PROTOCOL TYPE

Which IRB

(•) Medical ( ) NonMedical

Protocol Process Type

( ) Exemption
( ) Expedited (Must be risk level 1)
(•) Full

PROJECT INFORMATION

Title of Project: (If applicable, use the exact title listed in the grant/contract application).

Intervention for Cognitive Reserve Enhancement in delaying the onset of Alzheimer's Symptomatic Expression: The INCREASE Study

Short Title Description

Note: "Short Title" should consist of a couple key words to easily identify your study - these key words (rather than the whole title) will be displayed on the Dashboard in the listing for your study.

INCREASE

Anticipated Ending Date of Research Project: 5/1/2021

Number of human subjects: 90

Study is/will be open to new subject enrollment (or data/specimen collection): (•) Yes ( ) No

PI CONTACT INFORMATION

The Principal Investigator's (PI) contact information is filled in automatically based on who was logged in when the application was created (with LinkBlue ID). If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be the same person listed below.

If you are not the Principal Investigator, do NOT add yourself as study personnel. You may change the PI contact information on an application that is in Researcher edit mode by:

- clicking the "Change Principal Investigator" link below;
- searching for the PI's name using the search feature;
- clicking "Select" by the name of the Principal Investigator, then "Save Contact Information".

You will automatically be added as study personnel with edit authorization so you can continue editing the application.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to myUK and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a 'Name Change Form' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the HR Benefits Office for additional information.

Note: Principal Investigator (PI) role for E-IRB access
The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*).

Change Principal Investigator:

First Name:	Daniela	Room# & Bldg:	789 S. Limestone Room 241
Last Name:	Moga	Speed Sort#:	40356
Department:	Pharmacy Practice & Science	Degree:	
PI's Employee/Student ID#:	10921036	Rank:	
PI's Telephone #:	8593239682	Dept Code:	7K700
PI's e-mail address:	daniela.moga@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	Trained:	Yes
		Date Trained	5/6/2015

Do you, the PI, have a significant financial interest related to your responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2)?

○ Yes ◉ No

RISK LEVEL

Indicate which of the categories listed below accurately describes this protocol

- ○ (Risk Level 1) Not greater than minimal risk
- ◉ (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individuals subjects
- ○ (Risk Level 3) Greater then minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ○ (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests [45 CFR 46.102(i)]

Download UK's guidance document on assessing the research risk for additional information on risk [PDF]

SUBJECT DEMOGRAPHICS

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 65 yrs to N/A

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations
(Please note: The IRB will expect this information to be reported at Continuation Review time):

Enter Numbers Only!

Ethnic Origin	#Male	#Female
American Indian/Alaskan Native:	0	0
Asian:	1	1
Black African American:	4	5
Hispanic/Latino:	1	1
Native Hawaiian/Pacific Islander:	0	0
White/Caucasian:	38	39
Other or Unknown:		

If unknown, please explain why:

Indicate the categories of subjects and controls to be included in the study. Depending on the subject category applicable to your research you may be required to complete additional forms. [Note, if the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check mark populations which the research does not specifically target. For instance, a large record review of a diverse population may incidentally include a prisoner or an international citizen, but, if the focus or intent of the study has nothing to do with that status, you do not need to check those category(ies).]

Check All That Apply (at least one item must be selected)

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☑ Impaired Consent Capacity Adults

ADDITIONAL INFORMATION:

- Children
- Emancipated Minors
- Impaired Consent Capacity Adults: Instructions; Link to required Form
- Students as Subjects - Guidances: - University of Kentucky Students [PDF] - College of Medicine Students [requirement of OME] - K-12 [PDF]

☐ Pregnant Women/Neonates/Fetal Material	• UKMC Residents or House Officers [see requirement of GME]
☐ Prisoners	• Non-English Speaking [see instructions for recruitment and E-IRB Research Description section on same topic]
☐ Non-English Speaking	
☐ International Citizens	
☑ Normal Volunteers	• Prisoners
☐ Military Personnel and/or DoD Civilian Employees	• International Citizens [HTML] (DoD SOP may apply [PDF])
☑ Patients	• Military Personnel and/or DoD Civilian Employees (DoD SOP may apply [PDF])
☐ Appalachian Population	

The next questions involve assessment of the study relative to potential recruitment of subjects with impaired consent capacity (or likelihood).

☐ Check this box if your study does not involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). (you will not need to answer the impaired consent capacity questions)

Does this study focus on adult subjects with any of the clinical conditions listed below that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

○ Yes ◉ No

If Yes, go to the following link and complete and attach the indicated form unless you are filing for an exemption certification: http://www.research.uky.edu/ori/ORIForms/FormT/Scale.asp

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

You must check the box for at least one of the consent items and/or check mark one of the waivers, then if applicable attach the corresponding document(s) **as a PDF** (if open to enrollment).

After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

Consent/Assent Tips:

For your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and revise to be in accord with your research project.

- **It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.**
- **If you have multiple consent documents, be sure to upload each individually (not all in a combined file).**
- **Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".**
- **Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.**
  Document Types that do NOT get an IRB approval stamp are:
  - **"Highlighted Changes",**
  - **"Phone Script", and**
  - **"Sponsor's Sample Consent Form".**

☐ Informed Consent Form (and/or Parental Permission Form)
☐ Assent Form
☐ Cover Letter (for survey/questionnaire research)
☐ Phone Script (and/or Assent Script)
☑ Informed Consent/HIPAA Combined Form
☐ Debriefing and/or Permission to Use Data Form
☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol

Additional Resources:

- Issues and Sample Consent Language for Specimen Banking Studies [PDF]
- Sample Research Repository Consent [WORD]
- Instructions for Proposed Informed Consent Document [HTML]
- Instructions for Proposed Assent Form [HTML]

Attachments

Attach Type	File Name
Informed ConsentHIPAA Combined Form	INCREASE Form C V5.pdf

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval for waiver of the requirement for the informed consent process, or alteration of some or all of the elements of informed consent (i.e. medical record review, deception research, or collection of biological specimens), complete Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting waiver of the requirement for the informed consent process.

☐ I am requesting alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered, and/or omitted, and justify the alteration.

SECTION 2.

The IRB may consider your request provided that **all** of the following conditions apply to your research and are appropriately justified. Explain in the space provided for each condition how it applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

☐ Request for Waiver of Documentation of Informed Consent Process

If you are requesting IRB approval for waiver of the requirement for documentation of informed consent (i.e. telephone survey or mailed survey, internet research, or certain international research), your research activities must fit into one of two regulatory options:

1) The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves participants who use illegal drugs).

2) The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script).

Select the option below that best fits your study, and explain in the space provided how your study meets the criteria for the selected regulatory option.

