Sponsored Award Lifecycle

1. Develop an Idea & Identify Funding (PI)
2. Develop Proposal (Pre-Award RAS)
3. Review & Submit Proposal (OSP)
4. Sponsor Notice of Award (PI, OSP)
5. Award Set up in Compass/Issue eNOA (FGC)
6. Establish & Execute Sub-awards (OSP)
7. Post-Award Management (RAS, PI, FGC, AR)
8. Reporting (RAS, PI, FGC, FSR)
9. Close-outs (RAS, FGC)

Pre-Award

Post-Award

Award Set-up

- Prepare (PI) and submit (OSP) Final Invention Statement and Final Progress Report (PI submits in some cases)
- PACT preparation (RAS)
- PACT submission to FGC (RAS)
- Close in COMPASS (FGC)

- Create scientific progress report (PI)
- Create and submit Interim FSRs to sponsor (RAS)
- Create RPPRs (RAS/PI) and submit to sponsor (OSP)
- Prepare ART (RAS)
- Review and submit ART to FGC (RAS)
- Create Annual & Final FSR and submit to FGC (RAS)
- Submit Annual and Final FSR to sponsor (FGC)

- Ongoing reconciliation reports/meetings (RAS/PI)
- Invoice sponsor (FGC)
- Sub-award management (PI/RAS)
  - Determine if deliverables are met (PI)
  - Release post award invoice in Emory Express (RAS)
  - Release payment to sub-awardees (Payment services)
- Receive payment at AR (Cash AR – Finance Group)

- Compile (RAS) and submit (OSP) Just-in-Time materials
- Notification to PI & OSP often occur at different times and through different mechanisms
- Ensure all components of awards are complete, e.g., IRB, IACUC, etc. If not, gather as needed from RAS, Sponsor, etc. (OSP)
- Ensure the terms of the award are acceptable and the award is ready for setup (OSP)
- Initiate award set-up request in Compass (OSP)

- Set up award in Compass (FGC)
- Issue eNOA & SpeedType (FGC)

- Ensure all materials required for subaward have been received (RAS)
- Initiate the subaward award request in COMPASS (RAS)
- Draft/execute subaward (OSP)
- Forward executed subaward to FGC and RAS (OSP)
Sponsored Award Lifecycle - Industry Contracts

1. Develop an Idea & Identify Industry Sponsor (PI, Pre-Award RAS)
2. Develop Proposal (PI, Pre-Award RAS)
3. Negotiate Contract (OTT)
4. Receipt of Executed Contract (OTT)
5. Award Set up in Compass/Issue eNOA (FGC)
6. Establish & Execute Sub-awards (OTT)
7. Post-Award Management (RAS, PI, FGC, AR)
8. Reporting (RAS, PI, FGC)
9. Close-outs (RAS, FGC)

Pre-Award

Post-Award

Award Set-up

- Prepare and submit Final Progress Report (PI)
- PACT preparation (RAS)
- PACT submission to FGC (RAS)
- Close in COMPASS (FGC)

- Create scientific progress report (PI)
- Prepare and submit ARRT to FGC (RAS)
- Create Annual & Final FSR and submit to FGC, as required (RAS)
- Submit Annual and Final FSR to sponsor, as required (FGC)

- Ongoing reconciliation reports/meetings (RAS/PI)
- Invoice sponsor (FGC)
- Sub-award management (PI/RAS)
  - Determine if deliverables are met (PI)
  - Release post award invoice in Emory Express (RAS)
  - Release payment to sub-awardees (Payment services)
- Receive payment at AR (Cash AR – Finance Group)

- Compile and submit project materials (e.g., SOW, draft contract, budget, etc.) through EPEX (RAS)
- Ensure all required compliance approvals are complete (e.g., eCOI, IRB, IACUC, etc.) prior to execution of contract (OTT)

- Initiate award set-up request in Compass (OTT)
- Set up award in Compass (FGC)
- Issue eNOA & SpeedType (FGC)

- Ensure all materials required for subaward have been received (RAS)
- Initiate the subaward award request in COMPASS (RAS)
- Draft/execute subaward (OTT)
- Forward executed subaward to FGC and RAS (OTT)
1. Review Sponsor’s Protocol for Scientific Merit & Feasibility (PI, Dept, Pre-Award RAS)
2. Submit Concurrently to IRB, OCR & OTT (PI, Dept, Pre-Award RAS)
3. IRB Approval, Negotiate Budget, Finalize PRA, Negotiate Contract (IRB, OCR, OTT)
4. Receipt of Executed Contract (PI, OTT)
5. Award Set up in Compass/Issue eNOA (FGC, OCR)
6. Establish & Execute Subcontracts (OTT)
7. Post-Award Management (PI, RAS, FGC, OCR)
8. Reporting (RAS, PI, FGC, FSR, OCR)
9. Close-out (IRB, OCR, OTT, RAS, FGC)

