Novel Study Start-Up Agreement (SSUA) - guarantee compensation for start-up work performed prior to Clinical Trial Agreement (CTA) while reducing study start-up timelines

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Background

Considerable amounts of study start-up work to prepare clinical trials for opening happens prior to execution of the Clinical Trial Agreement (CTA) by Cancer Center staff including clinical, regulatory, finance, and contract team members. These start-up services are performed by sites without the guarantee of compensation. If sponsors no longer pursue the study, the site can be left with hours of work performed without reimbursement. Sites may then devote months to recuperating the costs from sponsors for start-up activities, ending with partial or no payment for services rendered due to the absence of a fully-executed CTA.

Goals

Create and implement a Study Start-Up Agreement (SSUA) to:

- Protect the site's financial interest by executing a separate contract—after site selection and before CTA negotiation—to ensure that start-up services performed are paid in full should the CTA fail to be fully-executed
- Reduce Time to Activation (TTA) by agreeing to the start-up fees before negotiations and creating study award accounts (AWD) earlier to reduce post-award processing

Solutions & Methods

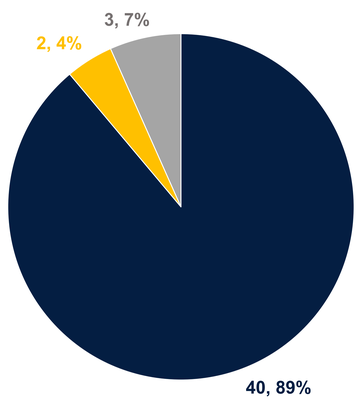
1. Create separate contract to be executed prior to CTA negotiations, to ensure start-up activities performed will be reimbursed by sponsor in full should the CTA not be FE or the study fail to open
2. Create SSUA calculator that generates total start-up amount based on departments involved
3. Propose SSUA to sponsor after site selection to allow time for execution
4. Begin back-end clinical trial account creation earlier in the process with an invoiceable FE contract.

SSUA Calculator

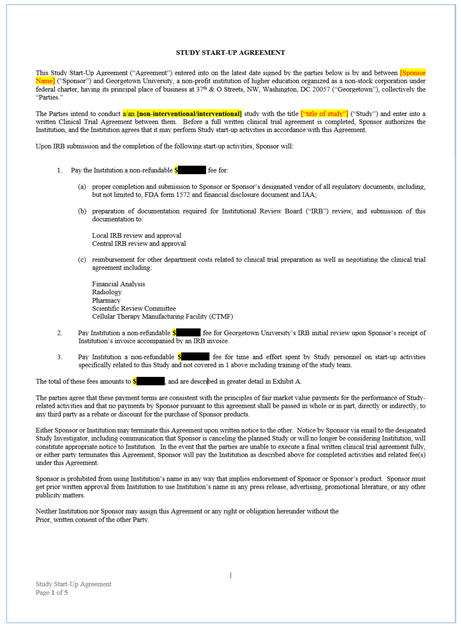
Questions:			**Admin Start Up**	[redacted]	[redacted]
Overhead	[redacted]		**IRB Initial Review**		
Oncology Study?	Yes		**Financial Analysis**		
Does the Study Utilize Radiology Scans/Imaging? (CT, MRI, PET, X-Ray, DEXA etc.)	Yes		**SRC Initial**		
			Site Prep for Initial Review		
			Radiology Start Up		
Will the Study Require Research Pharmacy?	Yes		**Pharmacy Start Up**		
			CRU Initial Review	*Not Applicable*	**Not Applicable**
Will the CRU be Involved in this study?	No		**CRU Initiation**	*Not Applicable*	**Not Applicable**
			Lombardi CTO Cellular Therapy Admin Start Up	*Not Applicable*	**Not Applicable**
Will the Cell Therapy be Involved in this study?	No		**CTMF Initiation**	*Not Applicable*	**Not Applicable**
			BMCP Initiation	*Not Applicable*	**Not Applicable**
Will the CTMF be Involved in this study? (If cell therapy study or a study with cell therapy involvement, usually both CTMF and BMCP will be utilized)	No				
			TOTAL		[redacted]
Will the BMCP be Involved in this study? (If cell therapy study or a study with cell therapy involvement, usually both CTMF and BMCP will be utilized)	No				
Is this Study Interventional? (If it's Even Just Taking Blood, it's Interventional) (Be sure to mark whether or not it's interventional in paragraph 2 of the agreement)	Yes				

Part 1	[redacted] (Other Depts)
(1 (c) items for agreement): (Copy and paste below section 1 (c))	
Clinical Research Operations Office (CROO) (See "Financial Analysis")	
Georgetown Regulatory (Prep fee for intial IRB Submission)	
Radiology	
Insitutional Research Pharmacy	
Scientific Review Committee	
Part 2	[redacted] (IRB Review (Not Prep))
Part 3	[redacted] (Admin Startup)

SSUA Execution Status



SSUA (First Page)



STUDY START-UP AGREEMENT

This Study Start-Up Agreement ("Agreement") entered into on the latest date signed by the parties below is by and between [Sponsor Name] ("Sponsor") and Georgetown University, a non-profit institution of higher education organized as a non-stock corporation under federal charter, having its principal place of business at 37th & O Streets, NW, Washington, DC 20057 ("Georgetown"), collectively the "Parties."

