ROCHESTER REGIONAL HEALTH

Institutional Review Board

Application for New Research Project

IRB#:	CIRB#	Select one category	
IRB Board:		☐	Full Board
Meeting Date:		☐	Expedited
Primary Reviewer:			
IRB Signature:			

This table for IRB use only.

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INSTRUCTIONS

This application is for internal and external Institutional Review Board (IRB) reviews. If sections do not apply to your application, please list n/a

****For an internal and external sponsored full board IRB review, please include a $2,000 check request transfer of funds payable to RRH Institutional Review Board*

****** For an internal and external sponsor expedited review please include a $1,000 check request transfer of funds payable to RRH Institutional Review Board*

Please send completed application via email to Renee Capizzi at Renee.Capizzi@rochesterregional.org or Lauren Fenclau at Lauren.Fenclau@rochesterregional.org

DEFINITIONS

Term	Definition
Confidentiality	Refers to how the participant's individually identifiable private information will be handled, managed, and disseminated by the primary investigator (PI) and research team.
Health Information Portability and Accountability Act (HIPAA)	An Legislative Act by the United States to amend the Internal Revenue Code of 1996 to improve portability and continuity of health insurance coverage in the group and individual markets, to combat waste, fraud, and abuse in health insurance and health care delivery, to promote the use of medical savings accounts, to improve access to long-term care services and coverage, to simplify the administration of health insurance, and for other purposes.
Protected (High Risk) Data - Payment Card Industry (PCI), Protected Health Information (PHI), Personally Identifiable Information (PII).	Data is considered to be confidential when protection of such data is required by law or regulation, protection is necessary in order for Rochester Regional Health (RRH) or its affiliates to meet compliance obligations, or the unauthorized disclosure, access, alteration, loss or destruction of those data could have a material impact on RRH or its affiliates' mission, assets, operations, finances, or reputation, or could pose material harm to individuals. Additional information is available in the RRH CAST standard [07.d Information Classification Standard and 07.e Information Labeling and Handling]. In research specifically, data is high risk when the disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.
Privacy	A person's desire to control the access over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
Protected Health Information (PHI)	Any individually identifiable health information that is transmitted by electronic media, maintained in any medium that falls within the definition of electronic media, or transmitted or maintained in any other form or medium.

SECTION 1 - GENERAL INFORMATION					
1.0	Project Title:				
1.1	Date Form Completed:				
1.2	Please select the IRB review type requested:	☐	Internal	☐	External
1.3	Will this study drug be dispensed by the RRH Pharmacy?	☐	Yes	☐	No
	If yes, please provide signature of Pharmacy Director:				
1.4	Will this study drug be dispensed by an external pharmacy?	☐	Yes	☐	No
	If yes, please provide name of external pharmacy:				
1.5	Is this an Investigator Initiated Study?	☐	Yes	☐	No
1.6	Is this Nursing Research (If YES, submit Nursing Research Committee approval)?	☐	Yes	☐	No
1.7	Is this a Medical Resident project?	☐	Yes	☐	No

SECTION 2 – PRINCIPAL INVESTIGATOR CONTACT INFORMATION								
2.0	Principal Investigator (PI) Name:							
2.1	Title:			2.2	Degree:			
2.3	Department Name:							
2.4	Work Phone:			2.5	Fax Phone:			
2.6	Mobile Phone:							
2.7	Email Address:							
2.8	Work Address:							
2.9	Does the Principal Investigator meet the educational requirements?					☐	Yes	☐ No
2.10	Select the research activities that this person will be involved in and has received training for (check all that apply):							
	☐	Screening	☐	Consenting	☐	Data Monitoring	☐	Dispensing Drugs
	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
2.11	HSPP Completed?					☐	Yes	☐ No
2.12	Principle Investigator Interests							
	Does the Principal Investigator have a generic conflict of disclosure on file with the Research Institute?					☐	Yes	☐ No
	Is the Principal Investigator URMC Faculty?					☐	Yes	☐ No

