

**Protocol Data Migration Key**

**Kushnir, Vladimir** 201501024  
Active  
You MUST click the Save Changes button to update the database.

Update Protocol Database Protocol ID: #173

Title: Adenoma Detection with Cap-Assisted Versus Endocuff Assisted Colonoscopy: A Randomized Crossover Study **1**

PRMC Number: 15-X042 **2**

WU-IRB Number: 201501024 **2** WU-IRB Legacy #

Coordinating Group #

CTRP #: NCI-2015-00839 **2** ClinicalTrials.gov #

Financial Tracking # **23**

Study Coordinator: Hollander, Thomas (314)747-1973 tholland@dom.wustl.edu **26**

Regulatory Coordinator: Haren, Betty (314)454-5960 bharen@dom.wustl.edu **25**

Phase: N/A **3** Date Submitted to PRMC: 1/29/2015

IND/IDE Number:  Yes  No  Exempt **12**

Initial WU-IRB Approval: 4/15/2015

Current WU-IRB Approval: 4/15/2015

HSC Expiration: 4/13/2016

Locations (Check all that apply):  BJH - St. Louis  BJH - West County  BJH - St. Peters  BJH - South County

Study Type: Institutional, Primary Primary Purpose: Diagnostic (DIA) **8** Study Category: Detection (early)

Managing Group: IM - Gastroenterology **5\* & 22** Tags: T1-

Investigator Initiated:  Yes **6** Therapeutic:  Yes  No **7** Interventional:  Yes  No Scope:  National  Local **4**

Study Section: 1.Agent or Device **9\*\*** Accrual Opened: 4/15/2015 **18** Accrual Closure: Length of Accrual: 2 yrs

Show on Summary **9\*\***

Original BJH Target Accrual: 360 **13 - 14** Current BJH Target Accrual: 360 1 yr Target Accrual: 180 **16**

National Target Accrual: **13** Current Total Accrual: 0 Current BJH Only Accrual: 0

% Accrual Completion: 0 Nat'l StudyWide Accrual: Date StudyWide Updated Through:

Comments:

**Demographics**

- Title
- Protocol #s (IRB, CTRP...) – The IRB Legacy number was not migrated. The Protocol Search will search a variety of numbers tied to the protocol.

**Classifications**

- Phase
- Scope
- Age - Set as Adults unless the Managing Group is Pediatrics.
- Investigator Initiated
- Therapeutic
- Protocol Type
- DT4 Report Type - If SCC DB Show on Summary 4 is not checked, DT4 Report Type should be Not Applicable.

**Parameters & Oversight**

- Multi-center (Yes, if National Scope)
- Data Monitoring – Institutional Primary studies will be marked either PI or QASMC. Coop Group and Industry studies will be marked as External.
- Investigational Drug or Device – Only marked 'Yes' if the study has an FDA issued #

**Accrual & Completion**

- Target - # of patients needed for data analysis across all sites
- RC Lower Goal - # of patients needed from WUStL
- RC Upper Goal - # of people to consent - # approved by HRPO
- RC Annual Goal - # to register each year at WUSTL
- Affiliate Goal – # expected from affiliate sites (#13-#14)
- Duration (AccrualClosed – AccrualOpened)
- Completion Dates – Update with data from ClinicalTrials.gov

**Admin Group**

- Programs (T&C=STTP)
- Onc Group = Working Group in SCC DB
- Management Group
- Internal Account #

**Staff/Study Team** – review Staff tab in Oncore

- Reg Coordinator - Should have a Regulatory access role
- Study Coordinator - Primary CRA migrated from SCC, may add Secondary CRAs
- Registering & Treating MDs - migrated as Sub-Is
- Data Coordinator

**Tags**

- T1. Upload = Summary Accrual
- T2. Non-Cancer = Non-Oncology

**PC Console:**

Details	Management	Staff	Sponsor	IND/IDE	ClinicalTrials.gov / CTRP
<b>Protocol Details</b> History					
Protocol No.	2015-2 <b>2</b>	NCT Number			
Library	Oncology <b>T2</b>	Department	Alvin J. Siteman Cancer Center		
Organizational Unit	Siteman Cancer Center				
Title	Test case test <b>1</b>				
Short Title	test				
Objectives					
Phase	II <b>3</b>	Scope	Local <b>4</b>	Age	Adults <b>5*</b>
Drug Accountability		Investigator Initiated Protocol	Yes <b>6</b>	Involves Therapy	Yes <b>7</b>
Open For Affiliates Only	No	Summary Accrual Info. Only	No <b>T1</b>	Protocol Type	Treatment <b>8</b>
Cancer Control		Cancer Prevention		Data Table 4 Report Type	<b>9**</b>
Registration Center	Research Center	Involves Correlates or Companions		Data Monitoring	DSMC <b>11</b>
Includes Specimen Banking?	No	Companion Study?	No <b>10</b>	Multi-site Trial	No <b>12</b>
				Investigational Drug	No
				Investigational Device	No
<b>Accrual Information</b> <b>13</b> <b>14</b> <b>15</b>					
Protocol Target Accrual	50	RC Total Accrual Goal (Lower)	10	RC Total Accrual Goal (Upper)	50
RC Annual Accrual Goal	30	Affiliate Accrual Goal	50	Accrual Duration (Months)	36
<b>Completion Dates</b> <b>16</b> <b>17</b> <b>18</b>					
Primary Completion Date	08/31/2016 (Anticipated) <b>19</b>				
Study Completion Date	08/31/2015 (Anticipated)				

Details	Management	Staff	Sponsor	IND/IDE	ClinicalTrials.gov / CTRP
<b>Management Details</b> History					
IRB No.	<b>2</b>	Pharmacy No.		Priority Score	
PRMC No.		PRMC Review Required	Yes	QASMC Review Frequency (months)	
GCRS Participation		GCRS No.		GCRS Approval Date	GCRS Category
PDQ No.		NCI Trial ID	<b>2</b>	CTMS Export	No
Comments					
Coding Scheme	CTCAE v4.0	Automated eMPI	No	Automated Sequence No.	No
Internal Account No.	<b>23</b>	Hospital Account No.		Allow Duplicate Enrollment?	No
Allow On Treatment date to be entered before On Study date	No	Populate On Follow-Up Date with Off Treatment Date	No	Use Randomization Algorithm	
<b>Administrative Groups</b>					
Program Areas	<b>20</b>	Planned	Primary	Oncology Group	<b>21</b>
Breast Cancer Research Program (BCRP)	N	N		Breast Oncology	N
				Management Group	<b>22</b>
				Barnes-Jewish Hospital	N
<b>Flowchart</b>					
Flowchart	Path				
No information entered					