The Parties intend to conduct a/an [non-interventional/interventional] study with the title ["title of study"] ("Study") and enter into a written Clinical Trial Agreement between them. Before a full written clinical trial agreement is completed, Sponsor authorizes the Institution, and the Institution agrees that it may perform Study start-up activities in accordance with this Agreement.

Upon IRB submission and the completion of the following start-up activities, Sponsor will:

1. Pay the Institution a non-refundable $[redacted] fee for:
   (a) proper completion and submission to Sponsor or Sponsor's designated vendor of all regulatory documents, including, but not limited to, FDA form 1572 and financial disclosure document and IAA;
   (b) preparation of documentation required for Institutional Review Board ("IRB") review, and submission of this documentation to:
   Local IRB review and approval
   Central IRB review and approval
   (c) reimbursement for other department costs related to clinical trial preparation as well as negotiating the clinical trial agreement including:
   Financial Analysis
   Radiology
   Pharmacy
   Scientific Review Committee
   Cellular Therapy Manufacturing Facility (CTMF)
2. Pay Institution a non-refundable $[redacted] fee for Georgetown University's IRB initial review upon Sponsor's receipt of Institution's invoice accompanied by an IRB invoice.
3. Pay Institution a non-refundable $[redacted] fee for time and effort spent by Study personnel on start-up activities specifically related to this Study and not covered in 1 above including training of the study team.

The total of these fees amounts to $[redacted] and are described in greater detail in Exhibit A.

The parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities and that no payments by Sponsor pursuant to this agreement shall be passed in whole or in part, directly or indirectly, to any third party as a rebate or discount for the purchase of Sponsor products.

Either Sponsor or Institution may terminate this Agreement upon written notice to the other. Notice by Sponsor via email to the designated Study Investigator, including communication that Sponsor is canceling the planned Study or will no longer be considering Institution, will constitute appropriate notice to Institution. In the event that the parties are unable to execute a final written clinical trial agreement fully, or either party terminates this Agreement, Sponsor will pay the Institution as described above for completed activities and related fee(s) under this Agreement.

Sponsor is prohibited from using Institution's name in any way that implies endorsement of Sponsor or Sponsor's product. Sponsor must get prior written approval from Institution to use Institution's name in any press release, advertising, promotional literature, or any other publicity matters.

Neither Institution nor Sponsor may assign this Agreement or any right or obligation hereunder without the Prior, written consent of the other Party.

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Study Start-Up Agreement
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SSUA (Fee Justifications)

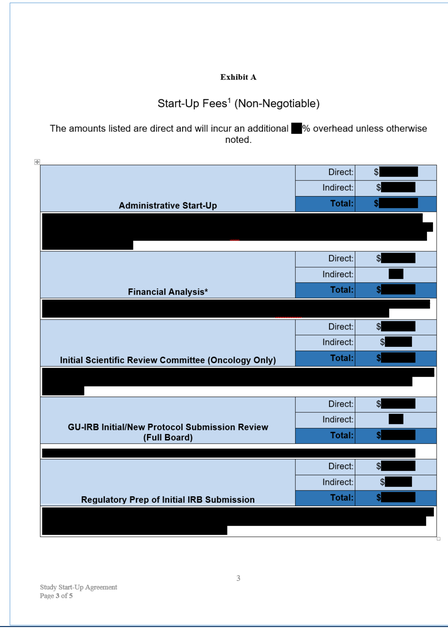

Exhibit A

Start-Up Fees[1] (Non-Negotiable)

The amounts listed are direct and will incur an additional [redacted]% overhead unless otherwise noted.

Administrative Start-Up	Direct:	$[redacted]
	Indirect:	$[redacted]
	Total:	$[redacted]
[redacted]		
Financial Analysis*	Direct:	$[redacted]
	Indirect:	[redacted]
	Total:	$[redacted]
[redacted]		
Initial Scientific Review Committee (Oncology Only)	Direct:	$[redacted]
	Indirect:	$[redacted]
	Total:	$[redacted]
[redacted]		
GU-IRB Initial/New Protocol Submission Review (Full Board)	Direct:	$[redacted]
	Indirect:	[redacted]
	Total:	$[redacted]
[redacted]		
Regulatory Prep of Initial IRB Submission	Direct:	$[redacted]
	Indirect:	$[redacted]
	Total:	$[redacted]
[redacted]		

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Study Start-Up Agreement
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Outcomes

- SSUA executed with over 88% of industry sponsors over a 20-month period
- Informational meetings leveraged to explain concepts to sponsors and subsequent SSUAs with those sponsors were quickly executed, with some agreed upon within one week
- Removed the need to negotiate the start-up fees in the CTA decreased the number of items requiring negotiation, leading to quicker activation
- Back-end account creation earlier in the process decreased the chances for delays in the opening of trials

Lessons Learned & Future Directions

1. Initial SSUA with sponsor often times required significant correspondence to educate sponsors and convey the need
2. Subsequent SSUAs executed quickly
3. SSUA template pivoted from a rigid template to a sponsor-customized approach while still preserving core functionality
4. With demonstrated success with oncology SSUAs, Georgetown plans to mirror process for non-oncology

Acknowledgements

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