SECTION 3 – CO-PRINCIPAL INVESTIGATOR CONTACT INFORMATION								
3.0	Co-Principal Investigator (PI) Name:							
3.1	Title:				3.2	Degree:		
3.3	Department Name:							
3.4	Work Phone:				3.5	Fax Phone:		
3.6	Mobile Phone:							
3.7	Email Address:							
3.8	Work Address:							
3.9	Does the Co-Principal Investigator meet the educational requirements?					☐	Yes	☐ No
3.10	Select the research activities that this person will be involved in and has received training for (check all that apply):							
	☐	Screening	☐	Consenting	☐	Data Monitoring	☐	Dispensing Drugs
	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
3.11	Human Subjects Protection Program Forms (HSPP) Completed?					☐	Yes	☐ No
3.12	Co-Principle Investigator Interests							
	Does the Co-Principal Investigator have a generic conflict of disclosure on file with the Research Institute?					☐	Yes	☐ No
	Is the Co-Principal Investigator URMC Faculty?					☐	Yes	☐ No

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3.0	Co-Principal Investigator (PI) Name:							
3.1	Title:				3.2	Degree:		
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3.8	Work Address:							
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	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
3.11	Human Subjects Protection Program Forms (HSPP) Completed?					☐	Yes	☐ No
3.12	Co-Principle Investigator Interests							
	Does the Co-Principal Investigator have a generic conflict of disclosure on file with the Research Institute?					☐	Yes	☐ No
	Is the Co-Principal Investigator URMC Faculty?					☐	Yes	☐ No

SECTION 3 – CO-PRINCIPAL INVESTIGATOR CONTACT INFORMATION								
3.0	Co-Principal Investigator (PI) Name:							
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3.8	Work Address:							
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	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
3.11	Human Subjects Protection Program Forms (HSPP) Completed?					☐	Yes	☐ No
3.12	Co-Principle Investigator Interests							
	Does the Co-Principal Investigator have a generic conflict of disclosure on file with the Research Institute?					☐	Yes	☐ No
	Is the Co-Principal Investigator URMC Faculty?					☐	Yes	☐ No

SECTION 3 – CO-PRINCIPAL INVESTIGATOR CONTACT INFORMATION								
3.0	Co-Principal Investigator (PI) Name:							
3.1	Title:				3.2	Degree:		
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3.9	Does the Co-Principal Investigator meet the educational requirements?					☐	Yes	☐ No
3.10	Select the research activities that this person will be involved in and has received training for (check all that apply):							
	☐	Screening	☐	Consenting	☐	Data Monitoring	☐	Dispensing Drugs
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	If other, please describe:							
3.11	Human Subjects Protection Program Forms (HSPP) Completed?					☐	Yes	☐ No
3.12	Co-Principle Investigator Interests							
	Does the Co-Principal Investigator have a generic conflict of disclosure on file with the Research Institute?					☐	Yes	☐ No
	Is the Co-Principal Investigator URMC Faculty?					☐	Yes	☐ No

SECTION 4 – RESEARCH COORDINATOR CONTACT INFORMATION (if applicable)								
4.0	Research Coordinator Name:							
4.1	Title:			4.2	Degree:			
4.3	Department Name:							
4.4	Work Phone:			4.5	Fax Phone:			
4.6	Mobile Phone:							
4.7	Email Address:							
4.8	Work Address:							
4.9	Does the Research Coordinator meet the educational requirements?				☐	Yes	☐	No
4.10	Select the research activities that this person will be involved in and has received training for (check all that apply):							
	☐	Screening	☐	Consenting	☐	Data Monitoring	☐	Dispensing Drugs
	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
4.11	HSPP Completed?				☐	Yes	☐	No
4.12	Research Coordinator Interests							
	Does the Research Coordinator have a generic conflict of disclosure on file with the Research Institute?				☐	Yes	☐	No
	Is the Research Coordinator URMC Faculty?				☐	Yes	☐	No

