REQUEST FOR PROPOSAL

Please select the services you require and provide as much detail as possible. You may e-mail this form to Jennifer Jawahir, Director of Clinical Operations, at jjawahir@c2rs.com or contact her via phone at (269) 532-9559 (mobile) if you have any questions or would like assistance completing this form.

1. SPONSOR COMPANY OR INVESTIGATIVE SITE INFORMATION:	
Company/Investigative Site Name:	
Mailing Address:	
Contact Name & Title:	
Contact Phone & E-mail:	
2. SPONSOR PROJECT BACKGROUND: *Product Information (if available)*	
Study Product Name:	
Study Product Indication:	
Study Product Description:	
Study Product Type:	☐ Device ☐ Drug ☐ Combination Product ☐ In Vitro Diagnostic ☐ Biologic
Study Type/Phase:	☐ Feasibility/Pilot ☐ Post-Market ☐ Human Factors ☐ Pivotal ☐ Registry ☐ Other _____ ☐ Phase II ☐ Phase III ☐ Phase IV
Product Regulatory Path:	☐ IND ☐ IDE ☐ 510(k) ☐ PMA ☐ HDE ☐ Other_____ ☐ Preparation & Submission for the path indicated above
Study Information (if available)	
Study Start-Up Date	
First Patient Visit Date	
Enrollment Duration	(months)
Treatment/Follow-Up Duration	(months)
Estimated Number of Sites	US: Canada: EU: Other:

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Number of Investigator Meetings	
Name of IRB	☐ Central IRB ☐ Local IRB

3. SPONSOR CLINICAL AFFAIRS SUPPORT:				
Activity	Responsibility		Requested Service	Comments
	C²RS	Sponsor		
Study Design			☐Develop s ☐Review & Comment	
Protocol			☐Develop ☐Review & Comment	
Informed Consent Form			☐Develop ☐Review & Comment	
Development of Other Study Documents (Device/drug/Biologic Accountability Log, Screening/Enrollment Log, etc.)			☐Develop ☐Review & Comment	
Clinical Regulatory Pathway			☐Prepare ☐Review	
Pre-IDE Submission Package: Clinical Evaluation Report/Clinical Protocol Development			☐Prepare ☐Compile ☐Review ☐Submit	
Clinical Protocol- and IRB-Related Supplements/ Amendments Submissions			☐Prepare ☐Compile ☐Review ☐Submit	
IRB-Related Annual Report Supplements / Amendments Submissions			☐Prepare ☐Compile ☐Review ☐Submit	

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Identify and Contract Central IRB (If applicable)			
Study Monitoring Services (prepare site reports; recommend CAPA, etc.)			

The following services are conducted on behalf of the sponsor for study-site related activities			
Activity	Responsibility		Comments
	C²-RS	Sponsor	
Site Identification			
Site Qualification Pre-Study Phone Call(s)			
Site Qualification Pre-Study Site Visit(s)			
Investigator Training/ Education			
Site Staff Training/ Education			
Clinical Protocol Training Material Development			
Monitoring Services			
Assist Study Site Investigators/Staff to Resolve Protocol Issues			
IRB Application Assistance			
Regulatory Document Collection (CVs, Medical Licenses, Financial Disclosure Forms, IRB Approval Documents, Informed Consent Forms, etc.)			

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4. STUDY SITE-RELATED SERVICES:			
Investigative Site Support			
Activity	Responsibility		Comments
	C²-RS	Sponsor	
Investigative Site Standard Operating Procedure(s)			We are requesting that C²-RS, Inc.: ☐Develop ☐Review & Comment
On-Site Coordinating Services			
Investigative Site Program Development	Please describe current program if applicable: (C²-RS, Inc. will complete a site audit to ascertain needs)		
Investigative Site Study Recruitment	Please describe the particular areas you wish to grow:		
5. OTHER SERVICES:			
Medical Writing: whitepapers; manuscripts, etc.	Please describe:		
Clinical Research Education Programs (staff training)	Please describe:		

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Coordinate Collaborations with Academia, Industry & Healthcare	Please describe:

Upon submission of this form, please allow seven business days for review and response. Thank you for your consideration of our services.

Completed by: _____ Date: _____

FOR INTERNAL USE ONLY:
Date Received:
Completed By:
Response Date: