



Office of Research Integrity  
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Continuation Full Review  
Modifications Approved: Study Personnel; Research Description

Approval Ends  
September 23, 2015

IRB Number  
11-0750-F6A

TO: Jeffery Talbert, Ph.D.  
Pharmacy Practice & Science/Institute for Pharmaceutical Outcomes & Policy  
185 BioPharm Complex 0596  
PI phone #: (859) 323-7141

FROM: Chairperson/Vice Chairperson  
Medical Institutional Review Board (IRB)

SUBJECT: Approval of Protocol Number 11-0750-F6A

DATE: September 25, 2014

On September 24, 2014, the Medical Institutional Review Board approved your protocol entitled:

*Umbrella IRB for Use of Health Information in the CCTS Enterprise Data Trust (EDT)-UK HealthCare dataset*

Approval is effective from September 24, 2014 until September 23, 2015 and extends to any consent/assent form, cover letter, and/or phone script. If applicable, attached is the IRB approved consent/assent document(s) to be used when enrolling subjects. [Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.] Prior to the end of this period, you will be sent a Continuation Review Report Form which must be completed and returned to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigator's responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" from the Office of Research Integrity's IRB Survival Handbook web page [<http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#PIresponsibilities>]. Additional information regarding IRB review, federal regulations, and institutional policies may be found through ORI's web site [<http://www.research.uky.edu/ori/>]. If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at (859) 257-9428.

*Terry Malone, Ed.D., P.T.*  
Chairperson/Vice Chairperson

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Umbrella IRB for Use of Health Information in the CCTS Enterprise Data Trust (EDT)-UK HealthCare dataset

Verified "Consent Authorized" Y

PI	Name	Trained:	Date:	DunnChad:	Citi:	Other Test	Authorized
PI	Talbert Jeffery	Y	12/19/12	N	Y		Y
	Jeff.Talbert@uky.edu					Co-investigator	
	HSP - Dunn/Chadwick - 12/20/2011, Group 4 HIPAA		12/19/2012			Ph.D.	

KP	Corum Kristi	Y	08/11/14	N	Y	N	N
	kcorum@uky.edu					DB Infrastructure Securi	

KP	Harper Tamela	Y	04/15/13	N	Y	Y	N
	tjharp00@email.uky.edu					Project Manager	

KP	Harris Daniel	Y	03/10/14	N	Y	N	N
	daniel.harris@uky.edu					Developer/Honest Brok	
						BS	

KP	Henderson Darren	Y	08/15/14	N	Y	N	N
	dwhend0@uky.edu					Developer- Pulls Data F	

KP	Henry Keith	Y	09/23/12	N	Y	N	N
	keith.henry@uky.edu					Data Warehouse Archit	

KP	Jones Keisha	Y	08/19/14	N	Y	N	N
	stellamae26@gmail.com					Developer - pull data H	
	HIPAA 8/19/14						

KP	Mainous Ryan	Y	08/19/14	N	Y	N	N
	ryan.mainous@uky.edu					Developer - pull data hc	

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Umbrella IRB for Use of Health Information in the CCTS Enterprise Data Trust (EDT)-UK HealthCare dataset

Verified "Consent Authorized" Y

			Trained:	Date:	DunnChad:	Citi:	Other Test	Authorized
KP	McLaughlin	Andrew	Y	08/11/14	N	Y	N	N
	ajmcla2@uky.edu					Developer- pull data Hc		

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KP	Richards	Peggy	Y	05/22/14	N	Y	N	N
	peggy.richards@uky.edu					Developer--Operations		

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KP	Wyatt	Marcy	Y	07/14/14	N	Y	N	N
	mwyatt@uky.edu					Developer pull data Hoi		
	HIPAA 7/15/14							

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KP	Zhong	Dongying	Y	04/21/14	N	Y	N	N
	dyzhong@kcr.uky.edu					Developer- ETL,pull da		

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