Note: The IRB cannot waive the requirement for documentation or alter the consent form for FDA-regulated research unless it meets Option #2 below. FDA does not accept Option #1.

Note: Even if a waiver of the requirement for documentation is approved by the IRB, participants must still be provided oral or written (e.g., cover letter) information including all required and appropriate elements of consent so they have the knowledge and opportunity to consider whether or not to participate. To help ensure required elements are included in your consent document, please use the **Cover Letter Template** as a guide: *English*- [WORD] [RTF], Spanish- [WORD] [RTF] The cover letter template was developed specifically for survey/questionnaire research; however, it may be useful as a guide for developing a consent document for other types of research as well.

○ **Option 1**

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant must be asked whether (s)he wants to sign a consent form; if the participant agrees to sign a consent form, only an IRB approved version should be used.

○ **Option 2**

a) The research presents no more than minimal risk to the participant:

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

STUDY PERSONNEL

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must save by hitting the 'Save Study Personnel Information' button.

◉ Yes ○ No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is being completed to meet the requirements of a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed as such below.
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR, MR) or 'Other Review", and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature, search for applicable personnel first, then click "select" by the listing for the person you want to add as study personnel to your protocol. For each individual selected, be sure to specify responsibility in the project, whether authorized by the principal investigator to obtain informed consent, AND denote who should regularly receive E-IRB notifications.

NOTE: Study personnel are required to receive human research protection (HSP) training before implementing any research procedures (e.g., CITI). For information about mandatory training requirements for study personnel, visit UK's FAQ's on Mandatory Training web page, or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (Jen.Hill@uky.edu) for credit.

Study personnel assisting in research project:

Add Personnel

My Study Personnel	Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	Removed?	Last Updated	Recorded Training	SFI
Details	Abner	Erin	Co-Investigator	SP	Y	N	PhD		Y	10/23/2015	N	12/18/2017	10025954	N
Details	Bardach	Shoshana	Co-Investigator	SP	Y	N	PhD		Y	01/16/2018	N	12/18/2017	10574656	N
Details	Beech	Brooke	Study Coordinator	DP	Y	Y			Y	07/31/2017	N	12/18/2017	12219565	N
Details	Bryant	Tammy	Data Collection	SP	N	N	PA-C		Y	06/01/2015	N	12/18/2017	00035014	N
Details	Burgess	David	Consultant/Advisor	DP	N	N	PharmD		Y	09/13/2016	N	01/11/2018	10925728	N
Details	Coy	Beth	Data Collection	SP	Y	N	ARNP		Y	07/02/2015	N	12/18/2017	00050716	N
Details	El Khouli	Riham	Data Analysis/Processing	SP	N	N	MD, PhD		Y	08/16/2016	N	12/18/2017	12216127	N
Details	Jicha	Gregory	Co-Investigator	DP	Y	N	MD, PhD		Y	03/10/2017	N	12/18/2017	00058463	N
Details	Lee	Kara	Consultant/Advisor	SP	N	N	PT, DPT		Y	11/10/2015	N	01/09/2018	10172905	N
Details	Martinez	Ashley	Data Analysis/Processing	SP	N	N	PharmD		Y	08/13/2016	N	12/18/2017	10987449	N
Details	Murphy	Richard	Co-Investigator	SP	Y	N	MBChB		Y	11/17/2016	N	12/18/2017	12002081	N
Details	Nichols	Heather	Project Assistance/Support	SP	N	N			Y	07/19/2017	N	12/18/2017	00004144	N
Details	Rigsby	Dorinda	Data Analysis/Processing	SP	N	N			Y	10/11/2017	N	12/18/2017	12058438	N
Details	Schmitt	Frederick	Co-Investigator	SP	N	N	PhD		Y	12/09/2015	N	12/18/2017	00003619	N
Details	Stevens	Hardin	Recruitment	SP	N	N			Y	05/17/2016	N	12/18/2017	00052953	N

RESEARCH DESCRIPTION

****!!!PLEASE READ!!!** Known Issue: The below text boxes do not allow symbols, web addresses, or special characters (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose unsaved information.**

Workaround(s):

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section, or under the Additional Information section to include the information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. For research involving investigational drugs, describe the previously conducted animal and human studies. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section. For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference in the applicable E-IRB "Study Drug" or "Study Device" section.

Alzheimer's disease (AD) is one of the most important public health issues facing our society today. Approximately 5 million Americans age 65 and older are currently living with AD,1 and this number will nearly triple by 2050.2 To forestall this impending burden, the 2015 National Alzheimer's Project Act (NAPA) report emphasized the need to identify effective prevention strategies that can delay onset of symptomatic AD.3 The biological disease course of AD has been elucidated, consisting of a 10-20 year prodromal period with buildup of amyloid plaques and neurofibrillary tangles, without overt symptomatic cognitive or functional decline. The duration of this prodromal period is dependent on the rate of pathologic progression offset by compensatory mechanisms, collectively referred to as cognitive reserve (Figure 1).4 While much emphasis has been placed on developing and testing effective disease-modifying strategies targeting this asymptomatic preclinical phase of AD (pAD), little emphasis has been placed on currently available strategies that target cognitive reserve during pAD. Previous research has validated the importance of building and preserving cognitive reserve to prolong the asymptomatic phase of pAD.4-6 Comorbid medical conditions, psychosocial stressors, and inappropriate medication use lower cognitive reserve leading to "unmasking" of dementia symptoms and hastening the onset of the symptomatic phase of AD. Interventions designed to bolster cognitive reserve including aerobic exercise,7,8 complex gameplay,9-11 diet,5,12-15 and, pharmacological interventions16,17 have shown promise but as yet have not been proven to delay onset of AD.4 As depicted in Figure 1, pharmacy interventions to optimize medication use may delay the substantial financial and societal impact of AD by maintaining elderly patients' cognitive reserve. In our recent pilot Medication Therapy Management (MTM) intervention trial we observed a 56% reduction in inappropriate anticholinergic drugs use in the elderly enrolled. These pilot data document theMTM efficacy to change inappropriate medication use and potentially delay AD symptoms by maintaining patients' cognitive reserve. Here we propose a randomized trial to expand this pilot and test MTM efficacy to reduce inappropriate medication use, bolster cognitive reserve and ultimately delay symptomatic AD.

Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section.

