Final Report and Recommendations

of the

Human Subject Research Improvement Working Group

August 15, 2022

The following members of the working group were in consensus with the summary presented. Some modest differences in specific wording existed among the working group. The final document reflects the chairperson's efforts to represent everyone's individual views. With that said, the document should be considered a consensus statement of the entire working group.

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The working group expresses their gratitude to the following individuals who provided technical/administrative assistance and served as moderators for some of the focus groups: Angela M. Avery, Allison M. Ivey, Jennifer Del Pilar Lanz, Dr. Kimberly A. Wollard, and Kristine M. Wynne.

Executive Summary:

The Human Subjects Research Improvement Working Group (HSRIWG) was established in March of 2022 with the goal of identifying opportunities for improvement in the UF Health human subjects research approval and activation process across the human research enterprise. The scope of the working group charge included all aspects of the human subject research approval and activation process at both the Gainesville and Jacksonville campuses. The working group, whose membership is detailed in Appendix A, met for over five months. In April 2022, the group commissioned a survey which was sent to faculty and staff that are current users (defined below) of the human subjects research enterprise. The HSRIWG also held multiple focus group meetings with faculty and clinical research staff to discuss the findings of the survey in greater detail. In addition, the HSRIWG held town halls with staff and board members of the Institutional Review Board (IRB) and the Office of Clinical Research (OCR), and met with leadership from the office of UF Information Technology (IT) Security and OCR.

Data gathered by the HSRIWG came from responses to the survey and the focus groups with faculty and staff involved in the UF human subjects research approval and activation process. Participation in the survey was voluntary and anonymous; participation in the focus groups was voluntary but not anonymous. The results presented may not represent the overall views of the entire UF community, thus may be skewed by the input of the voluntary participants. Nevertheless, within the limits of its charter, the HSRIWG believes that issues raised by the survey, focus groups, and town halls represent key issues currently facing UF faculty and research staff.

The HSRIWG offers a consensus of general and area-specific recommendations regarding the UF human subjects research approval and activation process based on the input described above, contextualized by the knowledge and experience of the HSRIWG membership.

Enterprise Level Recommendations[1]:

1) Currently, the various entities that comprise the human subject research approval and activation process have different reporting lines. This, i) is not efficient, ii) makes centralized changes among the entities difficult to coordinate, implement and maintain, and iii) results in a lack of uniform reporting of the entity's performance, including timeliness and responsiveness, essential for accountability.

   Oversight for the human subject research approval and activation process should be centrally organized under a single office that will provide leadership, track performance metrics, and implement process improvement and coordinate changes necessary for each entity and the overall research approval and activation process. The result will be a more cohesive "one-stop-shop" to support and simplify the submission process for investigators. To achieve this, it is recommended that an external consultant or vendor/contractor with experience in developing a Human Research Protection Program (HRPP) at a large university be commissioned to assist in the successful development and implementation of this Human Research Protection Program.
2) As part of this Program, the HSRIWG strongly recommends that there be one software entry portal within the HRPP when research protocols are submitted.
   i) The software will identify which regulatory and activation entities need to review the protocol.

[1] Specific Entity Level recommendations are on page 4

   ii) The software will be used to activate and notify those required entities that an application is submitted, rather than relying on the investigator and/or IRB to initiate and manage interactions with the other required entities.
   iii) The clinical research enterprise should develop a real-time electronic dashboard that tracks individual clinical research applications as they move through the research approval and activation process. This dashboard must be updated in real-time and be available to the research teams to identify where a proposal is within the approval and activation process. Such a dashboard will have the added benefit of allowing all research approval and activation entities to see a particular project's status across the enterprise.
   b) Operational metrics from the individual entities and the process as a whole must be readily available and used for process improvement (e.g., time from submission to review, time for total approval and activation, time for investigator reply to questions, etc.).
   c) Sufficient infrastructure should be provided to support the continued function and effectiveness of the proposed leadership position (described in item #1), software dashboard, and metric reporting.
3) Leadership of individual entities must be held accountable for defined goals to be set and mutually agreed upon by the entity leadership and the individual named in Recommendation #1. Goals should emphasize responsiveness to investigators and transparency of the process. A method to report goals and achievements from each research entity must be routinely available to the research community and administrators.
4) UF Health Shands leadership should bolster its position on human research and develop an infrastructure that, in coordination with the UF research entities, supports human research that is conducted by UF faculty.
   a) UF Health Shands should create a leadership position with a direct focus on integrating with the UF research enterprise. It is the opinion of many faculty that current UF Health Shands leadership and risk-management are averse to incorporating research into its missions.
   b) Although recent changes in the Nursing Impact Committee (NIC) have improved its responsiveness to investigators plans, the mission of the NIC needs to be clarified. Response rates and interactions with research staff could improve to clarify concerns raised by this committee.
5) An education and training curriculum should be developed and supported by UF and its individual Colleges. The curriculum must assist faculty and staff in understanding and navigating the human subjects research approval and activation process, including education on protocol development, the requirements of the human subjects approval and activation process, and UF Health Shands policies.
6) UF must provide sufficient support to faculty to traverse the human subject research approval and activation process as they fulfill their respective missions, while remaining eligible for promotion on their respective tracks. Potential suggestions include:
   a) Clarifying how much and what type of research should clinical-track faculty be required to conduct as part of their academic mission.
   b) Supporting and mentoring of early-career faculty who wish to be engaged in research, including extensive education in protocol development and the human subject research approval and activation process.
   c) Investigators would greatly benefit from an initial review of protocols emanating from the Center/Department/Division level. This local level review should be available for faculty, staff and students involved in the human subjects research.
7) A priority system should be developed and implemented with the goal of prioritizing approval and activation of applications with the greatest benefit to the institution and the patients served.

Currently most applications are reviewed in the order in which they are received. Serious consideration should also be given to reducing or removing regulatory requirements beyond institutional study cataloguing for low risk research.

8) Improve access to clinical data for research. The UF Health Integrated Data Repository (IDR), supported by the UF CTSI, is an important gateway to clinical data access in support of the research enterprise. Currently, faculty have complained about long wait times to receive requested data from the IDR which may be related to inadequate staffing. The working group recognizes that as the trend to greater use of artificial intelligence and machine learning expands throughout the health science center, demands on the IDR are expected to increase. At the present time, however, the working group is reluctant to make specific recommendations given the changes in data format availability forthcoming in the next few months. Given the continued and increasing significance of clinical data to research, we recommend ongoing assessment of researcher needs and where appropriate, additional investment and innovation in the IDR infrastructure to not only expand what is available but also improve how easily and quickly clinical data can be accessed.

Working Group Survey Methodology, Results, and Limitations:

The UF Bureau of Economic and Business Research (BEBR) was consulted by the HSRIWG for advice and aid in the development, distribution and analysis of a survey designed to benchmark investigator and their support staff issues concerning the UF human subjects research approval and activation process. Importantly, the survey was designed to assess all potential approval and activation entities, including the IRB, OCR, SRMC, IT Security, CTSI, etc. In April, 2022, the survey was finalized (Appendix B), and was distributed via email to 4,081 identified enterprise users via the Qualtrics platform. In addition, College Research Deans were asked to resend the email as a reminder to those who may not have completed the survey. The original survey distribution list included those who were a current UF employee at the Gainesville or Jacksonville campus and a research investigator, research manager or research coordinator, or other faculty or staff who submitted a human subjects research protocol to the UF IRB-01 approval within the last 3 years. When the survey was shared by the Research Deans, the distribution likely went beyond these strict criteria.

Over six weeks, 416 responses were obtained. Data summarizing survey results are included in the report generated by BEBR (Appendix C). Overall, 62% of respondents were faculty and 38% were staff. Faculty respondents reported an average of 12.5 years as a UF investigator, while staff reported involvement in submitting human research protocols for an average of 8 years. Of the faculty who responded, 65% were either tenured or on the tenure track, and 35% were on the clinical track. Of the staff who responded, 69% were research coordinators and 35% were research managers (the two positions not being mutually exclusive).

