

Study Name, Arm ____	Who performs or administers the service? (PI, Co-Investigator, Study Coordinator, Nurse, etc.) REQUIRED	If at UCSF, list the address where the procedure/service is performed. REQUIRED	List the time it takes to perform each service. OPTIONAL - complete if CTBSC builds the budget	Is the assessment an APeX charge? REQUIRED					
					Screening (Pre-LE 30 Days prior to OTLX)	Day of OTLX Baseline/Day 0	Randomizatio Post OTLX days 7-10	Treatment A 1,14,30,60,90,180,2 Post OTLX to hospital discharge	Day 14
List of Assessments									
Inclusion/Exclusion Criteria					R				
Informed Consent					R	R			
Randomization Inclusion/Exclusion Criteria							R		
Medical History						S			
Physical Exam						S	S	S	S
Height						S			
Weight						S	S	S	S
Vital Signs						S	S	S	S
HCG Pregnancy Test						S	R		
Hematology (local lab)					S	S	S	S	S
Serum Chemistry (local lab)					S	S	S	S	S
Biomarkers [d] (blood collected/shipped)									
Local Labs - AFP [k]									
Doppler Ultrasound [g]							R	R	R
Concomitant Medication						R	R	R	R
Adverse Events						R	R	R	R
Serious Adverse Events						R	R	R	R
Contrast imaging									
Blood draw					S	S	S	S	S
OPTIONAL - complete if CTBSC builds the budget ---> Misc. PI Time									
OPTIONAL - complete if CTBSC builds the budget ---> Misc. CRC Time									