Specific Aim 1: Conduct a 12-month, randomized, placebo-controlled trial to evaluate the impact of our patient-centered, pharmacist-physician team MTM intervention in reducing unnecessary and inappropriate medication use in community-dwelling, elderly, non-demented subjects. Our team will specifically target the Beers 2015 list of inappropriate medications for those 65 years and older, and implement individualized, patient-centered alternative management strategies. Primary outcome measures will include pre- to post- intervention measures of: (1) use of inappropriate medications as measured by the Medication Appropriateness Index (MAI); 2) Cognitive Reserve Change Score (CRCS), defined as the difference in the scopolamine- challenged vs unchallenged measures on the neurocognitive score (defined below). Specific Aim 2: Evaluate the impact of preclinical amyloid burden on cognitive reserve deficits and decline (measured as CRCS) to evaluate efficacy of delaying symptomatic disease progression in pAD. Baseline determination of total brain relative standardized uptake values for amyloid ß- positron emission tomography will be used to examine the relative impact of preclinical AD pathology on CRCS at baseline and over time in the placebo group, as well as the interplay of pAD pathology with inappropriate medication use at baseline and optimization of medication use after one year of MTM intervention. Objectives: 1) Examine the effectiveness of the MTM intervention in reducing inappropriate medication use over the study period as assessed by the MAI (Aim 1). 2) Investigate the effects of baseline Aß-PET and medication appropriateness index (MAI) 35 on cognitive reserve, operationalized as the CRCS = scopolamine challenged test performance z score - unchallenged cognitive test performance z score (Aim 1 and 2). 3) Investigate the effects of MTM and changes in MAI on CRCS in subjects that are Aß-PET positive or negative over the one-year study period (Aim 1 and 2).

Study Design: Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo medication at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in this study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section. (Including the study design table from a sponsor's protocol is helpful to IRB members.)

Community-Based Participatory Research: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the

study.

Research Repositories: If the purpose of this submission is to establish a research repository describe the repository design and operating procedures. For relevant information to include, see question 22 of the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [PDF].

This is a 12-month, parallel arm, placebo-controlled study to be conducted at the University of Kentucky. 90 non-demented subjects with varying levels of Aß-PET positivity (estimated that 30 will meet threshold criteria for pAD) will be randomly assigned to treatment with the MTM intervention or placebo. Those assigned in the intervention arm might have medication changes recommended by the research team. A letter describing all the proposed changes will be sent to the participant's primary care physician (PCP). These changes will be recommended, but not forced on the participant and their PCP. The participant and their PCP will have final decision on accepting or rejecting the proposed changes in the medication plan. All subjects will undergo cognitive testing under both scopolamine challenged and unchallenged conditions within 4 weeks, as well as physical and neurologic exam, and Aß-PET scan at baseline. Cognitive testing under both scopolamine challenged and unchallenged conditions within 4 weeks, as well as physical and neurologic exam will be performed at study completion. Randomization will be stratified by Aß positivity on PET scans. If unbalanced between groups after randomization, age, gender, education, NART, and number of targeted inappropriate medications using Beers 2015 Criteria will be included in the analyses.

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Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners or others who are likely to be vulnerable. If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of these groups requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Provide the following information:

• A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
• A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
• The proposed dates of enrollment (beginning and end);
• The proposed sample composition of subjects.

You may reference grant application/sponsor's relevant protocol pages and attach as an appendix using the below attachment button.

We plan to enroll 90 participants. Eligibility and inclusion/exclusion criteria have been selected on the basis of efficacy endpoints and safety concerns and contraindications to scopolamine therapy or PET scanning to minimize the potential for adverse events. Recognized contraindications and medical conditions preventing the use of scopolamine patches or those requiring dosage adjustments will be screened for and subjects excluded from the protocol. Inclusion Criteria: 1. 65 years and older 2. Non-demented 3. No previous reaction or contraindication to scopolamine patch, or medical condition warranting dose adjustment in scopolamine including but not limited to: open angle glaucoma, gastrointestinal or urinary outlet obstructions, seizures, or psychosis. 4. No contraindications to Aß-PET scan including hypersensitivity to PET ligand or radiation exposures in the past year that would exceed the acceptable safe annual exposure in combination with the Aß PET 5. Medically stable and able to complete all study activities, as determined by the investigator 6. Reporting at least one potentially inappropriate medication as listed in the Beers 2015 criteria 7. Living in the community 8. Able to identify a study partner who will drive the participant to and from the scopolamine-challenged visits. 9. Willing to participate in this intervention study. Exclusion Criteria: 1. Allergy or other know intolerance to scopolamine patches 2. Narrow-angle glaucoma 3. Difficulty swallowing 4. Stomach or bowel problems (e.g., blockage, muscle weakness, ulcerative colitis) 5. Bleeding 6. Myasthenia gravis 7. Blockage of the urinary tract. 8. Seizures 9. Psychosis

Attachments

Subject Recruitment Methods & Privacy: Describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information. Describe the setting in which an individual will be interacting with an investigator. If applicable, describe proposed outreach programs for recruiting women and minorities as participants in clinical research.

Please note: Based upon both legal and ethical concerns, the UK Medical Institutional Review Board (IRB) will not approve finder's fees for research studies.

Subjects will be recruited using the following avenues: a. The existing normal control group (500 participants) followed by the UKADC under IRB#88-00102. No advertising will be performed. We will send out a letter to subjects in the UK ADC normal control cohort alerting them to the study and asking them to contact us if interested in participating (attached as appendix). b. Voter registry list available through IRB# 79-01185 (2134 community elderly). No advertising will be performed. We will send out a letter to subjects in

the UK ADC normal control cohort alerting them to the study and asking them to contact us if interested in participating (attached as appendix). c. Use of UK IRB-approved media outlets and exposure, physicians engaged in the memory disorders clinic, community physician or personal referrals. We will used an IRB approved flyer (attached as appendix).

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Advertising: Specify if any advertising will be performed. If yes, please see "Advertisements - Application Instructions" for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment" or "Advertising" on ORI's IRB Survival Handbook web page for the PI Guide to Identification and Recruitment of Human Subjects for Research [D7.0000] document [PDF]. If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities.