Since participation was voluntary, it is recognized that the survey results, as well as results from the focus groups and town halls may not accurately represent the views of all participants of the human subjects research enterprise. A more robust quantitative assessment would require surveys of representative cohorts through a random sampling, and would include cohorts not interested in voluntary participation.

As summarized in the survey results (Appendix C), overall the majority of voluntary respondents were satisfied with the human subjects research approval and activation processes

currently in place. Depending upon the specific question, 70-80% of the respondents either answered neutral or positively.

Despite the overall impression, open-ended responses from a majority of the participating faculty and staff expressed some frustration with the current protocol submission processes relating to various entities and noted the need to overhaul and simplify the submission process across the enterprise. Notable and/or common suggestions for improvement from respondents included: 1) better integration and coordination between the various research approval and activation components, 2) eliminating redundancy of information requests, 3) better training for research community regarding the various reasons for and responsibilities of the different approval and activation entities, 4) better/more comprehensive overall training offered for researchers and research staff, 5) an overall reduction of administrative burden on researchers imposed by the system, and 6) decreased time for overall approval and activation and for approval from specific entities (i.e., OCR, IT Security). To quote one respondent:

> *"There should be more integration so that everything is managed by a central cloud-based management system. The connection and order of operations is confusing. The amount of regulatory hurdles in place for departments has become increasingly expensive and seems unnecessarily complex. Perhaps more synergy between the Cancer Center, OCR, CTSI, IRB, Privacy office, and IT security would reduce time, labor, and expenses for departments. Also, (enterprise) staff are between a rock and a hard place as they try to assist faculty who do not understand the complexities of the process and why it takes a year to open a study at UF."*

Focus Group Methodology and Results:

Based on the results of the Survey, the working group conducted a series of one-hour focus group meetings that were facilitated by at least two members of the HSRIWG or volunteers acknowledged on the cover page. The purpose of the focus groups was two-fold: 1) to further explore the concerns raised in the Survey, and 2) to solicit more detailed suggestions for improvement.

Participation in the focus groups was voluntary and open to the entire research community in Gainesville and Jacksonville. There were four focus groups involving Research Administrators/ Clinical Coordinators and seven focus groups involving Faculty. Separate town hall meetings were held with OCR staff, IRB staff, and IRB full board voting members. Additionally, the working group met with leadership from IT Security and OCR. Focus group discussion and feedback were organized into themes and documented in a deidentified manner, with one of the working group facilitators serving as a scribe. None of the sessions were recorded, except with the IRB members (which was later destroyed). The focus group summaries are attached in Appendix D.

The majority of focus groups participants felt that they could navigate the research approval and activation process, but also expressed the need for improving and optimizing that process. There was near consensus that the current process was suboptimal resulting in reduction in productivity of the investigators. There was, however, a distinct and vocal minority who expressed strong feelings that the entire UF research enterprise was not fulfilling its mission, and '*any research success was in spite of the enterprise*'.

General Assessments Based on Survey and Focus Group Responses:

The consistency of the responses across respondents to the survey, focus groups participants, town halls, and individual meetings suggests that the issues and recommendations raised represent prevailing views of the majority of those who participate in the UF human subjects research approval and activation process.

Overall, there was uniform criticism of the overall logistic structure of the research approval and activation process. Specifically, i) that the various regulatory entities do not communicate or communicate easily amongst themselves, and report to different leadership with different interests; ii) that some entities and their approval and activation processes lacked transparency and were not service-oriented; and iii) that it was difficult or impossible to obtain information about the status of a research application.

Of note, criticism also targeted leadership in the Gainesville Health Science Center and UF Health Shands. Common themes from focus group responses were: i) that the Gainesville Health Science Center and UF Health Shands leadership were overly risk-aversive; and ii) the enterprise often transferred responsibility and workloads to the investigator, which increased administrative complexity, and failed to provide basic infrastructure support to the clinical research enterprise. Support from UF Health Shands to conduct or support clinical research was generally considered to be deficient. We did not receive any comments or sufficient responses from Jacksonville investigators and staff to make recommendations regarding this aspect of the Jacksonville campus.

The HSRIWG found overall satisfaction with many of the research entities that contribute to the regulatory process as presented in more detail below in the Specific Recommendations section. However, several of the entities fared less well in terms of user satisfaction. In particular, the offices of IT Security and OCR were rated poorly in both the Survey and focus groups. The IT Security Office received overall negative reviews, although it is important to note that IT Security is utilized less frequently than other research approval and activation entities (although with the influx of AI research at UF, the HSRIWG wishes to note this frequency may increase). OCR received generally unfavorable reviews, with the major criticism being the length of time required to the OCR review process and the levels of bureaucracy involved. Interestingly, these criticisms were directed not at individuals who work in these entities, but the entities themselves and their structure. Multiple participants identified individuals in various approval and activation entities who they considered ‘heroes’, working above and beyond their job descriptions at service, but were hindered by the bureaucracy in the system.

Research Entity-Specific Recommendations:

Based on all the aforementioned work to date, the HSRIWG offers the following recommendations with the goal of improving the effectiveness, efficiency, and accountability of the human subjects research approval and activation process. Recommendations are categorized according to the approval and activation process entity.

- **Institutional Review Board (IRB-01)**
  - **Feedback**
    - **Survey:**

      Overall, more than 50 percent of respondents selected positive answer choices for all survey questions. Differences between types of respondents was low with the most

satisfaction reported by research managers (82 percent) when asked about ease of using the IRB software. The most common requests for improvement are increased consistency across IRB staff, reviewers, and board members; modification of the myIRB system questions for a more streamlined and easily understood experience for social science researchers; changed social media standards; IRB staff professionalism and knowledge as well as consistent information provided across staff; and full board issues such as more frequent meetings in order to decrease the time both waiting in the meeting for the protocol to be discussed and approval timeline.

- **Focus Groups – Selected Comments:**
  - "Lots of turnover in research staff lately – this is not helpful when someone is trying to get answers, and hurts consistency in the answers you get"
  - "I think IRB-01 has made a concerted effort to improve several of their processes. Staff have been very willing to try to connect researchers with questions to those who can provide some advisement."
  - "Lack of consistency in protocol and consent reviews"
  - "Simply the process"
  - "Navigating multisite IRBs are often faced with conflict between the UF IRB and the other University IRB, which cycles back and forth via emails, etc. until someone finally takes responsibility and moves the process forward."
  - "It would be great if the IRB could create a standard process for junior faculty. They are the ones that suffer."
  - "Website is not user friendly"
  - *(from IRB staff)* "PIs don't see value of submitting to us, assign a low-level person submitting that doesn't understand"
  - *(from IRB member)* "Would rather review a full board drug study dealing with cancer versus a study submitted by a student. No introductory system showing how things flow. No good resources for students and/or mentorship"
  - *(from IRB staff)* "Departments used to review IRBs first, but no longer. Some review at department level. Wasn't a priority for department chairs"

- **Recommendations**
  - Prioritize review process
    - Several individuals suggested that funded (IDC-generating) research should be expedited through the system.
    - Within the IRB administrative unit (or HRPP), there should be facilitators who would manage these applications through the associated entities to assure a priority processing.
  - Streamline the IRB process for exempt\non-human and chart review studies.
  - Evaluate the IRB membership:
    - How Board members are recommended for membership.
    - Is there adequate representation regarding colleges, departments, and under-represented minorities and women that better reflect the study populations they oversee.
    - Should there be term limits for IRB members?
  - Develop a pre-review process where assigned IRB Board Members communicate specific concerns about the application with the investigator prior to the meeting, and

the application is amended accordingly. This recommendation results from several individuals recommending that the IRB implement procedures similar to that used by the IACUC. The result will be a full board IRB meeting that transitions to more of a summary and confirmation of the review process that occurred prior to the meeting, with additional input from all voting members. This would minimize the number of applications that require repeated full-board review. Indeed, the IRB has piloted this process with good feedback from both investigators and full board members. Of note, this pre-review process will be enhanced by other recommendations that include pre-review of protocols and expanded faculty and staff research training.

