



## CLINICAL TRIAL KITTING QUESTIONNAIRE

**Client:** \_\_\_\_\_ **Date:** \_\_\_\_\_ **Completed by:** \_\_\_\_\_

The information from this questionnaire will be used to development a client specific blood collection kit plan and proposal for collection, preparation and shipping instructions. Please be very specific in answering the questions as to how you would like each of these items handled.

If additional text space is needed to answer a question; please use the area on page 3 and refer to the Item #.

General Clinical Trial Information			
Clinical Trial Name:		Trial Start Date:	
Estimated # Collection Sites:		Term of Trial (# years):	
Estimated # Participants: (Per Year and Total)		US Based Collection Sites:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Check applicable draw intervals:	<input type="checkbox"/> Baseline <input type="checkbox"/> 12 month <input type="checkbox"/> 24 month <input type="checkbox"/> 36 month	<input type="checkbox"/> 48 month <input type="checkbox"/> 60 month <input type="checkbox"/> Other	International Collection Sites: If yes, list the countries anticipated. <input type="checkbox"/> Yes <input type="checkbox"/> No
Collection Kit Specifics			
BLOOD COLLECTION			
1	List the specific blood tubes and/or supplies you would like included in each collection kit or describe what you would like collected and we will make some recommendation on blood containers.  (All kits will contain the appropriate labeling with a unique Kit Id and Expiration Date.)		
2	Will each collection site be separating the serum/plasma by centrifuge?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3	If No to question #2, does client wish for Kryosphere to centrifuge and aliquot serum, plasma or whole blood into smaller aliquots?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If Yes, was is the target # of aliquots client is anticipating: _____
4	If Yes to question #2, will each collection site be aliquoting an approximate 0.5 -1ml aliquot into cryovials? If so, what is the targeted number?	<input type="checkbox"/> Yes    Approx. # vials: _____ <input type="checkbox"/> No <input type="checkbox"/> N/A	
5	If specimens are to be aliquoted (either at the collection site or by Kryosphere), which tubes listed in #1 will be aliquoted?		
6	If aliquoted by Collection Site, what do you want the collection site to do with any serum/plasma left over? Discard? Send vials for storage?	<input type="checkbox"/> Discard <input type="checkbox"/> Prepare/Send additional aliquots <input type="checkbox"/> N/A	



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7	Will you want a par level of kits maintained at each Collection Site? If yes, is there a determined number?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> TBD
<b>SPECIMEN LABELING</b>		
8	Do you want the tubes that will be stored to be pre-labeled before sending to collection sites or send labels separately to be applied by collection sites?	<input type="checkbox"/> Kryosphere to provide pre-labeled collection tubes and cryovials for aliquots <input type="checkbox"/> Kryosphere to send pre-printed labels to Collection Sites for application by the site <input type="checkbox"/> N/A
9	What specific information do you want to capture on each label?  <i>Each vial/tube will be labeled with a unique identifier assigned by Kryosphere for inventory tracking purposes.</i>	<input type="checkbox"/> Participant name (Last, First) <input type="checkbox"/> Participant ID <input type="checkbox"/> Study ID <input type="checkbox"/> Date drawn (this would have to be hand written on the label by the collection site) <input type="checkbox"/> Blood draw interval (time interval) <input type="checkbox"/> Other
10	Are all tubes to have the same label or different? If different, please specify.	
11	Barcoding, in addition to text on the label?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>PARTICIPANT INFORMATION</b>		
12	Will the collection site be completing and sending any type of patient demographic information worksheet with the samples?	<input type="checkbox"/> Yes <input type="checkbox"/> No
13	If Yes to Question # 12, will you want Kryosphere to design the Participant Collection Form?	<input type="checkbox"/> Yes <input type="checkbox"/> No, Collection Report will be provided by Client
14	If Yes to question # 13, what information do you want captured from this worksheet to input into our inventory management system? <i>(There are a limited number of data fields that Kryosphere staff will work with you to customize the inventory management. Each client will be provided access to the on-line inventory management system for real time specimen tracking.)</i>	
15	If yes to question # 13, do you want the worksheet archived in the inventory management system, hard copy saved, or discarded?	<input type="checkbox"/> Archived electronically in Inventory System <input type="checkbox"/> Hard Copy filed <input type="checkbox"/> Discarded <input type="checkbox"/> Other <input type="checkbox"/> N/A
<b>COLLECTION &amp; SHIPPING INSTRUCTIONS</b>		
16	Will each kit include an Blood Collection and Shipping Instruction sheet with directions for the blood collection, specimen preparation, and shipping?	<input type="checkbox"/> Yes <input type="checkbox"/> No



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17	If Yes to Question # 16, will Client provide the Kit Instructions, or will you want Kryosphere to design this form? <i>(All Kryosphere forms will be drafted and sent to client for final sign-off)</i>	<input type="checkbox"/> Client provided <input type="checkbox"/> Kryosphere to design
18	Will you want Kryosphere to ship collected specimens to other laboratories at certain time intervals for assays and other testing?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>SPECIMEN SHIPPING</b>		
19	Will collected specimens be returned to Kryosphere for frozen storage?	<input type="checkbox"/> Yes <input type="checkbox"/> No
20	If Yes to Question # 19, Kryosphere's recommends clients only ship Monday – Wednesday to avoid packages arriving on the weekend. Would you like these instructions to the collection sites or would you prefer shipping Monday – Thursday? <i>(Shipments can be received Saturdays with pre-arrangements and at an additional charge)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No, prefer Mon – Thur shipping
21	Kryosphere recommends that all specimens be shipped via Overnight Air Courier, i.e. UPS or FedEx. Is this an acceptable form of shipping?	<input type="checkbox"/> Yes <input type="checkbox"/> No
22	Do you want the collection sites to ship the specimens with cold packs or dry ice? <i>(We recommend dry ice to prevent spoilage in the event the package does not arrive next day.)</i>	<input type="checkbox"/> Dry Ice <input type="checkbox"/> Cold Packs <input type="checkbox"/> Other
23	If Dry Ice is checked on Question # 15, Do the collection sites have access to a dry ice supply?	<input type="checkbox"/> Yes <input type="checkbox"/> No
24	Do you want postage paid/pre-addressed courier labels applied to the kits or will each collection site be doing their own shipping? <i>(Kryosphere's standard practice is to provide appropriate sized EPS foam shipper with applicable Category B &amp; Dry Ice labeling)</i>	<input type="checkbox"/> Kryosphere to provide <input type="checkbox"/> Collection site to provide
<b>ITEM #</b>	<b>ADDITIONAL TEXT SPACE</b>	