Below is a list of advertising venues we may employ during this study. We will ensure that any advertisement is reviewed and approved by the IRB prior to it being implemented. We will follow a social media site's terms of use for any posted recruitment efforts. Print advertisements: The study may recruit subjects through flyers, brochures, posters, Research Spotlights, bookmarks placed on campus and in the surrounding community (region) including but not limited to the UK Medical center, UK Clinics, Good Samaritan Hospital, student center, UHS, the 5 UK Center for Clinical and Translational Research wall mounts, Cardinal Hill, monitor screens, and area facilities and businesses. Paid print advertising: Subjects may be recruited through paid print advertisements: brochures, magazines, newspaper (e.g., Herald Leader, Bluegrass Area, Courier Journal, Cincinnati Enquirer, Health & Wellness, Chevy Chaser, Hamburg Journal, Business Lexington, or others surrounding area or region), radio (e.g., Sirius, Clear Channel, Cumulus, LM Communications, Public Radio), television spots, or scrolling information on community stations. Recruitment ads may also appear on billboards, Lextran buses, taxicabs, and other transportation methods. Internet and Social Media: This study may be advertised on internet webpages (e.g., UKclinicalresearch.com, ResearchMatch.org, CenterWatch, CISCRP, Craig's list, Lexington.MD, UK, CCTS); Social Media: e.g., UK_CCTS Facebook, UK_CCTS Twitter, or department research website,etc.). If advertised on UKClinicalresearch.com, the study flyer could include an option for interested individuals to enter and submit their contact information so that a research coordinator can contact them about participating. This study may also go out on email distributions list servs, e.g., the CCTS list serv. Research Participant Registries: Potential participants may be identified from registry databases. (e.g.: Vanderbilt University ResearchMatch.org, Women's Health Registry, Sanders Brown Center on Aging, Infectious Disease, Dentistry, Markey Cancer Center). Databases may also be owned and operated by non-UK research groups (e.g., Partnering groups and Health-related Associations, Recruitment Firms, Private Health Organizations: examples, MyTrialsFinder, PatientsLikeMe.com, etc.) UK Public Relations (College/Dept. PR personnel) and UK HealthCare venues: Articles and interviews about the researchers and research study may be promoted via UKNow, health columns in the Lexington Herald Leader or Kentucky living, and other media outlets. The study may also be promoted through UKPR and UHC social media webpages (Facebook and UK Twitter), and these posts may also use "boosts" to reach a larger audience. Research and study-related articles published on UKNow may contain standard language directing interested individuals on where to read more about research and current studies: You can make a difference through participating in research and discovery. To find more information, including a list of current studies at UK and access to studies nationwide, you can visit UKclinicalresearch.com, call 859.257.7856, or join ResearchMatch.org. UKPR and UK HealthCare marketing may create videos to promote research, researchers and their studies to local, regional and national media venues and on internal hospital monitors. UK HealthCare will place study recruitment flyers on their internal and external racks (e.g., UK pharmacies, clinics, UK Libraries and Lexington Libraries). Participants may be recruited using newsletters, such as In the Loop, Health Matters, Making a difference, and external news letters. The study may also be advertised through UKPR and UKHC outreach activities. UKHC and CCTS have booths at many events, and researchers and coordinators are invited to attend any events that pertain to their study populations. Researchers may participate in radio or TV interviews. General information about their research will be discussed and a phone number or website url for more information will be provided. Consenting members of the research team and/or consenting participants may be interviewed about the study for print, radio, or video which may be distributed via the aforementioned activities. ResearchMatch.org will be utilized as a recruitment tool for this protocol. ResearchMatch.org is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University as an IRB-approved data repository (see IRB#090207)." All interested participants that meet inclusion criteria will be invited for a screening visit. Doctors Jicha, Murphy or Beth Coy. ARNP will determine if potential subjects meet inclusion criteria. At this visit, the subject will receive an explanation of the purpose of the study, the nature of the participant's involvement, and will be asked to provide written informed consent if they remain interested in participating.

Attachments

Attach Type	File Name
Advertising	INCREASE_flyer_Version_3.pdf
Advertising	INCREASE Recruitment Letter Version 5 CLEAN.pdf

Informed Consent Process: Describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent (Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application), steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent (i.e., research involving adult subjects with impaired consent capacity) and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page. For additional information, see the "Informed Consent Standard Operating Procedures (SOPs)" [PDF].

Informed Consent for Research Involving Emancipated Individuals
If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the Informed Consent SOP [PDF].

Informed Consent for Research Involving Non-English Speaking Subjects
If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.

Research Repositories
If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the "University of Kentucky Issues to be Addressed and Sample Consent Language for Tissue/Specimen Repositories or Individual Studies Banking Material for Future Use" [PDF].

Prior to entering the study, the risks and benefits of participating will be explained to the participant by a member of the study team authorized to obtain informed consent. A signed and dated informed consent form will be retained by the investigator. The study participant will receive a copy of the informed consent form.

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Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project.

Screening Visit (Week -5 ± 2): Subject appropriateness and safety for the study will be assessed with thorough review of medical history, medication review, physical/neurological exam, vital signs, and ECG. SF-36 will assess pre- study perceived health status. Lifestyle Factor Questionnaire will further assess health history and current health status. A Baseline Questionnaire will assess motivation for participating and understanding of medications. Aß-PET will be performed to allow stratification at baseline. Approximately 4 hours. Baseline and EOS visit (Scopolamine-challenge; week -4 ± 1 & week 52 ± 1): Subject will apply scopolamine patch at ~8pm the night before this visit to ensure adequate plasma levels of scopolamine. Study partner will drive subject to and from appointment. Medical history and medication review will be performed to ensure no changes have occurred since prior visit. Vital signs will be obtained. Cognitive testing including TMTB, MoCA, CVLT will be performed. Following cognitive testing, subject will remove scopolamine patch. Baseline and EOS visit (Non-challenge; week 0 ± 1 & week 56 ± 1): Medical history and medication review will be performed to ensure no changes have occurred since prior visit. Vital signs will be obtained. Cognitive testing including TMTB, MoCA, and CVLT will be performed. MTM intervention vs. placebo distribution of educational materials on PIM use will be performed. SF-36, Lifestyle Factors Questionnaire, and End of Study (EOS) Questionnaire will be administered at the EOS visit to assess changes in health status. Month 3 & 9 visits (week 13 ± 1 & week 39 ± 1): Telephone check to screen for adverse effects, update medical history and medication review. Month 6 visit (week 26 ± 1): Medical history and medication review will be performed to ensure no changes have occurred since prior visit. Vital signs will be obtained MTM intervention vs. placebo distribution of educational materials on PIM use will be performed. Randomization: For randomization, subjects will be stratified by Aß positivity on PET scans; if age, gender, education, NART scores, and the number of targeted inappropriate medications using 2015 Beers Criteria are unbalanced between groups after randomization, they will be included in the analyses. Blinding: As the intervention is educational in nature, complete blinding of intervention is not possible. However, we will take the following steps in order to minimize potential bias and achieve the maximum level of blinding possible by this design: 1. When reviewing the medication list prior to the intervention, the coordinator, study pharmacist, and physician will be unaware of the group allocation. 2. Data analysis will be blinded to the intervention.

Attachments

Data Collection: List the data or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that the final copy will be submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form).

See attached data collection schedule table and surveys.

