multiple roles in the health care system: attending doctor's visits, coordinating care, and assisting with treatment regimens. The availability and adequacy of assistance provided by family and unpaid caregivers have direct implications for health care costs and quality of care of older adults. Yet, caregivers are not systematically identified in care delivery systems, and their abilities and needs are not routinely assessed. Caregivers receive inadequate preparation for the tasks they must assume. They report high levels of stress and are at risk for physical illness, depression and anxiety, and sleep disturbance. If these impairments and unmet needs are not assessed and addressed, they can impede the caregiver's ability to provide effective assistance to the older adult, ultimately leading to costly hospitalizations and nursing home placements. These caregiver factors (health impairments; unmet needs) are particularly influential in the context of dementia where patients require substantial caregiving assistance.

Primary care practices are well positioned to aid in identifying and addressing the needs of at-risk family caregivers – in particular, persons who suffer from caregiving-related stress or have unmet needs for training or support – through systematic screening and referral. Nearly 40% of patients over the age of 65 are accompanied by a caregiver to routine medical visits. Primary care providers are often the first point of contact in the health care system for patients and caregivers, and thus have the opportunity to detect issues early in the caregiving trajectory. In addition, the long-term nature of the patient-caregiver relationship with a primary care provider affords the opportunity for periodic reassessment. This aspect is critical as the caregiver's needs change in response to the patient's physical health and cognitive function.

The objective of this project is to pilot test a novel screening-referral system for family caregivers who accompany older adults to their primary care visits, The long-term goal of this research is to develop a clinically feasible and scalable caregiver screening system that is acceptable to providers and caregivers. This system will set the stage for a sustained line of intervention work that connects at-risk caregivers with appropriate resources, services, and supports. From a clinical perspective, broad implementation of this system has the potential to reduce demands on primary care providers by directing caregivers to services designed to support their well-being and caregiving capacity.

3. Study Design and Methods

3.1 Overall Design

Clinicians who see patients at the Center on Aging (COA) will be made aware of the study via individual meetings with co-investigators. These meetings will be by phone, Zoom, or in-person if/when feasible. Patients and caregivers will be identified through referrals from physicians practicing at the Center on Aging. They will be sent a recruitment letter in the mail one month prior to a co-investigator calling them to go over the screening and consent forms. Any study data collected for potential participants that do not meet eligibility will be immediately deleted. Informed Consent and HIPAA authorization for caregivers and patients, and informed consent for clinicians will occur orally over the phone or in-person at the COA just prior to in-person health visits when feasible as outlined in the Informed Consent section.

Patient-caregiver dyads will be randomized into either the CHEC (n=60; 30 caregivers and 30 patients) or control (usual care) condition (n=60; 30 caregivers and 30 patients). Randomization will occur through block randomization with alternative block sizes of 4 and 6 for each participating clinician.

Intervention Condition. Participants in the intervention condition will complete the Caregiver Checklist portion of CHEC at the beginning of their health visit. The participating clinician will then respond to the checklist following the guidelines on the accompanying Tip Sheet.

Control Condition. Caregivers in the control condition will receive their usual care from the participating clinician during the health visit.

Baseline (pre-visit). Caregivers in both conditions will be asked to complete identical pre-visit surveys. The survey will be scheduled to be completed over the phone, digitally on REDCap, or in-person depending on the participant's preference and COVID-19-related guidelines. We will ask about the participant's background, caregiving role, communication with providers, and feelings of caregiver preparedness. It will take approximately 20 minutes to complete. Medical chart abstraction will be used to collect patient's background characteristics, medications, diseases, and health events (e.g., hospitalization). Clinicians will complete a pre-intervention survey over the phone or in-person depending on the participant's preference and COVID-19-related guidelines. We will ask for the clinicians' personal characteristics and preparedness to assess and address caregivers' needs and concerns.

Visit. All participants will have their medical visit audio recorded.

Post-visit. All caregiver participants will complete a post-visit survey within 1 week of the visit. They will also complete follow-up surveys 2 months and 6 months after the visit.

Post-intervention. At the completion of the entire intervention period, clinicians will complete a post-intervention survey and interview. The clinician surveys and interview will take no more than 30 minutes total and will be conducted within 1 month of the conclusion of the intervention period.

