UFHealth
JACKSONVILLE

Policy Number:	**ORA-RSIRF-01**
Last Update:	**December 2020**
Initial Approval:	**October 2020**
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TITLE: Research Study Initiation Request Form (RSIRF) submission procedures

POLICY: All instructions for the RSIRF form should adhere to the format described below. The instructions are stored on the F:research studies/ORA drive, accessible from the Office of Research Affairs-Resources. All instructions must be available in close proximity for use by personnel submitting and approving the RSIRF.

DEFINITIONS:
1. Clinical Research Coordinator (CRC): Initiator
2. Audit Services: First approver
3. Clinical Data Quality (CDQ): Second approver
4. Billing analyst: Final approval
5. TECH: Technical Fees. The fields in this section will not be available unless the check box is checked.
6. PROF: Professional Fees.

PROCEDURE:
1. When a CRC needs to submit an RSIRF he/she will:
   a. Go to the UF Jacksonville Office of Research Affairs-Resources tab
      i. Select the web link to the RSIRF
      ii. Create New RSIRF Form and complete the following:
         1. Home: required fields
         2. TECH: only if there are hospital billing charges.
         3. PROF: only if there are professional billing charges
      iii. Option: Cancel
      iv. Option: Save (in the event the CRC is unable to complete the form in one sitting)
         1. When ready to return to the form:
            a. Go to the UF Jacksonville Office of Research Affairs-Resources tab
            b. Select the web link to the RSIRF
            c. Scroll down the right hand column to RSIRF FORM
            d. Search for your saved draft, select, continue editing and submit when ready
      v. Option: Submit and Process
   b. All emails listed on form will receive email confirmation of submission.
2. Audit Services receives email to:
   a. Review the RSIRF via web link
      i. Edit if necessary
         1. Save
         2. Return to the form by going to the link in the email received
   b. Approve/Reject via web link
         1. If rejected, CRC will be able to make edits to the rejected RSRIF and resubmit
         2. If approved, CRC will receive an email informing them of the approval status
      ii. CRC will receive email confirmation of Audit Services decision and comments
3. CDQ receives email to
   a. Review RSIRF via web link
      i. Edit if necessary

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       ii. Forward Review email to designated staff to
          1. Edit
          2. Save edits
   b. Upon completion of CDQ review and edits, CDQ will Approve/Reject via web link
   c. If PROFESSIONAL CHARGES were completed by CRC
       i. CDQ approves/rejects
          1. If rejected, CRC will be able to make edits to the rejected RSRIF and resubmit
          2. If approved, CRC will receive an email informing them of the approval status
             a. END. Skip to 5.
   d. If TECHNICAL CHARGES were completed by CRC
       i. CDQ approves/rejects
          1. If rejected, CRC will be able to make edits to the rejected RSRIF and resubmit
          2. If approved, CRC will receive an email informing them of the approval status
             a. Hospital Billing Analyst will receive.

4. Hospital Billing Analyst serves as final approver
   a. Edit if necessary
       a. Save
       b. Return to the form by going to the link in the email received

5. **If approved as initial**
   a. CRC is notified via email of RSRIF Initial Approval
   b. Initial approved RSIRF pdf document is added to share point library and will be available for 30 days
   c. Link to the editable 'Initial Approved RSRIF' will be included in email

6. **To submit Final Approval**
   a. CRC accesses link received in email notification of RSIRF Initial Approval
   b. Deselects 'Initial'
   c. Selects 'Final'
   d. Save and Submit
       i. Form is now resubmitted and will go through entire approval process again for Final Approval
       ii. Final approved RSIRF pdf document is added to share point library and will be available for 30 days
       iii. Link to the 'Final Approved RSRIF' pdf will be included in email

7. **To check the status of the form at any time during the approval process, go to the:**
   a. Link in the confirmation email
       i. View process status of all RSIRF forms you have submitted:
          1. Blank – Not Submitted
          2. Locked – In process
          3. Rejected – Returned to sender for Update
       ii. Approved and submitted drafts versions will be available for 30 Days on the same home page as above

8. **If Rejected at any time during the process CRC will be notified via email immediately**

END OF RSIRF PROCESS

REFERENCES:

A-01-001 Policy and Procedure Guidelines

A-01-001 _AppA Appendix Example

APPROVED BY: None