Attachments

Attach Type	File Name
DataCollection	INCREASE Study Procedures.pdf
DataCollection	Lifestyles Survey_V6.0_Initial Packet.docx
DataCollection	Lifestyles Survey_Follow-Up.docx
DataCollection	16 - SF-36.pdf
DataCollection	17 - Baseline Questionnaire.docx
DataCollection	11 - EOS Questionnaire.docx

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see FDA Guidance). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see ORI's Off-Site Research web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you have questions about the participation of non-UK sites/personnel.

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

Patient enrollment, medication and medical history data collection, and cognitive evaluations will be conducted in the UK-Alzheimer's Disease Center (ADC) Clinical Core facilities (1030 South Broadway). The participants will be followed by Dr. Daniela Moga and her research team which includes physicians (Dr. Greg Jicha will serve as primary medical contact), pharmacists, and postdoctoral assistants during the study. Dr. Lynne Eckmann is a local non-UK affiliated pharmacist with extensive experience in providing medication therapy management to elderly patients with multiple comorbid conditions. She is not affiliated with a company that has an IRB, and she has signed an Individual Investigator Agreement with the University of Kentucky. Though the likelihood of the participant having an acute untoward reaction during the study visits is very small, emergency medical equipment, medications and supplies will be at the physician's disposal should this need arise. PET scanning will take place at the UK PET facilities on Campus.

Potential Risks: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter while in the study. Please describe any physical, psychological, social, legal or other risks and assess their likelihood and seriousness.

Physical and neurological examinations, neuropsychological tests, and social and medical histories will be collected: Minimal physical, psychological, social, legal and other risks are associated with these procedures. However, the availability of health professionals, including an experienced dementia care clinical coordinator/neuropsychologist and the ready availability of two on-site social workers to work with patients and families throughout the clinical and research process further minimizes possible risks. Such risks by category include: • Memory and thinking testing: anxiety, stress or boredom • Social Risks: Breach of confidentiality could impact insurability, employability, reproduction plans, family relationships, immigration status, paternity suits, or result in stigmatization. • Psychological Risks: If information is disclosed, anxiety and stress may result from the impact of learning results. Additionally, the risk of psychological stress may exist for family members as well. Scopolamine challenge: Specific adverse events of concern regarding the scopolamine challenge include those associated with the use of anticholinergics in the elderly, including disorientation, confusion, and dizziness. Prior to baseline scopolamine challenge, medical history, concomitant medications, physical and neurologic exams, ECG will be performed to evaluate for potential unforeseen medical risks. The study physician will be responsible for determining if the subject is acceptable for randomization and scopolamine challenge. Subjects will be advised that the scopolamine patch may cause such effects and that they should avoid driving and operating heavy or otherwise dangerous machinery until off the patch for at least 24 hours. Study physicians are available 24-7 should any participant experience adverse side effects. Subjects are advised to have a study partner to drive and accompany them to and from the two study visits during which the scopolamine-challenge will occur. Aß-PET: Florbetapir F 18 Injection is approved by the United States Food and Drug Administration (FDA) to estimate amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's disease

and other causes of cognitive decline. Florbetapir (F 18) is an imaging agent that includes a small amount of radioactivity (radiation) necessary to create the PET scan images. The dose used in this study is below the level that has been shown to have an effect on the body. The total amount of radiation from the florbetapir (F 18) PET scan and PET scanner machine, is slightly more than a patient receives from a routine CT scan and about 3 to 6 times as much as the average person receives per year from natural and man-made radiation. Exposure to large amounts of radiation increases the risk of developing cancer. The most common side effect in completed studies with Florbetapir involving 555 subjects was headache. Additional uncommon side effects reported were nausea, dysgeusia, flushing, pruritus, urticaria, and infusion site rash. Musculoskeletal (muscle and bone) pain in the neck, shoulder, and back, fatigue, anxiety, claustrophobia, insomnia, dizziness, chills/feeling cold, and hypertension were also reported. There were other side effects, but none that occurred in more than one subject in the research studies.

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Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

a. Recruitment and Informed Consent: The study investigators will obtain Institutional Review Board (IRB) Approval for all proposed activities and IRB assurances have been filed with the Department of Health and Human Services. b. Assessment of Capacity: Our protocol includes capacity evaluation for all research subjects irrespective of cognitive status to ensure willingness to participate in the research which is performed by our trained licensed clinicians and recorded in our UK-specific research data collection for the proposed project for all subjects recruited from the ADC cohort. Subjects recruited from external sources including the Voter registration list, have not previously undergone capacity assessment. As such, we will require the mandatory use of the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) by the consenting staff member for all subjects enrolled. Subjects lacking capacity, will not be enrolled in the study, as their understanding and compliance with the medication management intervention is a critical part of the current study. c. Biobanking of Aß-PET: Biobanking of PET images will be required of all research subjects. This provides for sharing of de-identified images (as well as phenotypic) data with any investigators for the purpose of advancing research in the area of aging and dementia. This will be broadly defined in our consent to allow maximal use of these samples to further research in the field. The biobanking protocol will have no pre-specified time limit and images will be retained indefinitely unless they are withdrawn at the request of the study participant. d. Protections against Risk: The confidentiality of our research subjects will continue to receive high priority. Hard copies of data will be maintained in locked files with access only to key individuals. All information collected on human subjects will be stored in the ADC master database with access to this data strictly monitored. The research part of the database is referenced only by subject code numbers. We appreciate the confidence that our subjects place in us through their participation in our programs. Guaranteeing the privacy of subject records will continue to be an essential function for all personnel involved with this data. Procedures utilized as a part of our research, e.g., cognitive testing, should not require medical or professional intervention. The Inclusion/Exclusion criteria is specifically designed to minimize risk for the scopolamine challenge and Aß-PET scan. We do not anticipate SAEs in relation to the current protocol or interventions. However, our physicians and professional staff will be available if a problem is identified. e. Staff Qualifications, Training, and Certifications in Human Subjects Research: We will keep private all research records that identify participants to the extent allowed by law. Information obtained from the participant will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. The participant will not be personally identified in these written materials. Provisions to guard against the potential risks and discomforts discussed in section 9 are as follows: Every precaution to prevent a direct study injury will be taken by medical personnel and the investigators. The research participant will be followed by physicians, physician assistants, registered nurses, pharmacists, and other research staff members for the duration of the individual's participation in the research study. Routine care will be provided by the hospital staff. Emergency medical equipment, medications and supplies will be at the physician's disposal should the participants have an acute untoward reaction. The participants will be monitored for clinical adverse experiences throughout study therapy. Throughout the study, all adverse events will be monitored and recorded.

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc…), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for Protection of Vulnerable Subjects [C3.0100] [PDF].