- One concern raised by IRB members is the amount of time and effort required to serve, and a lack of understanding and appreciation by their chairs for such effort. Pre-meeting reviews would increase the amount of time and effort required, and should be met with some recognition by department chairs.

❖ **Office of Clinical Research (OCR)**

- **Feedback**
  - **Survey:**
    Overall, respondents were more positive than negative when asked about ease of using the OCR software, submission training effectiveness, and support for the respondent's research team. More respondents chose negative choices when asked about time from OCR submission to contract approval. The two subgroups that indicated the strongest negative sentiment about the time from submission to approval were those who reported being both research coordinator and research manager (57 percent) and those who have submitted, or have been involved in submitting, six or more human research protocols in the last year (56 percent). The most common requests for improvement are more efficient and accurate coverage analysis, and faster responses to researchers and overall time for contract approval.

  - **Focus Groups – Selected Comments:**
    - "Guidance documents for how to navigate this process is not clear and very hard to find. OCR has changed so much that. we don't even try anymore."
    - "OnCore and OCR are not working well….a lot more work on our end as coordinators."
    - "My concern is OCR, OnCore and RBO. I just think the way they interact with one another is terrible."
    - "The lack of expertise in OCR creates constant change. The office uses a task list in OnCore but the list isn't helpful for coordinators. OCR staff want to use the automated process (task list) rather than emails. This creates delays. The system is more of a hindrance than a benefit."
    - "OCR is understaffed for the amount of work. Everyone is very nice but working with the staff is very time prohibitive. Lack of communication or response. It takes weeks or months to get any movement back."
    - (*from OCR staff*)"OCR does not have authority to implement institutional policy."
    - (*from OCR staff*)"We have compliance guidelines that we are supposed to follow in this office but nothing is in writing to back us up."
    - "UF needs clearer policies in place for clinical research and billing compliance. IT Security"

- ♦ "Opportunity to meet expectations given the volume. One side doesn't understand what the other side is doing. Cross training between study teams and OCR could help. Education is needed across the board. Need realistic expectations"
- ♦ "The contracting team are great. They communicate, copy us on every email with the sponsor. When contacted they provide educated answers."

- **Recommendations**
  - The OCR seems overextended, likely due to its increasing mandates and staff turnover. Clarity of mission should be evaluated. Staffing needs may need to be reassessed in order to complete its mission in a timely manner.
  - A re-assessment of the utility of the layers of OCR's approval process is necessary to not only ensure efficiency for researchers but also staff retention. Implementation of certain individual policies from leadership seems to have placed an unnecessary burden on OCR staff and clinical researchers that need to be reviewed individually. One repeated concern by research staff was the requirement for OnCore for non-Cancer Center clinical studies.

IT Security

- **Feedback**:
  - **Survey:**
    Overall, the same number or more respondents were negative on questions than positive, with more than 50 percent of respondents selecting negative choices when asked about time from IT Security submission to IT Security process approval. The subgroup with the largest number of negative responses to the latter question (88 percent) is the staff role of research manager. The most common requests for improvement are increasing responsiveness and the speed of processing submissions, clarity and consistency in instructions, and the requirement when the hardware and software to be used for the project are already being used at UF or UF Health Shands [HSRIWG: there is a list of pre-approved hardware and software on the IT Security website (https://irm.ufl.edu/fast-path-solutions/), that may need to be better publicized].
    - A repeated concern was the participation of undergraduate students in research and their difficulty in obtaining access to EPIC™.

    Focus Groups – Selected Comments:
    - "IT is horrifying….it takes forever to work with an iPad. You have no idea who you have to talk to. The risk assessment has gotten a little bit better. There is mandatory training now."
    - "The electronic submission process for software that is needed for our trials is problematic. As a coordinator, it is difficult to answer some of the questions. Even faculty struggle with answering the questions. It's difficult to speak with someone for support with the submission."
    - "The questions are complicated and the language they use is confusing. You have to be an IT expert to complete the paperwork. "
    - "In Jax, the IT group works directly with the sponsor. This is much more efficient and productive."

- "I've had studies that are closed before UF IT attempts to address the issue."

➢ **Recommendations**
- A dedicated IT Security team for research applications should be developed. Currently that lack of such a team results in unnecessarily delays in review, and makes the review process inconsistent. IT Security Office has many University-wide functions, reviewing clinical research being only one.
- The IT Security Office in conjunction with University research leadership should benchmark research approval and activation metrics, and evaluate the overall risk tolerance of IT security risk assessments. This will help to address the many comments regarding IT security risk assessments, and to ensure the university can efficiently support the growing needs for this important function (eg. expansion of the AI Initiative).

❖ **Research Billing Office (RBO)**

➢ **Survey:**

Overall, more respondent's selected positive choices than negative choices on all four questions. Differences between subgroups are generally low. The highest satisfaction is with research managers when asked about ease of the RBO submission process (80 percent). The most common requests for improvement are related to billing accuracy, such as not relying on inaccurate numbers from OnCore billing grids, and more accurate professional fees.

➢ **Focus Groups – Selected Comments:**
- "Bill review for patients who are off study still show up in the coordinator's buckets. There was no testing for the new featured in OnCore intended to discontinue bill review and it doesn't work."
- "EPIC and OnCore still don't talk to each other well. We need IT support who is dedicated to work on these issues and find solutions. UF and UF Health need to work together to make this happen."

➢ **Recommendations:**
- Re-evaluate process by which billing decisions for research are made.
- Improve interactions with OCR.

❖ The HSRIWG received only limited comments regarding the follow research entities. The committee provides the most common feedback for each, as informational only.

The one recommendation is for the institution to provide a single location that contains a brief summary of each committee's role with a contact number for questions. This is addressed in greater detail in the Enterprise Level Recommendations Section where the recommendation for a centralized oversight process under a single office is presented.

➢ **Scientific Review and Monitoring Committee (SRMC):**
- To combine the SRMC and IRB applications (possibly in myIRB), eliminating the need for review by this component when already reviewed by an extramural agency (e.g. NIH), and increased efficiency (e.g. shorter time between submission and scheduling, more frequent

meetings).

- **Conflict of Interest (COI):**
  - Improve accessibility and increased speed of approval of the management plan.
  - "Received grant in February, it is still pending. I reach out every 3 weeks and get a general response that isn't a conclusion. Research community was never told about the changes in the COI office. Need to be more forthcoming."

- **Human Use of Radioisotopes and Radiation Committee (HURRC)**
  - Requests for improvement are in the area of clearer information (e.g. point of contact, when to initiate contact).

- **Clinical and Translational Science Institute (CTSI)**
  - Better communication (e.g. general information such as when to use the ancillary and who to contact, and when approval is obtained), update social media review and use policies, and decrease service charges.

- **International Research Ancillary**
  - Providing information about required procedures and support when the country doesn't have IRBs, and the speed of the review.

- **Environmental Health & Safety (EH&S)**
  - Provide clearer information on protocols that need the ancillary's review, and improved training.

- **ClinicalTrials.gov (CT.gov)**
  - Making the submission less time consuming, and providing more support (e.g. on wording).

- **Institutional Biosafety Committee (IBC)**
  - Simplifying the submission requirements and improved training.

- **Nursing Impact Committee**
  - "The length of time that it takes to get through the nursing impact committee is forever. It took 10 months for our last study."
  - "Another challenge is the nursing Impact committee. I am struggling to truly understand the purpose of this committee. Are they there to support the research team?"

- **DSP in Jacksonville**
  - No specific comments to address.

Appendix A

Human Subjects Research Improvement Working Group

Membership

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Michael Mahoney (UF Research)

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Appendix B

Appendix A

If you have submitted, or have been involved in submitting, a least one human research protocol within the last 3 years and would like to see changes in the human research regulatory submission and approval process, please take 15 – 20 minutes to complete this important survey.

The UF Office of Research has created a working group to examine where the entire human research regulatory process can be more streamlined, efficient and simplified while remaining compliant with federal, state and local guidelines. This survey is designed to obtain feedback regarding your experiences.

While you don't have to take the survey, we would appreciate you giving us your anonymous feedback. We expect it to take 15 to 20 minutes to complete the survey, although the time might be longer depending on the number of research regulatory components involved in your submissions. The results of the survey will be used by the *Human Subject Research Process Improvement Working Group* for the sole purpose of making recommendations for improving the UF research regulatory process experience for UF faculty and staff. The survey is **anonymous**, and you can skip any question you don't wish to answer, or if you feel a question doesn't apply to you. To maintain your anonymity, when answering open-ended questions, do not provide your name or any other identifying information.

Before we get started with the questions about UF human research, we'd like to confirm that you are qualified to complete this survey.

Are you currently employed at UF?

- ○ Currently employed at UF
- ○ Not currently employed at UF [skip to exit screen]

Do you work for UF in Gainesville, Jacksonville, or somewhere else?

- ○ Gainesville
- ○ Jacksonville
- ○ Somewhere else [skip to exit screen]

Are you a research investigator, research coordinator or other faculty or staff that have submitted a human research protocol for UF approval within the last 3 years?

- ○ Yes
- ○ No [skip to exit screen]

[Exit screen]

Thank you for your time, but the survey is intended only for current UF faculty and staff in Gainesville and Jacksonville involved in research submissions for UF approval in the last 3 years. Click next to end the survey.

You are eligible to take the survey. Please answer the questions to the best of your ability.

The UF Human Research Protection Program (HRPP) consists of many components. Some or all of these components are involved in human research protocols you submit. Which of the below components were involved in your recent submissions?

- ☐ IRB (Institutional Review Board) - Approves all human research
- ☐ *OCR (Office of Clinical Research) – Oversees and negotiates research contracting with sponsors
- ☐ †JAX DSP (Division of Sponsored Programs, also known as Office of Research Affairs) - Oversees and negotiates research contracting with sponsors
- ☐ *RBO (Research Billing Office, UFHealth) - Oversees both technical and professional research billing in the UF Health Epic billing system
- ☐ †JAX RBO (Research Billing Office, UFJ) - Oversees both technical and professional research billing in the UF Health Epic billing system
- ☐ SRMC (Scientific Review and Monitoring Committee) – Approves all cancer-relevant studies prior to IRB review
- ☐ HURRC (Human Use of Radioisotopes and Radiation Committee) – Reviews relevant protocols and provides radiation risk language for the Informed Consent Form
- ☐ COI (Conflict of Interest Office) – Approves UF Management plan for protocols that involve either Institutional or Investigator conflict of interest
- ☐ CTSI (Clinical & Translational Science Institute) – Approves all use of CTSI resources such as REDCap, eConsent, IDR, Social Media advertising, etc.
- ☐ *RCIC (Research Clinical Impact Committee) – Evaluates Shands nursing implications relating to research protocols
- ☐ †NRC (Nursing Research Council) – Evaluates UF Health Jacksonville nursing implications relating to research protocols
- ☐ IT Security - Ensures regulatory compliance with devices that record or transmit PHI
- ☐ COVID Committee - Approves all inpatient COVID related research prior to IRB review
- ☐ *IDS (Investigational Drug Service) – Reviews and supports all drug related research within a UF Health Gainesville facility
- ☐ †PCRS (Pharmacy Clinical Research Service) - Reviews and supports all drug related clinical trials in Jacksonville
- ☐ †VAC (Value Analysis Committee) – Reviews and supports all new device related research within a UF Health Jacksonville facility
- ☐ International research Ancillary - Ensures regulatory compliance for research conducted outside of the USA
- ☐ EH&S (Environmental Health & Safety) – Ensures regulatory compliance for research involving the transport of infectious material
- ☐ Ct.gov - Ensures regulatory compliance with reporting to ClinicalTrials.gov
- ☐ IBC (Institutional Biosafety Committee) – Approves all gene therapy research prior to IRB review

*Choice shown only to Gainesville respondents
†Choice shown only to Jacksonville respondents

The IRB (Institutional Review Board) approves all human research. Thinking about your recent experience with the IRB, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of using the IRB software	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from IRB submission to IRB protocol approval	○	○	○	○	○

Please list up to three issues you would like to see improved with the IRB submission and review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The OCR (Office of Clinical Research) oversees and negotiates research contracting with sponsors. Thinking about your recent experience with the OCR, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of using the OCR software	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from OCR submission to contract approval	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the OCR submission and review process

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The JAX DSP (Division of Sponsored Programs, also known as Office of Research Affairs) oversees and negotiates research contracting with sponsors. Thinking about your recent experience with the JAX DSP, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of submitting to the JAX DSP	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from JAX DSP submission to contract approval	○	○	○	○	○

Please list up to three issues you would like to see improved with the JAX DSP submission and review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The RBO (Research Billing Office, UFHealth) oversees both technical and professional research billing in the UF Health Epic billing system. Thinking about your recent experience with the RBO, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of the RBO submission process	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from RBO submission to billing issue resolution	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the RBO submission and review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The JAX RBO (Research Billing Office, UFJ) oversees both technical and professional research billing in the UF Health Epic billing system. Thinking about your recent experience with the JAX RBO, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of submitting to the JAX RBO	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from JAX RBO submission to billing issue resolution	○	○	○	○	○

Please list up to three issues you would like to see improved with the JAX RBO submission and review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

SRMC (Scientific Review and Monitoring Committee) approves all cancer-relevant studies prior to IRB review. Thinking about your recent experience with the SRMC, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of using the SRMC software	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from SRMC submission to protocol approval	○	○	○	○	○

Please list up to three issues you would like to see improved with the SRMC submission and review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The HURRC ((Human Use of Radioisotopes and Radiation Committee) reviews relevant protocols and provides radiation risk language for the Informed Consent Form. Thinking about your recent experience with the HURRC, please rate the following:

	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
I understand when to involve the HURRC Ancillary	○	○	○	○	○
I understand what this ancillary needs from my research team	○	○	○	○	○

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
Support for my research team	○	○	○	○	○
Ease of working with this ancillary	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the HURRC Ancillary review process

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

COI (Conflict of Interest Office) approves the UF Management plan for protocols that involve either Institutional or Investigator conflict of interest. Thinking about your recent experience with COI, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of submitting to COI	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from COI submission to management plan approval	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the COI submission and review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The CTSI (Clinical & Translational Science Institute) approves all use of CTSI resources such as REDCap, eConsent, IDR, Social Media advertising, etc. Thinking about your recent experience with the CTSI, please rate the following:

	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
I understand when to Involve the CTSI Ancillary	○	○	○	○	○
I understand what this ancillary needs from my research team	○	○	○	○	○

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
Support for my research team	○	○	○	○	○
Ease of working with this ancillary	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the CTSI Ancillary review process

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The RCIC (Research Clinical Impact Committee) evaluates Shands nursing implications relating to research protocols. Thinking about your recent experience with the RCIC, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of RCIC submission process	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from RCIC submission to acceptance of the protocol	○	○	○	○	○

Please list up to three issues you would like to see improved with the RCIC submission and review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The NRC (Nursing Research Council) – evaluates UF Health Jacksonville nursing implications relating to research protocols. Thinking about your recent experience with the NRC, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of NRC submission process	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from NRC submission to acceptance of the protocol	○	○	○	○	○

Please list up to three issues you would like to see improved with the NRC submission and review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

IT Security ensures regulatory compliance with devices that record or transmit PHI. Thinking about your recent experience with IT Security, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of submitting to IT Security	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from IT Security submission to IT Security process approval	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the IT Security submission and review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The COVID Committee approves all inpatient COVID related research prior to IRB review. Thinking about your recent experience with the COVID Committee, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of submitting to the COVID Committee	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from COVID Committee submission to protocol approval	○	○	○	○	○

Please list up to three issues you would like to see improved with the COVID Committee submission and review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The IDS (Investigational Drug Service) reviews and supports all drug related research within a UF Health Gainesville facility. Thinking about your recent experience with the IDS, please rate the following:

	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
I understand when to use the IDS	○	○	○	○	○
I understand how to submit a request to the IDS	○	○	○	○	○

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
Support for my research team	○	○	○	○	○
Ease of working with this ancillary	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the IDS review process

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The PCRS (Pharmacy Clinical Research Service) reviews and supports all drug related clinical trials in Jacksonville. Thinking about your recent experience with the PCRS, please rate the following:

	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
I understand when to use the PCRS	○	○	○	○	○
I understand how to submit a request to the PCRS	○	○	○	○	○

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
Support for my research team	○	○	○	○	○
Ease of working with this ancillary	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the PCRS review process

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The VAC (Value Analysis Committee) reviews and supports all new device related research within a UF Health Jacksonville facility. Thinking about your recent experience with the VAC, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of submitting to the JAX VAC	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from JAX VAC submission to approval	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the JAX VAC submission and review process

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The International Research Ancillary ensures regulatory compliance for research conducted outside of the USA. Thinking about your recent experience with the International Research Ancillary, please rate the following:

	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
I understand when to Involve the International Research Ancillary	○	○	○	○	○
I understand what this ancillary needs from my research team	○	○	○	○	○

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
Support for my research team	○	○	○	○	○
Ease of working with this ancillary	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the International Research Ancillary review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

EH&S (Environmental Health & Safety) ensures regulatory compliance for research involving the transport of infectious material. Thinking about your recent experience with EH&S, please rate the following:

	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
I understand when to Involve the EH&S Ancillary	○	○	○	○	○
I understand what this ancillary needs from my research team	○	○	○	○	○

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
Support for my research team	○	○	○	○	○
Ease of working with this ancillary	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the EH&S Ancillary review process

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

Ct.gov ensures regulatory compliance with reporting to ClinicalTrials.gov. Thinking about your recent experience with Ct.gov, please rate the following:

	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree
I understand when to Involve the Ct.gov Ancillary	○	○	○	○	○
I understand what this ancillary needs from my research team	○	○	○	○	○

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied
Support for my research team	○	○	○	○	○
Ease of working with this ancillary	○	○	○	○	○

Please list up to 3 issues you would like to see improved with the Ct.gov Ancillary review process

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The IBC (Institutional Biosafety Committee) approves all gene therapy research prior to IRB review. Thinking about your recent experience with the IBC, please rate the following:

	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied
Ease of using the IBC software	○	○	○	○	○
Submission training effectiveness	○	○	○	○	○
Support for my research team	○	○	○	○	○
Time from IBC submission to protocol approval	○	○	○	○	○

Please list up to three issues you would like to see improved with the IBC submission and review process.

○ Issue 1 _____

○ Issue 2 _____

○ Issue 3 _____

The next few questions are about your overall experience working in the UF research enterprise.

The individual human research regulatory component parts I answered questions about in this survey are adequately integrated.

- ○ Strongly Agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

UF provides sufficient resources to help me navigate the regulatory review process.

- ○ Strongly Agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

We have sufficient staff on our research team to adequately submit research to regulatory components and conduct human research.

- ○ Strongly Agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

I am given sufficient time to focus on my human research efforts.

- ○ Strongly agree
- ○ Somewhat agree
- ○ Neither agree nor disagree
- ○ Somewhat disagree
- ○ Strongly disagree

Please elaborate on anything else you would like to see improved regarding the UF Human Research Regulatory Enterprise.

_____

The last section is about you.

How many years have you been at UF?

_____

Are you faculty or staff?

- ○ Faculty
- ○ Staff

[If faculty]: How many years have you been an investigator at UF?

_____

[If faculty]: Are you tenure track or non-tenure track?

- ○ Tenure track
- ○ Non-tenure track

[If faculty}: Approximately how many human research protocols have you submitted in the last year?

_____

[If answer to above question is greater than zero]: What types of research protocols have you submitted in the last year?

- ☐ Non-human
- ☐ Exempt
- ☐ Expedited
- ☐ Full board

[If staff]: Are you a research coordinator?

- ○ Yes
- ○ No

[If staff]: Are you a research manager?

- ○ Yes
- ○ No

[If no to previous two questions]: What is your job title?

_____

[If staff]: How many years have you been involved in submitting human research protocols?

_____

[If staff]: How many human research protocols were you involved in submitting in the last year?

_____

[If answer to above question is greater than zero]: What types of research protocols have you been involved in submitting in the last year?

- ☐ Non-human
- ☐ Exempt
- ☐ Expedited
- ☐ Full board

If you are interested in providing additional non-anonymous information to the Working Group, please provide your name and email address for our group to get back to you directly. Otherwise, your responses to this survey will remain anonymous.

Name

_____

Email address

_____

The Human Subjects Research Process Improvement Committee thanks you for your valuable feedback! Click next to end the survey.

Appendix C

UF Research Regulatory Component Survey

Preliminary Results

Contents

The UF Human Research Protection Program (HRPP) consists of many components. Some or all of these components are involved in human research protocols you submit. Which of the below components were involved in your recent submissions? Select all that apply.

Overall	Percentage
IRB (Institutional Review Board) - Approves all human research	98.9%
CTSI (Clinical & Translational Science Institute) – Approves all use of CTSI resources such as REDCap, eConsent, IDR, Social Media advertising, etc.	50.8%
OCR (Office of Clinical Research) – Oversees and negotiates research contracting with sponsors	47.1%
IT Security - Ensures regulatory compliance with devices that record or transmit PHI	28.9%
COI (Conflict of Interest Office) – Approves UF Management plan for protocols that involve either Institutional or Investigator conflict of interest	26.5%
RBO (Research Billing Office, UFHealth) - Oversees both technical and professional research billing in the UF Health Epic billing system	23.9%
Ct.gov - Ensures regulatory compliance with reporting to ClinicalTrials.gov	22.1%
IDS (Investigational Drug Service) – Reviews and supports all drug related research within a UF Health Gainesville facility	19.1%
EH&S (Environmental Health & Safety) – Ensures regulatory compliance for research involving the transport of infectious material	18.2%
SRMC (Scientific Review and Monitoring Committee) – Approves all cancer-relevant studies prior to IRB review	17.1%
COVID Committee - Approves all inpatient COVID related research prior to IRB review	12.6%
HURRC (Human Use of Radioisotopes and Radiation Committee) – Reviews relevant protocols and provides radiation risk language for the Informed Consent Form	11.9%
RCIC (Research Clinical Impact Committee) – Evaluates Shands nursing implications relating to research protocols	7.4%
IBC (Institutional Biosafety Committee) – Approves all gene therapy research prior to IRB review	5.6%
JAX DSP (Division of Sponsored Programs, also known as Office of Research Affairs) - Oversees and negotiates research contracting with sponsors	5.0%
International research Ancillary - Ensures regulatory compliance for research conducted outside of the USA	4.6%
JAX RBO (Research Billing Office, UFJ) - Oversees both technical and professional research billing in the UF Health Epic billing system	3.3%
PCRS (Pharmacy Clinical Research Service) - Reviews and supports all drug related clinical trials in Jacksonville	1.3%
NRC (Nursing Research Council) – Evaluates UF Health Jacksonville nursing implications relating to research protocols	0.2%
VAC (Value Analysis Committee) – Reviews and supports all new device related research within a UF Health Jacksonville facility	0.2%
Total Respondents	461