SECTION 4 – RESEARCH COORDINATOR CONTACT INFORMATION (if applicable)								
4.0	Research Coordinator Name:							
4.1	Title:			4.2	Degree:			
4.3	Department Name:							
4.4	Work Phone:			4.5	Fax Phone:			
4.6	Mobile Phone:							
4.7	Email Address:							
4.8	Work Address:							
4.9	Does the Research Coordinator meet the educational requirements?				☐	Yes	☐	No
4.10	Select the research activities that this person will be involved in and has received training for (check all that apply):							
	☐	Screening	☐	Consenting	☐	Data Monitoring	☐	Dispensing Drugs
	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
4.11	HSPP Completed?				☐	Yes	☐	No
4.12	Research Coordinator Interests							
	Does the Research Coordinator have a generic conflict of disclosure on file with the Research Institute?				☐	Yes	☐	No
	Is the Research Coordinator URMC Faculty?				☐	Yes	☐	No

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4.0	Research Coordinator Name:							
4.1	Title:			4.2	Degree:			
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4.6	Mobile Phone:							
4.7	Email Address:							
4.8	Work Address:							
4.9	Does the Research Coordinator meet the educational requirements?				☐	Yes	☐	No
4.10	Select the research activities that this person will be involved in and has received training for (check all that apply):							
	☐	Screening	☐	Consenting	☐	Data Monitoring	☐	Dispensing Drugs
	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
4.11	HSPP Completed?				☐	Yes	☐	No
4.12	Research Coordinator Interests							
	Does the Research Coordinator have a generic conflict of disclosure on file with the Research Institute?				☐	Yes	☐	No
	Is the Research Coordinator URMC Faculty?				☐	Yes	☐	No

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	If other, please describe:							
4.11	HSPP Completed?				☐	Yes	☐	No
4.12	Research Coordinator Interests							
	Does the Research Coordinator have a generic conflict of disclosure on file with the Research Institute?				☐	Yes	☐	No
	Is the Research Coordinator URMC Faculty?				☐	Yes	☐	No

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	If other, please describe:							
4.11	HSPP Completed?				☐	Yes	☐	No
4.12	Research Coordinator Interests							
	Does the Research Coordinator have a generic conflict of disclosure on file with the Research Institute?				☐	Yes	☐	No
	Is the Research Coordinator URMC Faculty?				☐	Yes	☐	No

SECTION 5 – SUB-INVESTIGATOR CONTACT INFORMATION **(if applicable)**

This section must be completed for each sub-investigator participating in the project. Sub-investigators include but are not limited to: physicians, residents, fellows, research staff, registered nurses and/or students specific to the project defined in SECTION 1.

5.0	Sub-Investigator Name:							
5.1	Title:			5.2	Degree:			
5.3	Department Name:							
5.4	Work Phone:			5.5	Fax Phone:			
5.6	Mobile Phone:							
5.7	Email Address:							
5.8	Work Address:							
5.9	Does the Sub-Investigator meet the educational requirements?				☐	Yes	☐	No
5.10	Select the research activities that this person will be involved in and has received training for (check all that apply):							
	☐	Screening	☐	Consenting	☐	Data Monitoring	☐	Dispensing Drugs
	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
5.11	HSPP Completed?				☐	Yes	☐	No
5.12	Sub-Investigator Interests							
	Does the Sub-Investigator have a generic conflict of disclosure on file with the Research Institute?				☐	Yes	☐	No
	Is the Sub-Investigator URMC Faculty?				☐	Yes	☐	No

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5.3	Department Name:							
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5.6	Mobile Phone:							
5.7	Email Address:							
5.8	Work Address:							
5.9	Does the Sub-Investigator meet the educational requirements?					☐	Yes	☐ No
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	☐	Screening	☐	Consenting	☐	Data Monitoring	☐	Dispensing Drugs
	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
5.11	HSPP Completed?					☐	Yes	☐ No
5.12	Sub-Investigator Interests							
	Does the Sub-Investigator have a generic conflict of disclosure on file with the Research Institute?					☐	Yes	☐ No
	Is the Sub-Investigator URMC Faculty?					☐	Yes	☐ No