Our research subjects will receive regular medical and cognitive assessments in addition to the interdisciplinary medication management intervention that is specifically designed to ensure maximal quality of care for all research participants. In addition, our research subjects are traditionally altruistic individuals who want to aid in the advancement of knowledge related to AD. Many have had family members or friends affected by AD and appreciate the need for additional research. These benefits clearly outweigh the greater than minimal risks of the protocol and procedures in the proposed application.

Available Alternative Treatment(s): Describe alternative treatments and procedures that might be advantageous to the subjects, should they choose not to participate in the study. This should include a discussion of the current standard of care treatment(s).

Participants who do not want to take part in the study could review their medications with their physicians and pharmacist and have them adjusted accordingly outside the protocol.

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Research Materials, Records and Privacy: Identify the sources of research material obtained from individually identifiable living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):
If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [PDF].

The investigative team maintains the right to keep, preserve, use and dispose of the findings of this investigation in accordance with University of Kentucky IRB and Records Management guidelines. Data and study records will be maintained for six years after the completion of this study. Officials of the University of Kentucky maintain the right to inspect the records of the study at any time. Investigational records from this study will be maintained in a confidential manner; participant names will not be associated with any published results.

Confidentiality: Specify where the data/specimens will be stored and how the researcher will protect both the data and/or specimens with respect to privacy and confidentiality. Address physical security measures (e.g., locked facility, limited access); data security (e.g., password-protection, data encryption); safeguards to protect identifiable research information (e.g., coding, links, certificate of confidentiality); and procedures employed when sharing material or data, (e.g., honest broker (if applicable), written agreement with recipient not to re-identify). If you plan to procure, store, and/or share material (tissue/specimens/data) expressly for use in current or future research, describe measures that you will take to secure and safeguard confidentiality and privacy.

Provide a time table for destroying the data/specimens and identify how they will be destroyed, or provide rationale for perpetual maintenance [Note: The investigator is responsible for retaining the signed consent and assent documents and IRB research records for at least six years after study closure as outlined in the Study Closure SOP [PDF]. If the research falls under the authority of FDA or other regulatory agency, the investigator is responsible for retaining the signed documents and IRB records for the period specified if longer than six years after completion of the study]. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. Also, specify who will access the identified data/specimens, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable, describe procedures for sharing data/specimens with entities not affiliated with UK.

> *NIH-funded genomic research*: The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data consistent with the informed consent of study participants from which the data was obtained. If you are submitting genomic data to an NIH data repository, describe your NIH data sharing plan.

Please note: The IRB expects researchers to access the minimal amount of identifiers to conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "Confidentiality and Data Security Guidelines for Electronic Data" [PDF].

Also please note that storage of data on cloud services may not be appropriate and is subject to applicable university policies regarding the use of cloud services. If deemed too sensitive or inappropriate to be stored or collected using cloud services, the IRB may require an alternate method of data storage in accordance with applicable university policies and the electronic data security guidance document referenced above.

If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriate protected.

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We will make every effort to keep confidential all research records that identify the subject to the extent allowed by law. We will make every effort to prevent anyone who is not on the research team from knowing that the participant gave us information, or what that information is. Participant information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. Participants will not be personally identified in these written materials. We may publish the results of this study; however, we will keep the participant's name and other identifying information private. Electronic data with PHI are stored in the University of Kentucky's medical database that has limited medical personnel access, is password protected, and monitored for abnormal activity. Incidental materials containing subject identifiers will be shredded or incinerated. Participant consent forms and demographic sheets including each participant's name, date of birth, and contact information along with basic demographic information and a unique study-specific participant identification number (PIN) will be stored in a locked cabinets in the College of Pharmacy, 241 BPC or at Sander-Brown Center on Aging, 1030 South Broadway, Suite #5, Lexington, KY. There are some circumstances in which we may have to show participant information to other people. For example, the law may require us to show their information to a court or to tell authorities if they report

information about a child being abused or if they pose a danger to themselves or someone else. Officials of the University of Kentucky, the Sanders-Brown Center on Aging, Center for Clinical and Translational Science and their agents/representatives, and the College of Pharmacy may look at or copy pertinent portions of records that identify our subject.

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Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

Participants could receive up to $200 for taking part in the study. Participants will be compensated $100 for each scopolamine challenge visit, to allow for transportation or lost wages costs for study partners that provide such service. Participant payment will be in the form of a $100.00 Visa card which will be issued at the completion of the visit.

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

There will be no cost to participate in this study. All tests and procedure required by the protocol are being done for the sole purpose of the study. Parking during study visits will be provided at no cost. The participant and/or their insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment they receive during this study that they would normally receive for their condition. These are costs that are considered medically reasonable and necessary and will be part of the care they receive if they do not take part in this study. The University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because a participant gets hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages lost if a participant is harmed by this study. The medical costs related to care and treatment because of research related harm will be the subject's responsibility or may be paid by their insurer if they are insured by a health insurance company. Subjects will be instructed to ask their insurer if they have any questions regarding their insurer's willingness to pay under these circumstances. If the participant is covered by Medicare or Medicaid they will be instructed to contact Medicare by calling 1-800-Medicare (1- 800-633-4227) or Medicaid by calling 1-800-635-2570. A co-payment/deductible may be required by their insurer or Medicare/Medicaid even if the insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be substantial. In this study, the study doctors and pharmacists may recommend changes to the participant's medications that could potentially result in higher costs to them (deductible or other out-of-pocket expenses). The study team will work with the participant to find the lowest cost alternatives and if financial issues cannot be resolved, the study team is OK with the participant continuing with their current medications rather than accepting potentially higher cost changes. If participants choose to accept a higher cost medication as part of the recommended medication changes, this cost will be will be their responsibility.

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, clinical research, or NIH-funded/FDA-regulated clinical investigations.

If you are conducting greater than minimal risk research, clinical research, or your clinical investigation is NIH-funded/FDA-regulated, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, clinical research, or your clinical investigation is FDA-regulated, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

This protocol will be monitored by an independent DSMB comprised of a core multidisciplinary team that has been approved by the NIA. Contact information of the DSMB members can be found in the table below. Ad hoc members will be appointed as needed to provide specialized expertise. The DSMB will meet on a bi-annual basis to assess the ongoing safety of protocols. Protocols are scheduled for review prior to initiation and then on an interim basis during the trial. DSMB Information Neelum T. Aggarwal, MD (chair) - Rush University Medical Center. Experience in geriatric medicine. Email neelum_t_aggarwal@rush.edu Demetra E. Antimisiaris, PharmD, CGP, FASCP - University of Louisville. Experience in geriatric pharmacy and medication therapy management. Email demetra.antimisiaris@louisville.edu Chengjie Xiong, PhD - Washington University School of Medicine. Experience in conduct of randomized controlled trials. Email chengjie@wubois.wustl.edu

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Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

Participants will be encouraged to address any complaint to any member of the study team including the PI. They will be told that they can, at any time, call the Office of Research Integrity at the University of Kentucky at (859) 257-9428 or toll free at 1-866-400-9428.