Industry Clinical Trials Lifecycle

- Pre-Award
  - Review Sponsor’s Protocol for Scientific Merit & Feasibility (PI, Dept)
  - Submit Concurrently to IRB, OCR & OTT (PI, Dept, Pre-Award RAS)
  - IRB Approval, Negotiate Budget, Finalize PRA, Negotiate Contract (IRB, OCR, OTT)
  - Receipt of Executed Contract (PI, OTT)
  - Award Set up in Compass/Issue eNOA (FGC, OCR)
  - Establish & Execute Subcontracts (OTT)
  - Post-Award Management (PI, RAS, FGC, OCR)
  - Reporting (RAS, PI, FGC, FSR, OCR)
  - Close-out (IRB, OCR, OTT, RAS, FGC)

- Award Set-up
  - Set up award in Compass (FGC)
  - Issue eNOA & SpeedType (FGC)
  - Activate study in ERMS & PowerTrials (OCR)
  - Upload study level docs in Emory MR (OCR)
  - Update ct.gov# & speedtype in ERMS for billing (OCR)
  - If PII, register in ct.gov (OCR)

- Post-Award
  - Set up award in Compass (FGC)
  - Issue eNOA & SpeedType (FGC)
  - Activate study in ERMS & PowerTrials (OCR)
  - Upload study level docs in Emory MR (OCR)
  - Update ct.gov# & speedtype in ERMS for billing (OCR)
  - If PII, register in ct.gov (OCR)

- Pre-Award
  - Create scientific progress report (PI)
  - Prepare & submit ARRT to FGC (RAS)
  - Create Annual & Final FSR & submit to FGC, as required (RAS)
  - Submit Annual & Final FSR to sponsor, as required (FGC)
  - Update active clinical trials & subjects to Tableau (OCR)
  - Facilitate late ERMS enrollment (OCR)
  - Monthly update to PI for each study on invoicing, AR, AP, Compass expenses (OCR)

- Award Set-up
  - Complete mandatory clinical trial & human subject protections training Q 3yrs (PI/CRC)
  - Submit to eIRB/WIRB (PI) & EPEX (RAS)
  - Facilitate pre-award approvals (OCR/IRB/OTT)
  - Compile & submit project materials (e.g. SOW, draft contract, draft budget, PI effort calculation, OCR Submission Form, protocol, draft consent, FDA communication) in EPEX (RAS)

- Post-Award
  - Complete all required compliance approvals (e.g. CTRC, COI, Rad Safety, IBC, IRB) prior to execution of contract (WCI/COI/EHSO/IRB/OCR/OTT)
  - Review eIRB for FDA & NIH defined clinical trials & EHC/GHS billables (OCR)
  - Initiate award set-up request in Compass (OTT)

- Pre-Award
  - Register subject in ERMS same day as consent (CRC)
  - Enter subject in Emory & sets clinical trial flag (OCR)
  - Upload signed consent in Emory (OCR)
  - Keep visits in ERMS same day as visit (CRC)
  - Update ct.gov per FDA regulation & NIH Policy
  - Ongoing reconciliation reports/meetings (PI/RAS/OCR)
  - Invoice sponsor per PRA & CTA (OCR/Peds RAS)
  - Track AR for non-invoiceable (OCR)
  - Process vendor payments, sub-site pymts, subject stipends & travel reimbursements per CTA (OCR)
  - Manage subcontract (PI/RAS/OCR)
  - Determine if deliverables met (PI)
  - Release invoice in Emory Express (RAS/OCR if HMO)
  - Release payment to sub-awardees (Payment Svcs)
  - Receive payment for AR (OCR, Controller)

- Award Set-up
  - Ensure all materials required for subcontract have been received (RAS)
  - Initiate the subcontract award request in COMPASS (RAS)
  - Draft/execute subcontract (OTT)
  - Forward executed subcontract to FGC & RAS (OTT)

- Post-Award
  - Close in IRB, OTT & OCR (ERMS, EmMR, off-study subject, ct.gov, verify all funds received & posted to appropriate award)
  - Prepare PACT (RAS)
  - Submit PACT to FGC (RAS)
  - Close in COMPASS (FGC)

- Pre-Award
  - Create scientific progress report (PI)
  - Prepare & submit ARRT to FGC (RAS)
  - Create Annual & Final FSR & submit to FGC, as required (RAS)
  - Submit Annual & Final FSR to sponsor, as required (FGC)
  - Update active clinical trials & subjects to Tableau (OCR)
  - Facilitate late ERMS enrollment (OCR)
  - Monthly update to PI for each study on invoicing, AR, AP, Compass expenses (OCR)