	Gainesville	Jacksonville
IRB (Institutional Review Board) - Approves all human research	99.5%	91.4%
CTSI (Clinical & Translational Science Institute) – Approves all use of CTSI resources such as REDCap, eConsent, IDR, Social Media advertising, etc.	51.4%	42.9%
OCR (Office of Clinical Research) – Oversees and negotiates research contracting with sponsors	50.9%	0.0%
IT Security - Ensures regulatory compliance with devices that record or transmit PHI	28.9%	28.6%
COI (Conflict of Interest Office) – Approves UF Management plan for protocols that involve either Institutional or Investigator conflict of interest	27.0%	20.0%
RBO (Research Billing Office, UFHealth) - Oversees both technical and professional research billing in the UF Health Epic billing system	25.8%	0.0%
Ct.gov - Ensures regulatory compliance with reporting to ClinicalTrials.gov	22.5%	17.1%
IDS (Investigational Drug Service) – Reviews and supports all drug related research within a UF Health Gainesville facility	20.7%	0.0%
EH&S (Environmental Health & Safety) – Ensures regulatory compliance for research involving the transport of infectious material	18.8%	11.4%
SRMC (Scientific Review and Monitoring Committee) – Approves all cancer-relevant studies prior to IRB review	16.7%	22.9%
HURRC (Human Use of Radioisotopes and Radiation Committee) – Reviews relevant protocols and provides radiation risk language for the Informed Consent Form	12.0%	11.4%
COVID Committee - Approves all inpatient COVID related research prior to IRB review	11.7%	22.9%
RCIC (Research Clinical Impact Committee) – Evaluates Shands nursing implications relating to research protocols	8.0%	0.0%
IBC (Institutional Biosafety Committee) – Approves all gene therapy research prior to IRB review	5.2%	11.4%
International research Ancillary - Ensures regulatory compliance for research conducted outside of the USA	4.9%	0.0%
JAX DSP (Division of Sponsored Programs, also known as Office of Research Affairs) - Oversees and negotiates research contracting with sponsors	0.0%	65.7%
JAX RBO (Research Billing Office, UFJ) - Oversees both technical and professional research billing in the UF Health Epic billing system	0.0%	42.9%
NRC (Nursing Research Council) – Evaluates UF Health Jacksonville nursing implications relating to research protocols	0.0%	2.9%
PCRS (Pharmacy Clinical Research Service) - Reviews and supports all drug related clinical trials in Jacksonville	0.0%	17.1%
VAC (Value Analysis Committee) – Reviews and supports all new device related research within a UF Health Jacksonville facility	0.0%	2.9%
Total Respondents	426	35

The IRB (Institutional Review Board) approves all human research. Thinking about your recent experience with the IRB, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of using the IRB software	23.0%	41.0%	13.8%	15.8%	6.4%	405
Submission training effectiveness	17.3%	34.4%	26.9%	15.8%	5.5%	398
Support for my research team	28.2%	31.4%	19.7%	15.5%	5.2%	401
Time from IRB submission to IRB protocol approval	26.0%	33.4%	13.1%	18.3%	9.2%	404

Summary: Very positive

Details: More than 50% of respondents selected positive choices (either very satisfied or somewhat satisfied) for all questions.

The OCR (Office of Clinical Research) oversees and negotiates research contracting with sponsors. Thinking about your recent experience with the OCR, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of using the OCR software	12.3%	27.4%	26.8%	24.0%	9.5%	179
Submission training effectiveness	11.8%	25.8%	32.6%	20.2%	9.6%	178
Support for my research team	21.5%	25.4%	24.3%	22.1%	6.6%	181
Time from OCR submission to contract approval	12.1%	19.2%	24.7%	22.5%	21.4%	182

Summary: Mixed positive and negative

Details: A higher percentage selected positive choices (either very satisfied or somewhat satisfied) than negative choices (either dissatisfied or very dissatisfied) when asked all questions except time from OCR submission to contract approval. When asked about the latter, more respondents chose negative choices than positive.

The JAX DSP (Division of Sponsored Programs, also known as Office of Research Affairs) oversees and negotiates research contracting with sponsors. Thinking about your recent experience with the JAX DSP, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of submitting to the JAX DSP	26.1%	43.5%	21.7%	8.7%	0.0%	23
Support for my research team	26.1%	43.5%	21.7%	4.3%	4.3%	23
Time from JAX DSP submission to contract approval	18.2%	40.9%	9.1%	31.8%	0.0%	22
Submission training effectiveness	21.7%	34.8%	30.4%	13.0%	0.0%	23

Summary: Very Positive

Details: More than 50% of respondents selected positive choices.

The RBO (Research Billing Office, UFHealth) oversees both technical and professional research billing in the UF Health Epic billing system. Thinking about your recent experience with the RBO, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of the RBO submission process	16.5%	22.0%	41.8%	15.4%	4.4%	91
Submission training effectiveness	13.3%	17.8%	45.6%	14.4%	8.9%	90
Support for my research team	15.4%	20.9%	40.7%	12.1%	11.0%	91
Time from RBO submission to billing issue resolution	14.3%	23.1%	37.4%	15.4%	9.9%	91

Summary: Leans positive, although very neutral

Details: For all questions, a higher percentage selected positive choices than negative choices. Additionally, for each question, the same number or more respondents selected neither satisfied nor dissatisfied than selected the positive choices.

The JAX RBO (Research Billing Office, UFJ) oversees both technical and professional research billing in the UF Health Epic billing system. Thinking about your recent experience with the JAX RBO, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of submitting to the JAX RBO	21.4%	35.7%	21.4%	14.3%	7.1%	14
Submission training effectiveness	21.4%	28.6%	35.7%	7.1%	7.1%	14
Support for my research team	28.6%	28.6%	28.6%	0.0%	14.3%	14
Time from JAX RBO submission to billing issue resolution	21.4%	35.7%	28.6%	0.0%	14.3%	14

Summary: Very positive

Details: More than 50% of respondents selected positive choices for all questions.

SRMC (Scientific Review and Monitoring Committee) approves all cancer-relevant studies prior to IRB review. Thinking about your recent experience with the SRMC, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of using the SRMC software	28.6%	34.9%	27.0%	7.9%	1.6%	63
Submission training effectiveness	24.6%	27.9%	36.1%	11.5%	0.0%	61
Support for my research team	35.9%	37.5%	18.8%	7.8%	0.0%	64
Time from SRMC submission to protocol approval	34.4%	37.5%	14.1%	12.5%	1.6%	64

Summary: Very positive

Details: More than 50% of respondents selected positive choices for all questions.

The HURRC ((Human Use of Radioisotopes and Radiation Committee) reviews relevant protocols and provides radiation risk language for the Informed Consent Form. Thinking about your recent experience with the HURRC, please rate the following:

Question	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
I understand when to involve the HURRC Ancillary	65.9%	29.5%	4.5%	0.0%	0.0%	44
I understand what this ancillary needs from my research team	60.5%	34.9%	4.7%	0.0%	0.0%	43

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied	Total
Support for my research team	53.5%	25.6%	20.9%	0.0%	0.0%	43
Ease of working with this ancillary	55.8%	25.6%	16.3%	2.3%	0.0%	43

Summary: Very positive

Details: More than 50% of respondents selected positive choices (either strongly agree or somewhat agree, or very satisfied or somewhat satisfied) for all questions.

COI (Conflict of Interest Office) approves the UF Management plan for protocols that involve either Institutional or Investigator conflict of interest. Thinking about your recent experience with COI, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of submitting to COI	21.9%	41.0%	24.8%	9.5%	2.9%	105
Submission training effectiveness	17.5%	23.3%	40.8%	13.6%	4.9%	103
Support for my research team	19.0%	27.6%	41.0%	9.5%	2.9%	105
Time from COI submission to management plan approval	20.2%	27.9%	24.0%	20.2%	7.7%	104

Summary: Leans positive

Notes: More than 50% of respondents selected positive choices when asked about ease of submitting to the COI. For the other 3 questions, more respondents selected positive choices than negative choices. When asked about submission training effectiveness the same number selected neither satisfied nor dissatisfied as selected the positive choices.