Does your research involve **Non-English Speaking Subjects or Subjects from a Foreign Culture**?

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.

Include contact information for someone who can act as a cultural consultant for your study. The person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted. The consultant should not have any direct involvement with the study. If you do not know someone who would be willing to act as your cultural consultant, the Office of Research Integrity will try to find someone to fill this role (this may delay the approval process for your protocol). Please include the name, address, telephone number, and email of the person who will act as the cultural consultant for your study. For more details, see ORI's help page on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

For recruitment of Non-English speaking subjects, the consent document needs to be in the subject's native language. Download the informed consent template available in the E-IRB "Informed Consent/Assent Process" section and use it as a guide for developing the consent document. (Note: Your translated consent document can be attached to your application in the "Informed Consent" section; **be sure to save your responses in this section first**.)

If research is to be conducted at an international location, identify local regulations, laws, or ethics review requirements for human subject protection. If the project has been or will be reviewed by a local Ethics Committee, attach a copy of the review to the UK IRB using the attachment button below. You may also consult the current edition of the International Compilation of Human Research Standards

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?

○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing, and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

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1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the PI assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials, IDE regulatory requirements for SR device trials, and abbreviated regulatory requirements for NSR device trials. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe your (the PI's) experience/knowledge/training (if any) in serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if you have transferred any sponsor obligations to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for all investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the PI completed the mandatory PI-sponsor training prior to this submission?

○ Yes ○ No

If you (the PI) have completed equivalent sponsor-investigator training, you may submit documentation of the content for the IRB's consideration.

Attachments

HIPAA

Is HIPAA applicable? ◉ Yes ○ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

If yes, check below all that apply and attach the applicable document(s):

☑ HIPAA De-identification Certification Form
☐ HIPAA Waiver of Authorization

Attachments

STUDY DRUG INFORMATION

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve any use of a drug in a human other than the use of an approved drug in the course of medical practice?

◉ Yes ○ No

If yes, complete the questions below. Additional study drug guidance [HTML]

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Scopolamine patch

Note: Inpatient studies are required by Hospital Policy to utilize the Investigational Drug Service (IDS). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☑ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ◉ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Checkmark this if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND).

- FDA's Expanded Access Program Information (e.g., treatment IND)
- Guidance and definitions: "Expanded Access SOP" [PDF]

Please also complete and attach the Study Drug Form (required):

[PDF]

Attachments

Attach Type	File Name
StudyDrug	Study Drug Attachment INCREASE.pdf
StudyDrug	Transderm Scop Package Insert.pdf

STUDY DEVICE INFORMATION

A DEVICE may be a:

- component, part, accessory;
- assay, reagent;
- software or computer/phone application;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

○ Yes ◉ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer “no” above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE) or Humanitarian Device Exemption (HDE) application? See UK HUD SOP [PDF] for guidance.

○ Yes ○ No

If Yes, list IDE or HDE #(s) and complete the following:

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment or Compassionate Use IDE under the Food and Drug Administration (FDA) Early Expanded Access program.

- FDA's Early Expanded Access Program Information
- Guidance and definitions: "Medical Device Clinical Investigations, Compassionate Use, and Treatment IDE SOP" [PDF]

Does the intended use of any device used in this study meet the regulatory definition of Significant Risk (SR) device?

○ Yes. Device(s) as used in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential

for serious risk to the health, safety, or welfare of a subject.

○ No. All devices, as used in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Please also complete and attach the Study Device Form (required):

[PDF]

Attachments

RESEARCH SITES

In order for this section to be considered complete, you must click "SAVE" after ensuring all responses are accurate.

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☐ UK Classroom(s)/Lab(s)
- ☑ UK Clinics in Lexington
- ☐ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☑ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's Off-site Research Instructions web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

List all other non-UK owned/operated locations where the research will be conducted:*

*A letter of support and local context is required from non-UK sites. Click HERE for more information.

Attachments

B) Is this a multi-site study for which you are the lead investigator or UK is the lead site? ○ Yes ◉ No

If **YES**, you must describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites in the E-IRB "Research Description" section under *Resources*.

If the non-UK sites or non-UK personnel are *engaged* in the research, there are additional federal and university requirements which need to be completed for their participation, such as the establishment of a cooperative IRB review agreement with the non-UK site. Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

RESEARCH ATTRIBUTES

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

- ☐ Academic Degree/Required Research
- ☑ Aging Research
- ☐ Alcohol Abuse Research
- ☐ Cancer Research
- ☐ Certificate of Confidentiality
- ☑ CCTS-Center for Clinical & Translational Science
- ☑ Clinical Research
- ☑ Clinical Trial
- ☐ Clinical Trial Multicenter(excluding NIH Cooperative Groups)
- ☐ Clinical Trial NIH cooperative groups (i.e., SWOG, RTOG)
- ☐ Clinical Trial Placebo Controlled Trial
- ☑ Clinical Trial UK Only
- ☐ Collection of Biological Specimens
- ☑ Collection of Biological Specimens for Banking
- ☐ Community-Based Participatory Research
- ☐ Data & Safety Monitoring Board
- ☐ Data & Safety Monitoring Plan
- ☐ Deception
- ☐ Drug/Substance Abuse Research
- ☐ Educational/Student Records (e.g., GPA, test scores)
- ☐ Emergency Use (Single Patient)
- ☐ Genetic Research
- ☐ Gene Transfer
- ☐ GWAS (Genome-Wide Association Study) or NIH-funded study generating large scale genomic data
- ☐ International Research
- ☐ Internet Research
- ☐ Planned Emergency Research Involving Waiver of Informed Consent
- ☐ Pluripotent Stem Cell Research
- ☐ Recombinant DNA
- ☐ Survey Research
- ☐ Transplants
- ☐ Use of radioactive material, ionizing radiation, or x-rays [Radiation Safety Committee review required]
- ☐ Vaccine Trials

Click applicable listing(s) for additional requirements and/or information:

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality
- CCTS (Center for Clinical and Translational Science)
- Clinical Research
- Clinical Trial

  Determine if research meets NIH definition of clinical trial;
  *Reminder: Ensure compliance with clinicaltrials.gov registration requirements for applicable clinical trials and Good Clinical Practice (GCP) training requirements.

