HOLY CROSS HOSPITAL

Institutional Review Board
1500 Forest Glen Road
Silver Spring, MD, 20910-1484
(301) 754-7795
www.holycrosshealth.org

Holy Cross Hospital Institutional Review Board
Initial Review Submission Requirements

The following is a general list of items needed by Holy Cross Hospital Institutional Review Board to begin the review process for your research study. You will need to submit the Initial Review Submission Form once for each initial review submission. **If you have questions, call 301-754-7795 or 888-202-1859 or e-mailing hchmedstaff@onebox.com** for assistance.

ALL INITIAL REVIEW REQUESTS must include copies of the following:

- **Holy Cross Hospital IRB Initial Review Submission Form** (See attached)
- **Summary of research study**
- **Protocol**
- **Curriculum Vitae (CV)** for Principal Investigator and each Sub-Investigator
- **Consent form** (You will need to submit a paper copy and a copy on disk, Microsoft Word compatible. Refer to the Elements of Informed Consent for Holy Cross IRB Guidelines)
- **HIPAA Authorization Form** (Use Holy Cross IRB Template)
- **Research Agreement** (See attached)
- **Financial Conflict of Interest Screening and Disclosure Form** (See attached)
- **Investigational Brochure** (If Applicable)
- **Form FDA 1572** (if applicable)
- **Report of Prior Investigations** (If Applicable)
- **Copies of all information to be given to patients concerning the research project and the potential risks to patients** (If any information is to be given verbally, a written summary of such verbal information must be provided.)

If you would like to request review of a change in research or subject recruitment material for research that is currently under Holy Cross IRB oversight, please submit your requests using the Changes in Research Submission Form. These forms are available on our website or can be requested by calling 301-754-7795 or e-mailing royda@holycrosshealth.org.

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INITIAL REVIEW SUBMISSION FORM

PROTOCOL INFORMATION		
SPONSOR:	**SPONSOR PROTOCOL NO.**	**HOLY CROSS IRB NO.**
PROTOCOL NAME:		
EXPECTED TOTAL NUMBER OF SUBJECTS: **_____TO BE ENROLLED IN STUDY** **_____TO BE ENROLLED AT HOLY CROSS HOSPITAL**	**AGE RANGE OF SUBJECTS:** **GENDER OF SUBJECTS: __M __F**	
EXPECTED COMPLETION DATE:		
ASSESSMENT OF RISK: ☐ No more than minimal risk ☐ Greater Than Minimal ☐ High	**REVIEW TYPE:** ☐ Full Board ☐ Expedited ☐ Facilitated Review (NCI IRB)	
Does the principal investigator have privileges at Holy Cross Hospital? ☐ Yes ☐ No. If no, who will be the point of contact for the study at Holy Cross Hospital?		

ADMINISTRATIVE INFORMATION			
1.	**PI Name:**		
1a.	**PI Company Name**		
1b.	**PI Mailing Address**		
1c.	**City:**	**State:**	**Zip Code:**
1d.	**PI Phone:**	**PI Fax:**	**PI Email:**
2.	**Sub Investigator name(s):**		
2a.	**Sub-Investigator Phone:**	**Sub-Investigator Fax:**	**Sub-Investigator Email:**
3.	**Study Coordinator name:**		
3a.	**Study Coordinator Phone:**	**Study Coordinator Fax:**	**Study Coordinator Email:**

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TYPE OF RESEARCH		
4.	**Indicate the type of research study being submitted:** ☐ Biomedical ☐ Drug ☐ Biologic ☐ Device ☐ Social/Behavioral ☐ Tissue/Blood Bank ☐ Other (describe):	
FOR DRUG/BIOLOGIC STUDIES ONLY		
5.	Does this research involve either an Investigational New Drug, Biologic, or Investigational use of a Marketed Drug or Biologic?	☐ Yes ☐ No
	If so, provide a copy of the investigator's Drug Brochure.	
FOR DEVICE STUDIES ONLY		
6.	Is the device being used in this research study approved by FDA?	☐ Yes ☐ No
Provide one of the following: ☐ FDA letter granting an Investigational Device Exemption for the proposed use. ☐ Letter from the sponsor stating that the study is a non significant risk device study ☐ Letter explaining why the investigation is exempt from the IDE requirements under 21 CFR 812.2 (c).		
INFORMED CONSENT FORM PROCESS		
7.	Does the protocol allow for non-English speaking subjects?	☐ Yes ☐ No
If yes, indicate which languages are anticipated:		
ADVERTISEMENTS		
8.	Will any type of advertising materials be utilized to recruit research subjects for this study?	☐ Yes ☐ No
Please attach a copy of the recruitment materials and indicate the type. Check **all** that apply. ☐ Brochure ☐ Newspaper Advertising ☐ Internet Sites ☐ Direct Mailing ☐ Radio / TV Advertising ☐ Email Announcements ☐ Postings ☐ Public Service Announcements ☐ Other, please specify		

9.	**If this study will be utilizing any of the following resources at Holy Cross Hospital, please check all resources that apply and obtain signatures from the director of each department.** ☐ **Lab** _____ ☐ **Pharmacy** _____ ☐ **Radiology** _____

INVESTIGATOR ACKNOWLEDGEMENT	
I certify that all responses provided on this Initial Review Submission Form are true and accurate. I agree to promptly report to Holy Cross IRB, all changes in research activities and all unanticipated problems involving risks to human subjects. Additionally, I certify that I will not make any changes in the research without IRB approval.	
_____ **Signature of Principal Investigator**	_____ **Date**
_____ **Printed Name of Principal Investigator**	