3.2 Interviews, Focus Groups, Surveys, and/or Observations

A. Administration

- *Timing and Frequency*
  - Caregiver baseline (pre-visit) surveys will take no more than 20 minutes and will be conducted prior to the visit; caregiver post-visit surveys will take no more than 25 minutes and will be conducted within one week of the visit, either in-clinic or remotely (via telephone and secure web survey or mail), based on the participant's preference. Separate post-visit, follow-up surveys will take no more than 15 minutes and will be conducted at 2 months and 6 months following the visit.
  - Clinician baseline surveys will take no more than 5 minutes and will be conducted prior to the entire intervention period. Clinician post-intervention surveys and interviews will take no more than 30 total minutes and will be

conducted within 1 month of the conclusion of the intervention period. The post-intervention interviews will occur in-person or over the phone (based on the participant's preference) and will be audio-recorded.
    - Medical chart abstraction will be conducted following enrollment/consent but prior to the visit. The medical visit will be audio-recorded.

- *Procedures For Audio And Visual Recording*
    - Medical visits and interviews will be recorded (phone, video, or in-person encrypted recording) and stored on secure WCM servers via password protected tagged WCM computers.
    - Audio-recordings will be transcribed by study co-investigators and will not leave the institution. The transcripts will also be stored on secure WCM servers via password protected tagged WCM computers.

- *Person Identifiers*
    - Personal identifiers (e.g. names, email address, phone number, and address) will be collected for recruitment and compensation purposes. Voice and video recordings, as well as compensation identifiers, will be made on a voluntary basis.
    - Patient data will be abstracted from the medical chart. Information obtained will include name, address, phone number, age, gender, race/ethnicity, provider, MRNs, electronic mail addresses and health diagnosis information including primary visit diagnosis code and clinic location (from defined time window), and health events (e.g. hospitalization, visit from home health aide). A partial HIPAA waiver will be requested for access to this information. All participants will be provided with a participant ID and their survey responses will be de-identified. Records will be maintained and kept in secure locations for a minimum of 3 years; the length of time specified according to WCM and HIPAA policies.

B. Study Instruments

The primary instruments for this study are validated, widely-used patient- and caregiver-reported outcomes (PCRO) assessments that are commonly used in health services research and clinical practice. These validated and reliable self-report measures include: Preparedness for Caregiving scale (Zwicker, 2010), CAPACITY measure (Van Houtven et al., 2019), Perceptions of Visit Communication (Talen et al., 2011), Caregiver Satisfaction with Primary Care Interactions (Clair et al., 2014; Haley et al, 1992), Perceived Self Efficacy in Primary Care Interactions (Maly et al., 1998), knowledge and use of resources (Thomas et al., 2017), caregiver anxiety and depressive symptoms (Mauer, 2012; Wild et al., 2014), and burden (Zarit, Reever & Bach-Peterson, 1980). We will use short forms when possible in order to reduce participant burden. We also developed several specific questions about caregivers' perception of the screening tool and knowledge of resources. All study instruments are attached to the IRB application in the WRG-HS system.

- <u>Caregiver Subjects in CHEC (intervention group)</u>
    - CHEC Caregiver Screening Questions
    - CHEC Caregiver Demographics
    - CHEC Caregiver Pre-Test Questionnaire

- CHEC Visit Companion Checklist
- CHEC Caregiver 1-Week Post-Test Follow-Up Survey – Intervention
- CHEC Caregiver 2-Month Post-Test Follow-Up Survey – All Caregivers
- CHEC Caregiver 6-Month Post-Test Follow-Up Survey – All Caregivers

- Caregiver Subjects in control group
  - CHEC Caregiver Screening Questions
  - CHEC Caregiver Demographics
  - CHEC Caregiver Pre-Test Questionnaire
  - CHEC Caregiver 1-Week Post-Test Follow-Up Survey – Control
  - CHEC Caregiver 2-Month Post-Test Follow-Up Survey – All Caregivers
  - CHEC Caregiver 6-Month Post-Test Follow-Up Survey – All Caregivers

- Clinician Subjects
  - CHEC Clinician Pre-Test Demographics and Eligibility Questionnaire
  - CHEC Visit Companion Checklist + Provider Tip Sheet
  - CHEC Clinician Post-Test Questionnaire
  - CHEC Clinician Post-Test Interview Guide

4. Study Design

4.1 Study Population

The patient participant sample includes individuals who have upcoming appointments at the Center on Aging (COA) and are identified by COA clinicians as typically attending appointments by a family caregiver. Patient participants will vary in age, gender, race/ethnicity, and health conditions. The family caregiver sample will include caregivers of patients receiving care at the Center on Aging. They will also vary in age, gender, and race/ethnicity. Caregivers and patients will be recruited and enrolled as dyads. The clinician sample will include individuals who provide care at the Center on Aging. Clinicians will vary in age, be enrolled regardless of gender, and include those who have patient visits scheduled over the next year.