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5.0	Sub-Investigator Name:							
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5.3	Department Name:							
5.4	Work Phone:				5.5	Fax Phone:		
5.6	Mobile Phone:							
5.7	Email Address:							
5.8	Work Address:							
5.9	Does the Sub-Investigator meet the educational requirements?					☐	Yes	☐ No
5.10	Select the research activities that this person will be involved in and has received training for (check all that apply):							
	☐	Screening	☐	Consenting	☐	Data Monitoring	☐	Dispensing Drugs
	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
5.11	HSPP Completed?					☐	Yes	☐ No
5.12	Sub-Investigator Interests							
	Does the Sub-Investigator have a generic conflict of disclosure on file with the Research Institute?					☐	Yes	☐ No
	Is the Sub-Investigator URMC Faculty?					☐	Yes	☐ No

SECTION 5 – SUB-INVESTIGATOR CONTACT INFORMATION **(if applicable)**

This section must be completed for each sub-investigator participating in the project. Sub-investigators include but are not limited to: physicians, residents, fellows, research staff, registered nurses and/or students specific to the project defined in SECTION 1.

5.0	Sub-Investigator Name:							
5.1	Title:			5.2	Degree:			
5.3	Department Name:							
5.4	Work Phone:			5.5	Fax Phone:			
5.6	Mobile Phone:							
5.7	Email Address:							
5.8	Work Address:							
5.9	Does the Sub-Investigator meet the educational requirements?				☐	Yes	☐	No
5.10	Select the research activities that this person will be involved in and has received training for (check all that apply):							
	☐	Screening	☐	Consenting	☐	Data Monitoring	☐	Dispensing Drugs
	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
5.11	HSPP Completed?				☐	Yes	☐	No
5.12	Sub-Investigator Interests							
	Does the Sub-Investigator have a generic conflict of disclosure on file with the Research Institute?				☐	Yes	☐	No
	Is the Sub-Investigator URMC Faculty?				☐	Yes	☐	No

SECTION 5 – SUB-INVESTIGATOR CONTACT INFORMATION **(if applicable)** This section must be completed for each sub-investigator participating in the project. Sub-investigators include but are not limited to: physicians, residents, fellows, research staff, registered nurses and/or students specific to the project defined in SECTION 1.								
5.0	Sub-Investigator Name:							
5.1	Title:				5.2	Degree:		
5.3	Department Name:							
5.4	Work Phone:				5.5	Fax Phone:		
5.6	Mobile Phone:							
5.7	Email Address:							
5.8	Work Address:							
5.9	Does the Sub-Investigator meet the educational requirements?					☐	Yes	☐ No
5.10	Select the research activities that this person will be involved in and has received training for (check all that apply):							
	☐	Screening	☐	Consenting	☐	Data Monitoring	☐	Dispensing Drugs
	☐	Conducting Study Visits	☐	Data Analysis	☐	Manuscript	☐	Other
	If other, please describe:							
5.11	HSPP Completed?					☐	Yes	☐ No
5.12	Sub-Investigator Interests							
	Does the Sub-Investigator have a generic conflict of disclosure on file with the Research Institute?					☐	Yes	☐ No
	Is the Sub-Investigator URMC Faculty?					☐	Yes	☐ No

SECTION 6 – PROJECT INFORMATION

6.0	Is this a multi-center study?	☐	Yes	☐	No	
	If yes, is the Primary Investigator or this site considered the "lead" or "coordinating site?"	☐	Yes	☐	No	
	If RGH is the lead or coordinating center, describe the plans for communication among the sites in terms of protocol modifications, unanticipated problems involving risks to participants or others and interim results:					

6.1	**Funding Source**					
	☐	Federal (specify):		Grant Number:		
	☐	State (specify):		Number:		
	☐	Non-Profit (specify):		Number:		
	☐	Industry Sponsored (specify):		Industry Sponsor Protocol #:		
	☐	Cooperative Group Involvement	☐	Yes	☐	No
		Cooperative Group #:				
	☐	No External Funding (if checked, enter PI's cost center or department information:				

6.2	**Nature of Study**										
	☐	Bank of Tissue / Blood / Biological specimens / Data									
	☐	Social / Behavioral									
	☐	Genetics									
	☐	Quality Assurance / Quality Improvement									
	☐	Use of Clinical Samples, Charts / Records, Database Info w/ No Direct Subject Interaction									
	☐	Clinical Trial:									
	Type	☐	Drug	☐	Device	☐	Biologic	☐	Surgical Procedure	☐	Other (i.e., Humanitarian use, treatment use, etc.)
	Phase	☐	1	☐	2	☐	3	☐	4	☐	N/A

