NCI CIRB Advarra WCG Other IRB:_____

HSHS Wisconsin Clinical Research Institute: New Protocol

Sponsor: _____	Protocol: _____	Version Date: _____

Principal Investigator: _____

PRE-APPROVAL

Clinical Research Specialist

Month done _____

_____ TFF
- ☐ Completed (CRA and Specialist Reviewed)
- _____ Patient waiting? ICF needed by: _____

_____ MCA/Financial Review
- _____ Obtain/build MCA with funding sheet
- _____ Review NCORP Credits/funding
- _____ Email Pharmaseek details on invoicing
- _____ Patient Payment Evaluation

_____ IRB Submission (NCI CIRB)
- _____ Submit Pill Diary, Drug Information Sheet if needed
- _____ Change status to IRB Pending in CREDIT

_____ Setup folders
- _____ Create or move electronic protocol folder to appropriate "IRB New Protocol" folder
- _____ Implant "new protocol folder template" if necessary
- _____Complion folder set up (if applicable)

_____ Download/ Store:
- _____ Protocol
- _____ Funding Sheet (NCI only)
- _____ Consent(s)
- _____ Patient Materials

If CIRB: _____ Initial Approval _____ Continuing Review
_____ Current Amendment Approval and Acknowledgement
Expiration Date _____

_____ IND Drug (s):
- _____ IB needed/obtained

List Drugs:____ _____

- _____IB CIRB Approval downloaded
- _____ Notify CRA to print drug specific temp information

_____ Finalize Documents:
- _____ Consent(s) # _____ ☐ _____ 2nd Review ☐ _____ Sponsor
  Version Date: _____
- _____ HIPAA ☐ _____ 2nd Review ☐ _____ Sponsor
- _____ IRB Application (Advarra/WCG)

_____ Additional Materials/ Requirements:
- _____ BEACON Service Now ticket:_____
- _____ Email Protocol to "EWD-CRI-New Clinical Trial" group:_____
- _____ Email Dr. Burnette to blast investigators: _____
- _____ Email CTSU RegPref with participating sites:_____
- _____ CTSU Regulatory requirements: _____
- _____ Essential Documents (1572, FDF, DOA, signature pages, etc.):_____
- _____ Patient materials: _____
- _____ Training: _____
- _____ Imaging/Credentialing: _____
- _____ Other: _____

_____ Research Sites conducting trial:

Check box if CTSU notified to open site; fill in blank with status to be entered in CREDIT at SVCRI activation

- ☐ _____ WI027 STV
- ☐ _____ WI153 SB
- ☐ _____ WI019 SHEC
- ☐ _____ WI067 STM
- ☐ _____ MI363 Manistique
- ☐ _____ MI175 OSF (email approval letter with application)
- ☐ _____ WI117 OF
- ☐ _____ WI022 SNS

NCI CIRB Advarra WCG Other IRB:_____

Clerical Support Associate

Done	Post approval	
_____	Copy IRB New Protocol Folder to Archives, then Rename IRB folder "Use Archived Folder".	
_____	Save New Protocol in Research Protocols drive.	
_____	Save New Protocol in GBO Research Protocols drive.	
_____	Save New Protocol in WI-Cancer Research Affiliates SharePoint.	
_____	Consent(s) and HIPAA:	_____ Verify Protocol and Consent Version Date
		_____ Save Word Copy _____ Archive PDF _____ Save PDF (ZZCOG)
_____	Submit Reg Docs:	☐ Email ☐ Upload Documents To: _____ Sponsor/Vendor System Date
		☐ Archive email ☐ Archive email received
		☐ _____ IRB Approval ☐ _____ Consent (s)
		☐ _____ Other:_____
_____	Update CREDIT:	☐ _____ Upload 1572 (if applicable) ☐ _____ Upload W9 (if applicable)
		_____ Upload HIPAA _____ Upload Consent(s)
		_____ NCT # _____ Confirm Arms Open
		_____ Consent Version Date _____ Protocol Version Date
		_____ Status to "Open further action needed at this site"
_____	EMR:	_____ Create "Research Study" in EPIC through Research Admin Billing Set Up SA: ☐ EWD ☐ WWD
		_____ Add protocol to EWD & WWD upcoming pt reports in EPIC

Clinical Research Specialist

_____	CREDIT:	_____ Check "Patient Registration Allowed"	_____ Assign: ☐ PI ☐ Staff
		_____ Uncheck "Disable Financial Tracking"	_____ Upload patient materials
		_____ Check "Financial Milestone Collection" for appropriate institutions	_____ Add to Review History Tab (CIRB – add approval and expiration date)
		_____ Update Protocol Status Note per site as needed	_____ Add Arms/Drugs/Credits/Trial Financials as applicable
		_____ COG study – Age 18 contacts for email of pt. birthdays	_____ Add MCA note to each arm status note (including if "Qualifying Trial" or "Not Qualifying Trial:
		_____ Add consent note for Optional Studies	_____ Add consent funding note
		_____ Type In Patient Statuses	_____ Add Protocol Notification for Medicare
_____	Verify complete	_____ Training Documentation	_____ MCA signed and filed
		_____ Essential docs Filed/Submitted	_____ BEACON protocol in production (if applicable)
		_____ Notify CRA to create DAR	_____ Notify CRA to order kits/QOLs (if appropriate)
_____	Study Specific Folder	_____ Create	_____ Update/Move Protocol Data Form
		_____ Move pertinent documents	_____ Upload Medicare Form
_____	ISF/Binder Check	_____ Create/rcvd physical binder from sponsor	
		_____ NTF about essential documents	
_____	Site approval	_____ CTSU Reg Pref/Sponsor Approval received	
		_____ Check CTSU Site Registration status for each site	
		_____ Change status in CREDIT to open at applicable sites (reference Page 1)	
		_____ Activated Date (enter date open to enrollment at site)	