4.2 Inclusion Criteria

Patients

1. Age 65-89
2. English speaking
3. Women and men
4. Of varying race/ethnicity
5. Accompanied to primary care visits at the Center on Aging by a family caregiver
   5.1. Family caregiver also consents to participating in this study.
6. Sufficient cognitive capacity to consent themselves or through a legal representative

Caregivers

1. Age 21+
2. English speaking

3. Women and men
4. Of varying race/ethnicity
5. Accompany an older adult to his or her primary care visits at the Center on Aging
   5.1. Older adult also consents to participating in this study.
6. Cognitively intact (on basis of a 6-item cognitive screen)

Clinicians

1. Age 21+
2. Women and men
3. Of varying race/ethnicity
4. Treat patients at the Center on Aging

4.3 Exclusion Criteria

1. Patients, caregivers, and clinicians that do not meet the inclusion criteria.
2. Patients and caregivers who are deaf or have hearing impairments that limit their ability to answer telephone queries.
3. Caregivers who are visually impaired and cannot see well enough to read large print and complete paper-based surveys.
4. Patients and/or caregivers whose dyad counterpart does *not* consent to take part in the study (i.e., Patients gives consent and their caregiver does not).

4.4 Strategies for Recruitment and Retention

Co-investigators will meet with clinicians who see patients at the Center on Aging to make them aware of the study protocol, including the request for their participation in the study and the plan to send recruitment letters (postal mail or email) to their patients and their family caregivers. An IRB-approved, informative study flyer will be sent with the recruitment letters (via postal mail or email). These meetings will be by phone, Zoom, or in-person if/when feasible. Co-investigators will review the consent form with each clinician, allowing for questions and reminding him or her that participation is voluntary. The co-investigator will subsequently ask each clinician who agrees to a) complete the pre-intervention survey (which will be administered orally by the trained co-investigator) and b) review his or her patient list and identify individuals who typically attend appointments with a caregiver (family or friend). When meeting with these clinicians, co-investigators will verify that the caregiver lives with the patient and/or obtain the caregiver contact information from the providers. A study team member will then query EPIC to determine the dates of upcoming appointments for those patients. Pre-notification recruitment letters will then be sent by mail, email (when available), or Weill/EPIC Connect to the patients and caregivers of the identified patients one month prior to his or her next scheduled appointment. Recruitment letters may also be sent to potential participants via EPIC Pool of WCM/NYP Consent to be Contacted for Research (CCR) patients and chart review to determine potential eligibility. When possible, letters will be sent to the emergency contact (i.e., caregiver) if their telephone matches that of the patient, or by email. The recruitment letter will describe the study and advise potential participants that they may decline participation by emailing or placing a telephone call to the study team. Approximately two weeks after the initial letter (postal mail or email) is sent, patients and caregivers who have not opted-out will be telephoned or emailed by the trained co-investigator to confirm their interest. Participants complete the consent form and pre-visit survey over the

phone, for both their convenience and safety during the COVID-19 pandemic. COA waiting rooms are presently closed and patients/caregivers are met at the door and brought immediately to an exam room. Once these restrictions are lifted, patient/caregiver participants will be given the option to complete their informed consent process and study pre-visit survey in the waiting room prior to the patient's next visit. Participants who elect to do so in person will be asked to arrive 30 minutes prior to their scheduled visit to ensure sufficient time to review the consent form and complete the survey.

Trained co-investigators will use the caregivers' preferred method of contact to inform them about the study (phone or email) after sending the pre-notification letter. If it is safe to do so and if time allows, co-investigators may choose to have participants consent in-person at The Center on Aging, and in that case, they will also be given the first survey at this time prior to their health visit.

Caregivers in both the intervention and control group will be voluntarily compensated $25 via AmEx gift cards for their participation in the initial post-visit survey. They will receive an additional $10 via ClinCards for their participation in each of the follow up surveys (at 2 months and 6 months). In total, caregivers may be compensated up to $45.

5. Registration Procedures

5.1 Subject Registration (WCM only)

Subjects will be registered within the WRG-CT as per the standard operating procedure for Subject Registration.