The CTSI (Clinical & Translational Science Institute) approves all use of CTSI resources such as REDCap, eConsent, IDR, Social Media advertising, etc. Thinking about your recent experience with the CTSI, please rate the following:

Question	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
I understand when to Involve the CTSI Ancillary	32.0%	39.7%	9.3%	14.4%	4.6%	194
I understand what this ancillary needs from my research team	27.8%	30.9%	16.0%	19.1%	6.2%	194

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied	Total
Support for my research team	35.8%	26.9%	18.7%	15.5%	3.1%	193
Ease of working with this ancillary	30.1%	32.6%	19.2%	13.5%	4.7%	193

Summary: Very positive

Details: More than 50% of respondents selected positive choices for all questions.

The RCIC (Research Clinical Impact Committee) evaluates Shands nursing implications relating to research protocols. Thinking about your recent experience with the RCIC, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of RCIC submission process	10.0%	40.0%	33.3%	10.0%	6.7%	30
Submission training effectiveness	3.4%	17.2%	44.8%	31.0%	3.4%	29
Support for my research team	0.0%	43.3%	36.7%	13.3%	6.7%	30
Time from RCIC submission to acceptance of the protocol	0.0%	30.0%	30.0%	16.7%	23.3%	30

Summary: Mixed positive and negative

Details: 50% selected positive choices when asked about ease of RCIC submission process. More respondents selected positive choices than negative choices when asked about support for my research team. More respondents selected negative choices than positive when asked about submission training effectiveness and time from RCIC submission to acceptance of the protocol, although for the former, neither satisfied nor dissatisfied was selected more often than the negative choices.

The NRC (Nursing Research Council) – evaluates UF Health Jacksonville nursing implications relating to research protocols. Thinking about your recent experience with the NRC, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of NRC submission process	0.0%	0.0%	0.0%	0.0%	0.0%	0
Submission training effectiveness	0.0%	0.0%	0.0%	0.0%	0.0%	0
Support for my research team	0.0%	0.0%	0.0%	0.0%	0.0%	0
Time from NRC submission to acceptance of the protocol	0.0%	0.0%	0.0%	0.0%	0.0%	0

IT Security ensures regulatory compliance with devices that record or transmit PHI. Thinking about your recent experience with IT Security, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of submitting to IT Security	12.7%	25.5%	23.6%	17.3%	20.9%	110
Submission training effectiveness	10.8%	20.7%	31.5%	14.4%	22.5%	111
Support for my research team	15.3%	19.8%	29.7%	15.3%	19.8%	111
Time from IT Security submission to IT Security process approval	13.5%	15.3%	19.8%	22.5%	28.8%	111

Summary: Very negative

Details: For all questions, the same or more respondents selected negative choices than positive choices. Additionally, when asked about Time from IT Security submission to IT Security process approval, more than 50% of respondents selected negative choices.

The COVID Committee approves all inpatient COVID related research prior to IRB review. Thinking about your recent experience with the COVID Committee, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of submitting to the COVID Committee	31.4%	27.5%	33.3%	2.0%	5.9%	51
Submission training effectiveness	21.6%	17.6%	43.1%	9.8%	7.8%	51
Support for my research team	27.5%	21.6%	39.2%	7.8%	3.9%	51
Time from COVID Committee submission to protocol approval	31.4%	21.6%	31.4%	7.8%	7.8%	51

Summary: Leans positive

Details: More than 50% selected positive choices when asked about ease of submitting to the COVID Committee and Time from COVID Committee submission to protocol approval. When asked about submission training effectiveness and support for my research team, more respondents selected positive choices than negative choices, although for the former, more respondents selected neither satisfied nor dissatisfied than selected the positive choices.

The IDS (Investigational Drug Service) reviews and supports all drug related research within a UF Health Gainesville facility. Thinking about your recent experience with the IDS, please rate the following:

Question	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
I understand when to use the IDS	77.3%	20.0%	1.3%	0.0%	1.3%	75
I understand how to submit a request to the IDS	69.3%	17.3%	10.7%	2.7%	0.0%	75

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied	Total
Support for my research team	77.3%	14.7%	4.0%	1.3%	2.7%	75
Ease of working with this ancillary	77.3%	16.0%	4.0%	2.7%	0.0%	75

Summary: Very Positive

Details: More than 50% of respondents selected positive choices for all questions.

The PCRS (Pharmacy Clinical Research Service) reviews and supports all drug related clinical trials in Jacksonville. Thinking about your recent experience with the PCRS, please rate the following:

Question	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
I understand when to use the PCRS	50.0%	50.0%	0.0%	0.0%	0.0%	4
I understand how to submit a request to the PCRS	50.0%	50.0%	0.0%	0.0%	0.0%	4

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied	Total
Support for my research team	33.3%	66.7%	0.0%	0.0%	0.0%	3
Ease of working with this ancillary	33.3%	66.7%	0.0%	0.0%	0.0%	3

Summary: Very positive

Details: More than 50% of respondents selected positive choices for all questions.

The VAC (Value Analysis Committee) reviews and supports all new device related research within a UF Health Jacksonville facility. Thinking about your recent experience with the VAC, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of submitting to the JAX VAC	0.0%	0.0%	0.0%	0.0%	0.0%	0
Submission training effectiveness	0.0%	0.0%	0.0%	0.0%	0.0%	0
Support for my research team	0.0%	0.0%	0.0%	0.0%	0.0%	0
Time from JAX VAC submission to approval	0.0%	0.0%	0.0%	0.0%	0.0%	0

The International Research Ancillary ensures regulatory compliance for research conducted outside of the USA. Thinking about your recent experience with the International Research Ancillary, please rate the following:

Question	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
I understand when to Involve the International Research Ancillary	42.1%	52.6%	5.3%	0.0%	0.0%	19
I understand what this ancillary needs from my research team	15.8%	42.1%	15.8%	10.5%	15.8%	19

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied	Total
Support for my research team	35.3%	29.4%	5.9%	17.6%	11.8%	17
Ease of working with this ancillary	33.3%	22.2%	11.1%	22.2%	11.1%	18

Summary: Very positive

Details: More than 50% of respondents selected positive choices for all questions.

EH&S (Environmental Health & Safety) ensures regulatory compliance for research involving the transport of infectious material. Thinking about your recent experience with EH&S, please rate the following:

Question	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
I understand when to Involve the EH&S Ancillary	57.4%	20.6%	10.3%	10.3%	1.5%	68
I understand what this ancillary needs from my research team	44.1%	26.5%	13.2%	13.2%	2.9%	68

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied	Total
Support for my research team	41.8%	28.4%	20.9%	6.0%	3.0%	67
Ease of working with this ancillary	38.8%	28.4%	20.9%	9.0%	3.0%	67

Summary: Very positive

Details: More than 50% of respondents selected positive choices for all questions.

Ct.gov ensures regulatory compliance with reporting to ClinicalTrials.gov. Thinking about your recent experience with Ct.gov, please rate the following:

Question	Strongly Agree	Somewhat agree	Neither agree nor disagree	Somewhat disagree	Strongly disagree	Total
I understand when to Involve the Ct.gov Ancillary	48.9%	31.8%	13.6%	4.5%	1.1%	88
I understand what this ancillary needs from my research team	44.3%	35.2%	13.6%	4.5%	2.3%	88

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Somewhat dissatisfied	Very dissatisfied	Total
Support for my research team	42.0%	27.3%	23.9%	6.8%	0.0%	88
Ease of working with this ancillary	39.8%	28.4%	25.0%	5.7%	1.1%	88

Summary: Very positive

Details: More than 50% of respondents selected positive choices for all questions.

