UF Human Subjects Research Task Force
Recommendations to Steering Committee – January 2016

Over the past several years, key stakeholders of the human subjects research process identified the need to conduct a comprehensive review of the steps involved to develop and implement human subject research protocols at the university. Study start-up is a highly intricate process that involves constant communication and coordination across six central business offices and the university hospital system. In addition to review and approval with central administration, managing and tracking the changing state and federal regulation adds an additional layer of complexity for investigators and research teams.

In August 2015, executive leadership formed a Human Subjects Research (HSR) Task Force to examine all aspects of the current process and corresponding regulation. The HSR Task Force was charged with identifying opportunities for improving and streamlining the process. The HSR Task Force convened on August 31 and held eight working sessions throughout the fall semester.

In an effort to gather input from the community, the HSR Task Force solicited feedback from more than 10 faculty groups and held feedback sessions with over 15 seasoned research coordinators. The Task Force concluded the in-depth analysis with a clinical research billing compliance panel discussion, which included experts from the UF Health Research Billing Office, EPIC IT staff, UF research teams and the Research Administration and Compliance Office.

This document summarizes the key issues and corresponding recommendations for the Steering Committee's consideration.

Issue 1: Information Availability and Operational Efficiency

An effective human subject research (HSR) enterprise includes comprehensive and validated data and seamless integrated processes resulting in accurate metrics and operational efficiencies.

Proposed Solution

Implement a Clinical Trial Management System (CTMS) that is integrated with EPIC and other enterprise systems to facilitate the human subjects research process from start to finish. A CTMS would allow UF to manage, track and report all study protocol and participant related activities. Benefits of an electronic system include:

- Elimination of redundant data entry and forms through integrated systems, thereby improving efficiency of study start-up
- Reduction of billing error risks
- Integration of an electronic billing plan with participant calendars
- Increased participant safety measures
- Improved financial management including cash recovery
- Improved participant payment process
- Maintenance of auditable management controls and compliance checkpoints
- Availability of a central and real-time repository for HSR studies and relevant metrics
- Improved data regarding actual study costs and recovery to inform feasibility outcome measures
- Access to data such as screening and enrollment targets, timelines, and actuals required to reach NCI cancer designation and to be responsive to CTSI program requirements

Next Steps

External evaluation of various CTMS systems to determine the system most appropriate for the UF portfolio. Since UF already utilizes OnCore for the Cancer Center, the CTSI Clinical Research Center, and

the CTSI biorepository, other CTMS systems will be vetted against OnCore to determine best fit for the institution. This evaluation will result in an implementation plan including resources, governance, and timeline.

Issue 2: IRB Operations

Operational efficiencies can be gained within the IRB to increase the pace of reviews while maintaining compliance and appropriate subject protections. At a high level, proposed solutions are listed below.

Proposed Solutions

- Develop and implement a UF policy that allows for the University to administratively close studies with low accrual that utilize resources for an unsupported research gain.
- Construct robust, disease-type, de-identified data sets that are considered, from an IRB and Privacy Board perspective, as not meeting the definition of "human research", and therefore do not require any UF regulatory oversight (which includes the IRB). Any researcher using this data set would not be required to seek IRB approval.
- IRB01: Replace part-time executive reviewers with 1.5 FTE administrative reviewers to increase pace of expedited reviews. The cost would be covered in part by reducing current Vice Chair commitments.
- IRB02: Hire a 0.5 FTE administrative executive reviewer to support current and growing workload and ensures proper back up to what is now a single 0.5 FTE chair operation.
- Establish a process to provide additional services and resources to "priority" protocol review based on approved University criteria
- Provide a meaningful recognition plan for IRB members that incentivizes faculty to participate on the IRB
- Develop a long-term plan to address issues with student research, international research, and single/central IRB mandates

Next Steps

Should the Steering Committee support this direction, detailed cost, resource and implementation plans will be developed for each proposed solution and presented to Dr. David Norton who can then work with the appropriate deans as needed for budget authority.

Issue 3: Administrative Burden and Organization of Resources

The increasing and constantly changing regulations place an increased burden on the faculty thus reducing time available to conduct research. The current decentralized nature of UF's human subjects research infrastructure and the manual processes still in effect create numerous inefficiencies, resulting in study startup delays, lost revenue and frustrated investigators and research teams.

Proposed Solutions

- Implement an HSR "storefront" to operate as a single organizational unit overseeing all phases of human subjects research. Benefits of this structure could include:
    - Support of investigator needs from study inception to study close-out to promote competitive, timely, and compliant research

  - Expansion of services provided to include support for protocol development, feasibility (biostatistics support), budget development and negotiation, marketing, enrollment management, and financial management
  - Improved quality of clinical studies in the pipeline to reduce burden and reduce cycle times of IRB and other regulatory reviews
  - Improvement of cycle times from sponsor engagement to study start-up increasing potential for more activity
  - Relieve faculty of management of certain administrative functions thereby opening bandwidth for more research activity
  - Improved communication and issue resolution with key stakeholders
- Standardize research coordinator training and provide appropriate platforms and support to encourage networking and to increase efficiency and effectiveness.
- Implement a governance structure to constantly engage key stakeholders, including faculty and coordinators, to monitor regulations, University response to managing the increase in administrative burden, educational requirements, coordinator competencies, workload distribution, salaries, hospital relations and all other community concerns
- Explore all possibilities to improve the efficiency of collecting information for the pricing and billing processes. For example, consider qualified coordinators and investigators submitting COS forms without approval from Shands ancillaries; evaluate UFIRST, COS, MCA, Billing Grid, SRIC checklist and CTA checklist to identify and eliminate redundant questions; and enhance the pricing tool to incorporate more current and comprehensive information.

Next Steps

- External evaluation of various HSR organizational models to determine the one most appropriate for the UF portfolio and culture. This evaluation will result in an implementation plan including resources, governance, and timeline.
- Create and maintain an interactive electronic process map with a decision-based questionnaire that guides investigators to regulation information and resources based on their research needs
- Incorporate improved processes, navigators and tools during new faculty onboarding
- Remove autoclave functions from RAC responsibilities (assign elsewhere in the Health Science Center).

Issue 4: Collaborative Interactions between UF Health Academic Research and UF Health Clinical Operations

There is a disconnect in communication and collaboration between UF faculty and study team members and UF Health clinical personnel. Moreover, the UF Health academic and clinical relationship is essential for the support and success of human subjects research. With the steady increase and complexity of sponsor-funded clinical studies conducted by UF faculty in the hospital setting, investigators need additional support to facilitate timely contracting with external sponsors.

Proposed Solutions

- Expand collaborative support offered to research study teams, especially in areas relating to research billing and pricing, including the Confirmation of Services (COS) process.
- Provide a strong leadership message to service providers, clinical staff and unit management and other personnel within UF Health of the importance of the research mission.

- Promote active appreciation, awareness and attention to require the establishment of compliant workflow processes when interacting with research study subjects.

Next Steps

- Identify UF Health resources who can assist with the Confirmation of Services (COS) process
- Provide a strong leadership message to service providers, clinical staff and unit management and other personnel within UF Health of the importance of the research mission