- Collection of Biological Specimens for Banking
- Collection of Biological Specimens
- Community-Based Participatory Research
- Data & Safety Monitoring Board
- Data & Safety Monitoring Plan
- Deception*

  *For deception research, also go to the Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Emergency Use (Single Patient) [attach Emergency Use Checklist]
- Genetic Research
- Gene Transfer
- HIV/AIDS Research
- Screening for Reportable Diseases [E2.0000]
- International Research
- Planned Emergency Research Involving Waiver of Informed Consent*

  *For Planned Emergency Research Involving Waiver of Informed Consent, also go to the Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Use of radioactive material, ionizing radiation or x-rays for research

FUNDING/SUPPORT

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☐ Not applicable

Check All That Apply

- ☐ Grant application pending
- ☑ (HHS) Dept. of Health & Human Services
  - ☑ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Other:

Click applicable listing(s) for additional requirements and/or information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info]
- National Science Foundation
- (DoEd) U.S. Department of Education
- (DoJ) Department of Justice or Bureau of Prisons
- (DoE) Department of Energy
- (EPA) Environmental Protection Agency

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

National Institute on Aging

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application:

Add Related Grants

Grant/Contract Attachments

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP [PDF] for details).

○ Yes ◉ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

OTHER REVIEW COMMITTEES

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

○ Yes ◉ No

Additional Information

- ☐ Institutional Biosafety Committee
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- Institutional Biosafety Committee (IBC)--Attach required IBC materials
- Radiation Safety Committee (RSC)-- For applicability, see instructions and/or upload form [WORD] [RTF]
- Radioactive Drug Research Committee (RDRC)--information
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)**--Attach MCC PRMC materials, if any, per instructions
- See requirement of Office of Medical Education (OME)
- See requirement of Graduate Medical Education Committee (GME)

Attachments

**** If you are proposing a study involving cancer research, be sure to have "Cancer Research" marked in the E-IRB "Research Attributes" section.** If your study involves cancer research, ORI will provide a copy of your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

Do you want specific information inserted into your approval letter? ○ Yes ◉ No

Approval Letter Details (e.g., serial #):

Submission Description: If you wish to have specific details included in your approval letter (e.g., serial #, internal tracking identifier, etc…), provide that information here as you wish it to be seen on the approval letter. These details will be automatically merged into a field at the top of the approval letter when it is generated. If these details need to be changed as a result of revisions or modifications to the application, you are responsible for updating the content of the field below accordingly.

Protocol/Product Attachments - For each item checked, please attach the corresponding material.

- ☐ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☐ Drug Documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.)
- ☐ Device Documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.)
- ☑ Other Documents

Protocol/Product Attachments

NOTE: Instructions for Dept. of Health & Human Services (DHHS)-approved protocol [HTML]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

Additional Materials:

If you have other materials you would like to include in your application for the IRB's consideration, please attach using the Attachments button below.

[To view what materials are currently attached to your application, go to "Application Links" in the menu bar on the left and click "All Attachments".]

Attachments

Attach Type	File Name
AdditionInfoConsiderations	CR 16-0375-F2L SN017.pdf
AdditionInfoConsiderations	INCREASE Form T.PDF

SIGNATURES (ASSURANCES)

On all IRB applications there is a requirement for additional assurances by a Department Chairperson (or equivalent) [hereafter referred to as "Department Authorization"], and when applicable, a Faculty Advisor (or equivalent), which signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans.

For a list of responsibilities reflected by signing the Assurance Statement, download the guidance document "What does the Department Chairperson's Assurance Statement on the IRB application mean?"

Required Signatures:

First Name	Last Name	Role	Department	Date Signed	
Daniela	Moga	Principal Investigator	Pharmacy Practice & Science	01/11/2018 11:45 AM	View/Sign
David	Burgess	Department Authorization	Pharmacy Practice & Science	01/11/2018 01:10 PM	View/Sign

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☑ Furthermore, by checking this box, I also attest that I have appropriate facilities and resources for conducting the study. If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the categories specified in the Protocol Type: Exemption Categories section.

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Please notify the personnel required for signing your IRB application after sending for signatures. Once all signatures have been recorded, you will need to return to this section to submit your application to ORI.

Department Authorization

☑ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator is knowledgeable of the additional regulatory requirements of the sponsor and can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

SUBMISSION INFORMATION

Each Section/Subsection in the menu on the left must have a checkmark beside it indicating the Section/Subsection has been completed; otherwise your submission for IRB review and approval will not be able to be sent to the Office of Research Integrity/IRB.

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and a message will be forthcoming to notify you of the date.

Your protocol has been submitted.

The PI must login to submit this protocol.

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.059	pkma223	3/6/2018 3:56:01 PM
	Stamped Consent Form	INCREASE Form C V5.pdf		0.222	pkma223	3/6/2018 3:56:01 PM
	AdditionInfoConsiderations	INCREASE Form T.PDF	Form T	0.224	pkma223	1/31/2018 3:56:02 PM
	AdditionInfoConsiderations	CR 16-0375-F2L SN017.pdf	Continuation Review 2018	2.245	bfbe223	1/11/2018 10:18:21 AM
	DataCollection	11 - EOS Questionnaire.docx		0.015	bfbe223	1/9/2018 5:17:46 PM
	DataCollection	17 - Baseline Questionnaire.docx		0.018	bfbe223	1/9/2018 5:17:32 PM
	DataCollection	16 - SF-36.pdf	SF-36	0.064	bfbe223	1/9/2018 5:16:55 PM
	DataCollection	Lifestyles Survey_Follow-Up.docx	EOS Lifestyles Survey	0.091	bfbe223	1/9/2018 5:16:24 PM
	DataCollection	Lifestyles Survey_V6.0_Initial Packet.docx	Initial Lifestyles Survey	0.062	bfbe223	1/9/2018 5:15:59 PM
	DataCollection	INCREASE Study Procedures.pdf		0.261	bfbe223	1/9/2018 5:15:10 PM
	Advertising	INCREASE Recruitment Letter Version 5 CLEAN.pdf		0.045	bfbe223	12/19/2017 12:45:36 PM
	Advertising	INCREASE_flyer_Version_3.pdf		1.191	bfbe223	12/19/2017 12:45:22 PM
	StudyDrug	Transderm Scop Package Insert.pdf		0.543	bfbe223	12/19/2017 9:34:20 AM
	StudyDrug	Study Drug Attachment INCREASE.pdf		0.304	bfbe223	12/19/2017 9:32:16 AM
	Informed ConsentHIPAA Combined Form	INCREASE Form C V5.pdf		0.100	bfbe223	12/18/2017 4:04:52 PM

Protocol Changes

Protocol Number: 43239

No Changes

There are no recorded changes tracked for this protocol.

Study Personnel Changes:

No Changes

There are no recorded changes to study personnel.