The IBC (Institutional Biosafety Committee) approves all gene therapy research prior to IRB review. Thinking about your recent experience with the IBC, please rate the following:

Question	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very Dissatisfied	Total
Ease of using the IBC software	13.6%	27.3%	36.4%	18.2%	4.5%	22
Submission training effectiveness	18.2%	18.2%	45.5%	9.1%	9.1%	22
Support for my research team	27.3%	31.8%	36.4%	0.0%	4.5%	22
Time from IBC submission to protocol approval	18.2%	36.4%	27.3%	13.6%	4.5%	22

Summary: Leans positive

Details: More than 50% of respondents selected positive choices when asked about support for my research team and time from IBC submission to protocol approval. More respondents selected positive choices than negative choices when asked about ease of using the IBC software and submission training effectiveness, although for the latter, more respondents selected neither satisfied nor dissatisfied than the positive choices.

The individual human research regulatory component parts I answered questions about in this survey are adequately integrated.

	Percentage
Strongly Agree	15.4%
Somewhat agree	31.4%
Neither agree nor disagree	22.3%
Somewhat disagree	17.0%
Strongly disagree	13.8%
Total	376

Summary: Leans positive

Details: More respondents selected positive choices than negative.

UF provides sufficient resources to help me navigate the regulatory review process.

	Percentage
Strongly Agree	10.7%
Somewhat agree	35.4%
Neither agree nor disagree	12.5%
Somewhat disagree	29.2%
Strongly disagree	12.2%
Total	384

Summary: Leans positive

Details: More respondents selected positive choices than negative.

We have sufficient staff on our research team to adequately submit research to regulatory components and conduct human research.

	Percentage
Strongly Agree	17.1%
Somewhat agree	26.5%
Neither agree nor disagree	17.1%
Somewhat disagree	22.8%
Strongly disagree	16.5%
Total	381

Summary: Leans positive

Details: More respondents selected positive choices than negative.

I am given sufficient time to focus on my human research efforts.

	Percentage
Strongly agree	20.1%
Somewhat agree	25.1%
Neither agree nor disagree	16.9%
Somewhat disagree	20.6%
Strongly disagree	17.2%
Total	378

Summary: Leans positive

Details: More respondents selected positive choices than negative.

Are you faculty or staff?

	Percentage
Faculty	61.8%
Staff	38.2%
Total	380

Faculty questions

If faculty: Are you tenure track or non-tenure track?

	Percentage
Tenure track	64.8%
Non-tenure track	35.2%
Total	230

If faculty: What types of research protocols have you submitted in the last year? Select all that apply.

	Percentage
Non-human	22.9%
Exempt	67.3%
Expedited	73.8%
Full board	41.1%
Total	214

Staff Questions

If staff: Are you a research coordinator?

	Percentage
Yes	68.5%
No	31.5%
Total	143

If staff: Are you a research manager?

	Percentage
Yes	35.5%
No	64.5%
Total	141

If staff: What types of research protocols have you been involved in submitting in the last year? Select all that apply.

	Percentage
Non-human	22.1%
Exempt	67.2%
Expedited	77.0%
Full board	68.9%
Total	122

Appendix D

Research Administrators/Clinical Coordinators

Summary of Focus Group: Friday, June 7, 2022….. Kris Wynne, Facilitator and Jennifer Lanz, Note Taker. There were 5 participants.

One Word Impressions

Frustrating

Took the words right out of my mouth

Clunky

Acceptable

Disconnected

Any place where you are generally satisfied?

I am satisfied with the IRB, timely response, it is problematic when you have different reviewers.

OCR is at least receptive to communications and who is assigned to it.

I like the systems that are tied together like the OnCore platform is tied to EPIC.

The IRB the end result…we are usually able to work out a solution.

The IRB is great, sometimes we get different answers, but they work it out.

IRB

I have more issues with the IRB. They tend to be short and rude when we are trying to get an answer. It is impossible to consent a baby. We don't have a client relationship and we have a gray area. Leadership is unreachable. The submission process is clunky. The ICF forms haven't been updated in over 10 years. They are outdated.

IRB predictability. We don't know what we will get. Contradictory. Interactions with the staff is just knowing how to play the game. You can't argue with them. Easier to just comply and do what they say even if we don't agree. The pre-review process fine. But the full board it just depends who you get.

Office of Clinical Research

I have lots of problems with OCR. Coverage analysis is a problem…the people that are doing it do not understand clinical practice at all.

A big waste of their time and our time because they do not understand clinical practice.

Amendments- An amendment can sit there waiting on a calendar build even though it is just a contract amendment and has nothing to do with the calendar.

I negotiate my own budgets and I have asked them to not reach out to the sponsor directly. They sent them the master charge file which they are never supposed to do.

I will echo her examples. OCR has a lot of green people that are trying to do the jobs of experienced people in their own departments. They mandated this deal that if the sponsor says that they will pay for a fee even if can be covered by Medicare…they say the sponsor has to pay for that. This is a big problem for cancer research because it is difficult to filter through the different charges. The charge master that OCR has is always wrong and it was just recently updated. This is challenging for our research. If you are trying to budget around the linking in OnCore, it is going to be a problem. I have my own cheat sheet because I don't trust OnCore.

OCR has been slow over the last year. They have lost track of amendments. I have had to wait 6 months for an amendment. I agree with the other comments. The people are inexperienced in clinical practice. You never know what you are going to get. Our Investigators have no time to help with all of this paperwork. The paperwork that we have to do just for UF is too much. There is a disconnect between UF and sponsor.

All of our studies are outside of the hospital. Our submissions don't deal with OCR.

Our department does not work with OCR.

Research Billing Office

RBO is a problem. They keep pushing us to use EPIC timelines and they don't work correctly. Even if we get the billing grid set up correctly and there is a window, EPIC will automatically pull these charges.

RBO is challenging. Same issues and invoicing problems.

IT Security

IT risk assessment takes at least 4 months. I submitted one 3 years ago and it just was approved even though the study closed. It has gotten so bad, that investigators start the study without the risk assessment being done.

It took 11 months for them to approve de-identified data that would be stored on a hard drive. AI is a hot ticket item. I don't see how we will be able to do AI research here at UF.

Not everyone knows what IT security even does. That is part of the problem. Disconnect what is important and what we should be worried about.

Other departments

Research payments…our patients hate the visa cards. Every adverse event that we have is because someone's payment doesn't go through. It feels that people that don't understand research are the one's telling us how to do research.

DSP has taken on too much and they have slowed things down. I spend $2000 a day by not doing research because I have to wait for so many different areas to sign off.

What One Thing Would You Want to Address?

OCR…give some of the work back to the coordinators. Like what we did before.

Ancillary department (Shands)…they change their policies quite frequently. There is a disconnect in the people that are working in those departments and Shands policy.

I want the billing grids to come back. The billing grids provide the services, codes, locations. The people that complete these have clinical experience and we provide that to OCR and OCR can be then do a double check. OCR has effectively taken the experts out of the picture.

IT risk assessment

Simplify the participants payments. Adds so much time to the process.

Accountability at the college level, department level….we can't always wait for people to start a study.

Additional Comments

UFirst system…I don't like how you can't reply to their emails. You have to start a new email.

Summary of Focus Group: Wednesday June 8, 2022 11am-12pm
Alison Ivey, Facilitator and Kim Wollard, Note Taker
There were 5 participants.

One Word Impressions

- Clusterfuck
- Frustrating
- Needlessly lengthy
- Pleasant
- Complex/Complicated

Areas of Satisfaction

- IDS - Organized, very responsive, the staff work well with coordinators, flexible when needed, can-do attitude, very communicative. *(4 participants verbalized agreement)*
- CRC – Extended hours for procedures, quick to analyze and provide costs for services. Have made substantial improvements. Change in management has created a stronger team with excellent customer service. *(3 participants verbalized agreement)*
- The various individual systems work great independently of each other. Particularly the click system. I wish it was integrated across all research management systems at UF.

Areas that could use improvement

- One unified system (a dashboard) would be much better than the numerous individual systems. Need support from IT to make this happen. Stanford is an example of another academic institution that has made strides in this direction.
- Communication - