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Investigational Drug Service Epic Investigational Product Build Form

Form Instructions: Please fill out all fields below. For questions regarding this form, please call the Investigational Drug Service at 5-2060.

[1]Project Title				IRB Number
Study Sponsor				
[2]Project Nicknames				
Principal Investigator (PI):				
[3]Department:		[4]Department Account Number:		
Study Coordinator (SC):		SC Phone Number:		
Name and Contact Information for Person Completing Form:				
Age Range of Study Participants:				
Is the Study Blinded? ◯ Yes ◯ No		Is the Study Double Blinded? ◯ Yes ◯ No		
Is the Study Placebo-Controlled? ◯ Yes ◯ No				
Who Will Randomize?	☐ Sponsor	☐ RN-SC	☐ UMMC Pharmacy	
How Will Study Drug Be Provided?	☐ Inpatient	☐ Outpatient	☐ Take-Home	
Is the Study Drug Currently Marketed? ◯ Yes ◯ No				
Will the Sponsor Provide the Study Drug? ◯ Yes ◯ No				
Who will be billed if the sponsor does not provide study drug? ◯ Sponsor ◯ Patient				
Is the study drug considered hazardous? ◯ Yes ◯ No				
Is the study drug a controlled substance? ◯ Yes ◯ No				
Name of Study Drug:				
Comparator(s):				
[5]How is the Study Drug and Comparator(s) Supplied? (i.e. 200mg Tablet, 500mg Vial)				
[6]Is the Study Drug Ready-To-Use? ◯ Yes ◯ No				
What dose will the patient receive?				
Route of Administration	☐ Oral	☐ NG/OG Tube	☐ G-Tube	Other (Specify):
	☐ IV (Push)	☐ IV (IVPB)	☐ IV (Continuous or Titratable)	
Frequency of Administration:				
Duration of Therapy:				

[1] Project Title is the exact name of the study as defined in the study protocol.
[2] Include all potential project nicknames (i.e. mnemonics, investigational product names, etc.)
[3] Department of the primary investigator where study fees will be billed.
[4] Department Account Number for the primary investigator which pharmacy fees will be paid out of.
[5] Please include all dosage forms that will be used.
[6] A Ready-To-Use Drug would require no repackaging, manipulation or compounding by the pharmacy.

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For IVPB Medications, Fill Out The Section Below		**For Continuous or Titratable Infusions, Fill out The Section Below**	
Diluent (Base Fluid)	☐ 0.9% Sodium Chloride (NS) ☐ D5W ☐ Other _____	Diluent (Base Fluid)	☐ 0.9% Sodium Chloride (NS) ☐ D5W ☐ Other _____
Volume of Diluent (mL)		Volume of Diluent (mL):	
[7]Total Infusion Volume (mL)		Total Infusion Volume (mL):	
Duration of Infusion		[8]Continuous Infusion Dose Rate (if applicable):	
If a one-time infusion or scheduled IVPB has an escalating rate (i.e. reaction prevention rate increases), please include that information in the titration parameters section.		[9]Titratable Starting Dose Rate (if applicable):	
Does the study drug need any special filters for preparation or administration? If yes, please explain.	◯ Yes ◯ No		
Does the study drug need any special infusion lines or administration sets? If yes, please explain.	◯ Yes ◯ No		
[10]Titration Parameters:			
Administration Instructions:			
Disposal Instructions:			

[7] Total Infusion Volume may or may not be the same as the volume of diluent.
[8] Continuous Infusion Dose Rate should be stated as a dose per unit of time
[9] Titratable Starting Dose Rate should be stated as a dose per unit of time
[10] Titration parameters should include objective endpoints with dose

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Volume of Diluent (mL)		Volume of Diluent (mL):	
[11]Total Infusion Volume (mL)		Total Infusion Volume (mL):	
Duration of Infusion		[12]Continuous Infusion Dose Rate (if applicable):	
If a one-time infusion or scheduled IVPB has an escalating rate (i.e. reaction prevention rate increases), please include that information in the titration parameters section.		[13]Titratable Starting Dose Rate (if applicable):	
Does the study drug need any special filters for preparation or administration? If yes, please explain.		◯ Yes ◯ No	
Does the study drug need any special infusion lines or administration sets? If yes, please explain.		◯ Yes ◯ No	
[14]Titration Parameters:			
Administration Instructions:			
Disposal Instructions:			

[11] Total Infusion Volume may or may not be the same as the volume of diluent.
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Volume of Diluent (mL)		Volume of Diluent (mL):	
[15]Total Infusion Volume (mL)		Total Infusion Volume (mL):	
Duration of Infusion		[16]Continuous Infusion Dose Rate (if applicable):	
If a one-time infusion or scheduled IVPB has an escalating rate (i.e. reaction prevention rate increases), please include that information in the titration parameters section.		[17]Titratable Starting Dose Rate (if applicable):	
Does the study drug need any special filters for preparation or administration? If yes, please explain.		◯ Yes ◯ No	
Does the study drug need any special infusion lines or administration sets? If yes, please explain.		◯ Yes ◯ No	
[18]Titration Parameters:			
Administration Instructions:			
Disposal Instructions:			

[15] Total Infusion Volume may or may not be the same as the volume of diluent.
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Volume of Diluent (mL)		Volume of Diluent (mL):	
[19]Total Infusion Volume (mL)		Total Infusion Volume (mL):	
Duration of Infusion		[20]Continuous Infusion Dose Rate (if applicable):	
If a one-time infusion or scheduled IVPB has an escalating rate (i.e. reaction prevention rate increases), please include that information in the titration parameters section.		[21]Titratable Starting Dose Rate (if applicable):	
Does the study drug need any special filters for preparation or administration? If yes, please explain.		◯ Yes ◯ No	
Does the study drug need any special infusion lines or administration sets? If yes, please explain.		◯ Yes ◯ No	
[22]Titration Parameters:			
Administration Instructions:			
Disposal Instructions:			

[19] Total Infusion Volume may or may not be the same as the volume of diluent.
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Volume of Diluent (mL)		Volume of Diluent (mL):	
[23]Total Infusion Volume (mL)		Total Infusion Volume (mL):	
Duration of Infusion		[24]Continuous Infusion Dose Rate (if applicable):	
If a one-time infusion or scheduled IVPB has an escalating rate (i.e. reaction prevention rate increases), please include that information in the titration parameters section.		[25]Titratable Starting Dose Rate (if applicable):	
Does the study drug need any special filters for preparation or administration? If yes, please explain.		◯ Yes ◯ No	
Does the study drug need any special infusion lines or administration sets? If yes, please explain.		◯ Yes ◯ No	
[26]Titration Parameters:			
Administration Instructions:			
Disposal Instructions:			

[23] Total Infusion Volume may or may not be the same as the volume of diluent.
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