

Health Science Center – Jacksonville Office of Research Affairs (904) 244-9478 580 West Eighth Street Tower II, 9th Floor, Suite 9015 Jacksonville, FL 32209

CTA (Fund 214) Process

- 1. UFIRST:
 - a. Create a <u>New UFISRST Proposal</u>, complete the SmartForm and <u>Access Budget Workspace</u> to create a new Budget (Review F:\Research Studies\Office of Research Affairs (ORA)\UFIRST UPDATES for helpful hints).
 - i. <u>Request PI Certification</u> and <u>Send SFI Certification Reminders</u>.
 - ii. Attach the following <u>Submission Documents</u>:
 - 1. Sponsor's draft CTA;
 - 2. PI signed CTA checklist (IF not signed at time of Proposal submission, please attach signed CTA checklist to the UFIRST AGREEMENT record); and
 - 3. Payment terms & Budget.
 - b. Create a New UFIRST Agreement (do not wait for PI Certification or completed SFI),
 - i. Complete the Agreement SmartForm (Review F:\Research Studies\Office of Research Affairs (ORA)\UFIRST UPDATES for helpful hints).
 - ii. Attach the completed and PI signed <u>CTA Checklist</u> (if it was not attached to the Proposal);
 - iii. <u>Submit for Review</u>; and
 - iv. Remind PI to complete the UFISRT Agreement <u>SFI and Compliance forms</u>. (DSP/Jax assignment is dependent on completion of these SFI and Compliance forms.)
- 2. Forward <u>CRO/Sponsor's CTA email</u> to the DSP/Jax Document Negotiator.
- 3. Negotiate Budget:
 - Process the RSIRF form, edit the Study Budget, and send edited Study budget to DSP/Jax Document Negotiator prior to sending it for CRO/Sponsor's review to ensure UF's overhead and standard site fees are included.
 - b. Negotiate UF's edited Study budget with CRO/Sponsor.
 - c. Attach finalized Budget to UFIRST Agreement.
- 4. ICF Review/IRB Submission
 - a. Red-line ICF per UF IRB policy, the selected CTA Checklist and Cost Template terms, and the negotiated Budget.
 - b. Send a <u>red-lined ICF</u> to CRO/Sponsor for their review and approval;
 - c. Upon CRO/Sponsor approval, proceed with IRB submission;
 - d. Attach IRB approval and IRB-approved ICF to the Draft Fund 214 (or Agreement if Draft Project is not yet created); and
 - e. Email DSP/Jax Document Negotiator and request their review of the IRB-approved ICF.
 - f. DSP/Jax Document Negotiator review of the ICF to verify the Cost terms are consistent with IRB policy, the selected CTA Checklist and Cost Template terms, and the negotiated CTA and Budget.
 - i. If the ICF is verified, DSP/Jax Document Negotiator to request activation of the Draft Fund

214 Project and Study enrollment may begin.

- ii. If the ICF is not verified, DSP/Jax Document Negotiator to request the department:
 - 1. resubmit a corrected ICF for sponsor and IRB review/approval,
 - 2. attach the revised IRB-approved ICF to UFIRST, and
 - 3. request DSP's verification of this revised IRB-approved ICF.
 - a. If the ICF <u>is verified</u>, DSP/Jax Document Negotiator to request activation of the Draft Fund 214 Project and Study enrollment may begin.
- 5. Submit completed electronic Medicare Qualifying Studies Form (CMS).
- 6. If applicable, send a completed ACH-Wire Request Form (<u>https://www.fa.ufl.edu/directives/request-for-incoming-ach-eft-and-wire-payments/</u>) to <u>tmhelp@admin.ufl.edu</u>. Upon receipt, Banking & Merchant Services will provide UF's Banking details to Sponsor via a password protected email.

** Bookmark the UFCOM/Jacksonville's <u>Resources</u> page for easy access to the RSIRF, CTA Checklist, CMS Form, Recorded CTA and NDA Trainings, ORA Portals, Research Manual, OnCore, Grant Opportunities, and more. (<u>https://med.jax.ufl.edu/research/resources</u>)

Additional ORA resources located at F:\Research Studies\Office of Research Affairs (ORA).