5.2 Subject Registration (Sub-sites)

N/A

6. Study Procedures

6.1 Schedule of Assessments

Table 1. Schedule of events

	Pre-Study	Pre-visit (Baseline)	Visit 1	Post-visit 1 (within 1 week of Visit)	Post-visit 2 (2-month follow-up)	Post-visit 3 (6-month follow-up)	Post-intervention
Cognitive Screen	X						
Informed Consent	X						
Demographics		X					
Caregiver Surveys		X		X	X	X	
Clinician Surveys		X					X

Audio-Recording of Medical Visit			X				
Medical Chart Abstraction	X						
Medical Events Log Six Months Post						X	

7. Data Reporting / Regulatory Considerations

7.1 Data Collection

The data collection plan for this study is to utilize REDCap to capture all data for all enrolled subjects.

7.1.1 REDCap

REDCap (Research Electronic Data Capture) is a free data management software system that is fully supported by the Weill-Cornell Medical Center CTSC. It is a tool for the creation of customized, secure data management systems that include Web-based data-entry forms, reporting tools, and a full array of security features including user and group-based privileges, authentication using institution LDAP system, with a full audit trail of data manipulation and export procedures. REDCap is maintained on CTSC-owned servers that are backed up nightly and support encrypted (SSL-based) connections. Nationally, the software is developed, enhanced and supported through a multi-institutional consortium led by the Vanderbilt University CTSA.

7.2 Regulatory Considerations

7.2.1 Institutional Review Board/Ethics Committee Approval

As required by local regulations, the Investigator will ensure all legal aspects are covered, and approval of the appropriate regulatory bodies obtained, before study initiation.

Before initiation of the study at each study center, the protocol, the ICF, other written material given to the patients, and any other relevant study documentation will be submitted to the appropriate Ethics Committee. Written approval of the study and all relevant study information must be obtained before the study center can be initiated or the IP is released to the Investigator. Any necessary extensions or renewals of IEC/IRB approval must be obtained for changes to the study, such as amendments to the protocol, the ICF, or other study documentation. The written approval of the IEC/IRB together with the approved ICF must be filed in the study files.

The Investigator will report promptly to the IEC/IRB any new information that may adversely affect the safety of the subjects or the conduct of the study. The

Investigator will submit written summaries of the study status to the IEC/IRB as required. On completion of the study, the IEC/IRB will be notified that the study has ended.

All agreed protocol amendments will be clearly recorded on a protocol amendment form and will be signed and dated by the original protocol approving signatories. All protocol amendments will be submitted to the relevant institutional IEC/IRB for approval before implementation, as required by local regulations. The only exception will be when the amendment is necessary to eliminate an immediate hazard to the trial participants. In this case, the necessary action will be taken first, with the relevant protocol amendment following shortly thereafter.

Once protocol amendments or consent form modifications are implemented at the lead site, Weill Cornell Medicine, updated documents will be provided to participating sites. Weill Cornell Medicine must approve all consent form changes prior to local IRB submission.

Relevant study documentation will be submitted to the regulatory authorities of the participating countries, according to local/national requirements, for review and approval before the beginning of the study. On completion of the study, the regulatory authorities will be notified that the study has ended.

7.2.2 Ethical Conduct of the Study

The Investigators and all parties involved should conduct this study in adherence to the ethical principles based on the Declaration of Helsinki, GCP, ICH guidelines and the applicable national and local laws and regulatory requirements.

This study will be conducted under a protocol reviewed and approved by the applicable ethics committees and investigations will be undertaken by scientifically and medically qualified persons, where the benefits of the study are in proportion to the risks.

This study will have been reviewed by the WCM IRB, Protocol Review and Monitoring Committee, and the Data Safety and Monitoring Committee (WCM DSMC), prior to conducting any human subjects research activities. The WCM Data Safety and Monitoring Committee has determined that their oversight & monitoring is not required for this low-risk study. Only surveys and chart abstraction are involved and it does not involve the evaluation of intervention on health outcomes of human subjects.

7.2.3 Informed Consent

The co-investigator or qualified designee must obtain documented consent according to ICH-GCP and local regulations, as applicable, from each potential subject or each subject's legally authorized representative prior to participating in the research study. Subjects who agree to participate will receive an oral consent document prior to speaking to a co-investigator.

Informed Consent will occur prior to administration of the pre-visit survey (for caregivers) and pre-intervention survey (for clinicians), by oral consent for participants until in-person

consent measures are safely feasible. For oral consent, a member of the study team will review the ICF in-full (see Oral Consent Script attachment) by phone, allowing for questions and reminding the potential subject that participation is voluntary. Oral confirmation of consent to participate will be documented by the study team member.