6.3	Has Pharmacy approved this study?	☐	Yes	☐	No	

6.4	Handling of Investigational Items for Dispensation Specific to Clinical Drug / Biologic / Device Studies:				
	Have all staff responsible for investigative item(s) received training regarding control and dispensation of the investigational item(s)? *(Physical documentation of this training is subject to verification through the audit process.)*	☐	Yes	☐	No
	If YES, describe when the training occurred and who provided the training (i.e., sponsor site meeting):				
	If NO, the PI maintains that IRB policies 502 A, B and C have been reviewed with study staff for proper investigational item control.	PI initial here to acknowledge policy requirements:			
6.5	Is the investigational item being stored and dispensed from a licensed pharmacy?	☐	Yes	☐	No
	If YES, list the participating pharmacy(ies):				
	If NO, describe the plan to control the investigational item(s) with regard to storage and dispensation:				
6.6	If the above plan involves investigational drugs / biologics, has the plan been reviewed with a licensed pharmacist?	☐	Yes	☐	No
	If YES, state the pharmacist's name and date of review:				
	If NO, the IRB Chairperson reviews the above plan for appropriate controls regarding the investigational item.				
6.7	Request for Expedited Status:				
	Are you requesting EXPEDITED status?	☐	Yes	☐	No

SECTION 7 – RISKS AND BENEFITS

7.0 Will the research involve any of the following risks? (check all that apply)

☐	Physical	☐	Psychological	☐	Economical	☐	Social
☐	Legal	☐	Information Security	☐	Accidental Disclosure of Protected Data (PCI, PHI, PII)	☐	Other

If other, please describe:

7.1 Describe the nature and degree of all risk or harm associated with participation in the study (this information should be included in the consent form):

7.2 Explain what steps will be taken to minimize risks or harms and to protect participant welfare:

7.3 Describe any anticipated benefits that may result from the research:

7.4 Methods of Enrollment

Check all that apply		Please enter related location below & attach copies of recruitment materials:
☐	Your Practice Referral	
☐	Outside Practice Referral	
☐	Chart Review	
☐	Advertisement	
☐	Web Listing	
☐	Other	If Other, please describe:

7.5 Indicate how candidates for participation will be approached (check all that apply):

☐	Direct Contact	☐	Letter	☐	Phone Call	☐	Email
☐	Other	If other, please describe:					

7.6	Please indicate the source(s) of data for this study (check all that apply):							
	☐	Interviews	☐	Focus groups	☐	Medical records	☐	Photos / videos
	☐	Registries	☐	Questionnaires / Surveys	☐	Public records	☐	Biological Specimens
	☐	Voice recordings	☐	Other				
	If other, please describe:							
7.7	Will data be linked to participants / cases or contain any personal identifiers?				☐	Yes	☐	No
7.8	Will data be de-identified and if so, will study personnel have any links / keys to identifiers?				☐	Yes	☐	No
7.9	Does this study involve genetic analysis?				☐	Yes	☐	No

SECTION 8 – INFORMED CONSENT / ASSENT / PRIVACY FORMS								
	Consent Process							
8.0	Will informed consent be obtained from participants:					☐ Yes	☐	No
						If **YES**, then *skip* Section 9 "Waiver of Consent"	If **NO**, then *complete* Section 9 "Waiver of Consent"	
8.1	Who will be consenting to participate in the research?							
	☐	Participant	☐	Child	☐	Parent of child	☐	Guardian
	☐	Legally authorized representative						
8.2	Is the primary language of the consent process English?					☐ Yes	☐	No
							If **NO**, submit appropriately translated consent document(s).	
8.3	Does your study involve children?					☐ Yes	☐	No
						If YES, child assent is required by regulation if the child is capable of providing such assent (typically ages 7 to 17).		
8.4	Does your study involve the collection, use or sharing or Protected Health Information (PHI)— (see definitions)?					☐ Yes	☐	No

SECTION 9 – Waiver of Consent

Only complete this section if you answered "NO" to question 8.0 in Section 8 of this form.

