

Pharmacy Checklist

Protocol Submission Checklist for Human Subject Research

Study Title:

Detailed medication preparation section of protocol must be attached to this sheet and submitted to **EACH** pharmacy impacted.

Greg Nocito, PharmD
Pharmacy Sr Manager
Good Samaritan Hospital
513-862-1933

Steve Shepherd, RPh
Pharmacy Manager
Bethesda North Hospital
513-865-1495

Jeff Coutts, RPh, BCOP
Infusion Pharmacy Manager
TriHealth Cancer Institute
513-853-1378

Leonard Kaes, RPh Pharmacy
Manager Ambulatory & Retail
Services
TriHealth
513-862-3550

THE FOLLOWING MUST BE RESOLVED TWO WEEKS PRIOR TO IRB MEETING:

- 1) Who is responsible for randomizing the patients? Research Pharmacy
*Randomization will be done by coordinator, but pharmacist will need to check system for assignment
- 2) Is the sponsor supplying all the study drug(s) and supplies? YES NO
◆ If not, what drug(s) is(are) the pharmacy responsible for supplying and charging?
- 3) Is a “dummy” medication ID and entry needed for charting? YES NO
- 4) How many patients are you expecting to enroll over what time period?
- 5) How much pharmacist time in minutes per patient is expected, including preparing and dispensing the medication and filling out accountability logs? /per patient *Per Visit
- 6) Is pharmacy expected to prepare the placebo for the control arm? YES NO
◆ If yes, did you budget for this? YES NO How much?
- 7) Pharmacy Fee. A Pharmacy fee of \$1,500 per site is due after the first patient is enrolled. An invoice will be cut by research and sent to the sponsor after IRB approval. When the fee is received it will be forwarded to the pharmacy manager. **Non-industry sponsored studies do not pay the pharmacy fee, i.e. COOPs and fellow/resident studies.**
- 8) Will the sponsor (or study nurses) provide protocol or IB to the pharmacists prior to study initiation?
 YES NO
◆ If no, why not?
- 9) Is the pharmacy manual available? YES NO
◆ If so, please submit with application.
◆ If no, why not?
- 10) Lead Study Coordinator
Contact number

TriHealth Pharmacy Use Only:

Signed/Approved _____ Date _____