Older adults – who are the focus of this study – are at higher risk of severe illness from COVID-19. To minimize exposure of this vulnerable group, we are requesting a waiver of documentation of written consent. We have two points of justification. First, administering oral, rather than written consent would reduce the time participants spend in the waiting room prior to the study and unnecessary contact (i.e. with study co-investigators). Second, given that the Center on Aging is conducting a combination of video and in-person visits, oral consent is needed in order to accommodate those participants who cannot leave their homes at this time.

The initial ICF, any subsequent revised written ICF and any written information provided to the subject must be approved by IRB prior to use. The ICF will adhere to IRB/IEC requirements, applicable laws, and regulations.

7.2.4 Compliance with Trial Registration and Results Posting Requirements

Under the terms of the Food and Drug Administration Modernization Act (FDAMA) and the Food and Drug Administration Amendments Act (FDAAA), the Sponsor-Investigator of the trial is solely responsible for determining whether the trial and its results are subject to the requirements for submission to **http://www.clinicaltrials.gov**. Information posted will allow subjects to identify potentially appropriate trials for their disease conditions and pursue participation by calling a central contact number for further information on appropriate trial locations and trial site contact information.

7.2.5 Record Retention

Essential documents are those documents that individually and collectively permit evaluation of the study and quality of the data produced. After completion of the study, all documents and data relating to the study will be kept in an orderly manner by the Investigator in a secure study file. Essential documents should be retained for 2 years after the final marketing approval in an ICH region or for at least 2 years since the discontinuation of clinical development of the IP. In addition, all subject medical records and other source documentation will be kept for the maximum time permitted by the hospital, institution, or medical practice.

8. Statistical Considerations

Feasibility and acceptability will be examined by conducting frequency and descriptive statistics (i.e. mean, median, standard deviation, range) for enrollment rates and Likert-scale items assessing satisfaction with CHEC and perceived helpfulness.

Effectiveness will be measured by the number of completed checklists that result in a conversation with providers about caregiver needs and the receipt of relevant support. The effect of CHEC on the primary outcome variable, discussion of caregivers' needs, will be examined in a general linear mixed model with intervention group and time (pre-posttest) as fixed classification

factors, and individuals as levels of a random classification factor. The model will account for pre-intervention measures and will include a group x time interaction. Additional covariates (e.g., caregiver and care recipient age) and fixed classification factors (e.g., caregiver gender, race) will also be examined. Prior to model fitting, the distribution of all study variables will be assessed.

9. Adverse Event Reporting Requirements

Adverse event (AE) monitoring and reporting is a routine part of clinical research. Safety is monitored by evaluation of adverse events reported by subjects or observed by investigators or research staff, as well as by other investigations such as clinical laboratory tests, x-rays, electrocardiographs, etc.

9.1. Adverse Event Definition

An adverse event (also referred to as an adverse experience) can be any unfavorable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, and does not imply any judgment about causality. An adverse event can arise with any use of the drug (e.g., off-label use, use in combination with another drug) and with any route of administration, formulation, or dose, including an overdose.

9.1.1 Adverse Event Characteristics and Related Attributions

CTCAE term (AE description) and grade: The descriptions and grading scales found in the revised NCI Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 will be utilized for AE reporting. A copy of the CTCAE version 4.0 can be downloaded from the CTEP web site (**http://ctep.cancer.gov**).

- Attribution of the AE:
  - Definite – The AE *is clearly related* to the study treatment.
  - Probable – The AE *is likely related* to the study treatment.
  - Possible – The AE *may be related* to the study treatment.
  - Unlikely – The AE *is doubtfully related* to the study treatment.
  - Unrelated – The AE *is clearly NOT related* to the study treatment.

9.1.2 Recording of Adverse Events

All adverse events will be recorded on a subject specific AE log. The AE log will be maintained by the research staff and kept in the subject's research chart.

9.1.3 Reporting of AE to WCM IRB

All AEs occurring on this study will be reported to the IRB according to the IRB policy, which can be accessed via the following link:
http://researchintegrity.weill.cornell.edu/forms_and_policies/forms/Immediate_Reporting_Policy.pdf.

9.1.4 Reporting Events to Participants

Not applicable

9.1.5 Events of Special Interest

Not applicable

9.1.6 Reporting of Pregnancy

Not applicable

10. Unanticipated Problems Involving Risks to Subjects or *Others*
Not applicable

10.1 Definition of Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO)
Not applicable

10.1.1 Unanticipated Problem Reporting
Not applicable