Participants will not be required to sign a consent document when a waiver of signed written consent is reviewed and approved by the IRB. If the IRB waives the requirement of documentation of informed consent, the IRB may require the investigator to provide a written statement of the research to the participant. The IRB shall review and approve the written statement prior to the investigator providing the statement to the participant. The consent form reviewed and approved by the IRB may also serve as the written statement.

9.0	Is a waiver of consent requested?	☐	Yes	☐	No
		If YES: 1. Select and explain the reason for the waiver 2. Category 1 OR 2 below must be indicated as "**YES.**"			
	Category 1 The only record linking the participant and the research is the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether they want documentation linking them with the research and their wishes will govern. The research is not subject to FDA regulations	☐	Yes	☐	No
	Please explain your selection of Category 1:				
	Category 2 The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of research context.	☐	Yes	☐	No
	Please explain your selection of Category 2:				

SECTION 10 – PRIVACY AND CONFIDENTIALITY	
10.0	Describe how information will be accessed from or about participants and the provisions used to protect the privacy—see definitions—interests of participants (e.g., Participant interactions are conducted in a private room, discussions are held in a private exam room, only designated personnel are present during discussions):
10.1	Describe the instituted measures to protect the confidentiality of identifiable private data of study participants (e.g., PHI kept in locked storage cabinets, use of password protected computer files containing PHI, limited access to PHI, use of identifiers, processes for appropriate data destruction) and who will access to the data:

SECTION 12 – ELECTRONIC ENCLOSURES SUBMITTED			
	Check all that apply		Quantity Required
12.0	☐	IRB Application	1 electronic copy
	☐	Abstract	1 electronic copy
	☐	Application fee - $2,000 (for sponsored and funded research only)	Not applicable
	☐	Expedited review fee - $1000 (for sponsored and funded research only)	Not applicable
	☐	Advertisements	1 electronic copy
	☐	Letters of Support	1 electronic copy
	☐	Package Insert	Investigator initiated Drug/Device Studies - 1 electronic copy
	☐	Protocol	1 electronic copy
	☐	Informed Consent	1 electronic copy
	☐	Human Subjects Protection Program (HSPP)—for each research team member if not previously filed with the RRH Institutional Review Board (IRB)	1 electronic copy for each research team member
	☐	Questionnaire / Survey	1 electronic copy
	☐	Investigator's Brochure	1 electronic copy
	☐	Other	If other, please describe:

SECTION 13 – APPROVAL LETTER REQUIREMENTS	
13.0	Note any specific information related to the protocol which needs to be included in the approval letter (i.e., version dates, consents, protocol, etc.):

SECTION 14 – REQUIRED SIGNATURES

14.0	Research Study Title:				
14.1	Principal Investigator, by signing this application form: • I agree to accept responsibility for the rights and welfare of the research participants involved with this study. • I agree that the benefits outweigh the risks to the participants in the study. • I agree to comply with the Rochester Regional Health's Guidelines of the use of Human Studies in Research. • I certify that, to the best of my knowledge, I am in compliance with the Department of Health and Human Services and Federal Drug Administration policies and procedures regarding the protection of human subjects.				
	Principal Investigator Signature:			Date:	
14.2	Department Chair, by signing this application form: • I certify that the research proposed in this human studies application is of sound design, which is able to address the scientific question or questions posed. Furthermore, I certify that the Principal Investigator has adequate time and resources to meet the study design requirements and complete the study as proposed in this application form.				
	Department Chair Signature:			Date:	
	Print Department Chair Name:				
14.3	Will staff from other departments or units participate in this project or will resources of another department, unit or office be used?		☐ Yes	☐	No
		Dept./Unit 1 Name:	Dept./Unit 2 Name:	Dept./Unit 3 Name:	
	I have read the protocol:	Initials:	Initials:	Initials:	
	I have no concerns with the protocol:	Initials:	Initials:	Initials:	
	I approved the study to be conducted:	Initials:	Initials:	Initials:	
14.4	Signature(s) of Department, Unit Director or Manager				
	Dept. / Unit 1 Signature:			Date:	
	Dept. / Unit 2 Signature:			Date:	
	Dept. / Unit 3 Signature:			Date:	