Industry Funded Intake Process Acronym Glossary CA - Contract Analyst OCR@usf.edu CDA - Confidentiality Disclosure Agreement COI -Conflict of Interest Program **START** CTA - Clinical Trial Agreement EC - Export Control Study Team OCR receives FAST - USF Financial System receives CDA/ CDA/NDA from FECTA - Fully Executed Contract NDA from Sponsor Sponsor GBR - Grant Budget Release IC - Intake Coordinator ICF - Informed Consent Form IF- Internal Form IRB - Institutional Review Board CDA/NDA sent to NDA - Non-Disclosure Agreement OCR@usf.edu OCR - Office of Clinical Research OGC - Office of General Counsel PA - Project Analyst PI - Principal Investigator SR - Sponsored Research TTO reviews, negotiates TTO - Technology Transfer Office and executes CDA/NDA and provides executed copy to Study Team & OCŘ Study Team informs Sponsor/CRO to Study Team decision to send all relevant Yes move forward with trial? documents to OCR@usf.edu Initial documents Intake Process required to trigger New Study Confirmation- Study Team to confirm relevant intake: contacts and Hospital/Affiliate component **Draft Budget** OCR will communicate with CRO/Sponsor to seek any missing Protocol documents Draft Research Hospital/Affiliate Component-Agreement OCR notifies Hospital/Affiliate of new study if applicable (CTA) Contract processing Budget review and development General contract language is processed and The study budget is processed by the OCR PAs in consultation with the study team, department, third negotiated by OCR's CA in consultation with OGC, party vendors/hospital and CRO/Sponsor. The TTO, and specialty departments (IT Security, EC, COI), as applicable. The length of time for full length of time for budget development varies based on protocol complexity and responsiveness execution varies based upon agreement of the above stated parties. complexity. Final Contract Final Budget **FECTA** Language OCR sends Approval To Enroll notification (ATE) with final vendor OCR distributes OCR sends agreements upon receipt of: SR Financial Research Award Account Open in GBR, FECTA, **FECTA** Management Notice (RAN) with FAST with Initial IRB approval, IF triggered to chartfield string to IRB Approval/Final ICF (send to **Budget** to SR to setup in activate in FAST study team upon OCR@usf.edu upon receipt) FAST system receipt from SR Hospital/Affiliate approval if applicable Study is Open to Enrollment Upon Sponsor's Approval

OFFICE OF CLINICAL RESEARCH