Clinical Research Specialist: _____ Date:_____

NCI CIRB Advarra WCG Other IRB:_____

Clerical Support Associate: _____ Date: _____ _____ Archive Worksheet

HSHS St. Vincent Hospital Cancer Center

SWOG S1900E Drug Information Sheet

Name:_____ **MD:**_____

Drug: AMG 510

When To Take:

Total Dose:_____mg

- Take ____ mg (___ # of tablets of 120mg) by mouth daily (take all tablets at the same time)

- Take medication once a day, at the same time each day (no more than 2 hours prior to scheduled time and no later than 6 hours after that scheduled time).

- Take tablets with or without food. If you take stomach acid reducing medicines called proton pump inhibitors (i.e., Prilosec® and Nexium®), AMG 510 must be taken with food.

- Avoid eating grapefruit, grapefruit juice, or Seville oranges while taking AMG 510.

- Swallow tablets whole with plenty of water. Do not chew, crush, or break tablets. Do not take any tablets that are broken, crushed or partially dissolved.

- If you miss a day's dose, do not "make it up." Take the normal dose the next day. to the normal schedule the following day.

- If you vomit a dose within 15 minutes of the dosing and the total number of tablets taken are intact after visual inspection, dose should be re-taken.

- If you vomit more than 15 minutes after the dose, the dose should not be re-taken.

- If you accidentally take an extra dose during a day, skip next day's dose.

- If you need to take any histamine-2 (H2) blocking medicines, such as ranitidine (Zantac®) or famotidine (Pepcid®), record the date and time they were taken. Only take H2 blocking medicine 10 hours before AMG 510 and/or 2 hours after AMG 510.

Storage: Store AMG 510 tablets at controlled room temperature (59-86 °F) and protect from light.

Common Side Effects:

- Diarrhea

- Nausea

Please bring the empty bottle or any leftover capsules and your medication calendar to your next clinic visit.

HSHS St. Vincent Hospital Cancer Center

Patient Pill calendar SWOG S1900E

Name: _____ Pt ID:_____

Cycle # _____ Start Date _____ Start day (circle one): Sun M TU W Th F Sat

1. Take medication once a day, at the same time each day (no more than 2 hours prior to scheduled time and no later than 6 hours after that scheduled time).
2. Put the date in the box on the calendar and note the time of the dose each day.
3. Check off if the dose was taken or not.
4. Take tablets with or without food. If you take stomach acid reducing medicines called proton pump inhibitors (i.e., Prilosec® and Nexium®), AMG 510 must be taken with food.
5. Avoid eating grapefruit, grapefruit juice, or Seville oranges while taking AMG 510.ke up a missed dose.
6. Swallow tablets whole with plenty of water. Do not chew, crush, or break tablets. Do not take any tablets that are broken, crushed or partially dissolved.
7. Document any changes to taking the doses in the comments section provided below.

- If you miss a day's dose, do not "make it up." Mark it as a "missed" dose with the date and time. Take the normal dose the next day.
- If you vomit a dose within 15 minutes of the dosing and the total number of tablets taken are intact after visual inspection, dose should be re-taken. Record that this happened with date and time.
- If you vomit more than 15 minutes after the dose, the dose should not be re-taken. Record this as a "vomited" dose with the date and time.
- If you accidentally take an extra dose during a day, skip next day's dose. Record as "extra dose."
- If you need to take any histamine-2 (H2) blocking medicines, such as ranitidine (Zantac®) or famotidine (Pepcid®), record the date and time they were taken. Only take H2 blocking medicine 10 hours before AMG 510 and/or 2 hours after AMG 510.

8. If you develop any side effects from the capsule, record the side effect in the comments section with the date and time you developed the side effect.

If you have any questions,contact:_____ Telephone:_____

DAY	DATE	Dose taken	Time of dose	Comments
1		□ Yes □ No	____:____ am/pm	
2		□ Yes □ No	____:____ am/pm	
3		□ Yes □ No	____:____ am/pm	
4		□ Yes □ No	____:____ am/pm	
5		□ Yes □ No	____:____ am/pm	
6		□ Yes □ No	____:____ am/pm	
7		□ Yes □ No	____:____ am/pm	
8		□ Yes □ No	____:____ am/pm	
9		□ Yes □ No	____:____ am/pm	
10		□ Yes □ No	____:____ am/pm	
11		□ Yes □ No	____:____ am/pm	
12		□ Yes □ No	____:____ am/pm	
13		□ Yes □ No	____:____ am/pm	
14		□ Yes □ No	____:____ am/pm	
15		□ Yes □ No	____:____ am/pm	
16		□ Yes □ No	____:____ am/pm	
17		□ Yes □ No	____:____ am/pm	
18		□ Yes □ No	____:____ am/pm	
19		□ Yes □ No	____:____ am/pm	
20		□ Yes □ No	____:____ am/pm	
21		□ Yes □ No	____:____ am/pm	

Patient Signature:_____ Date:_____

CRA Review Signature:_____ Date:_____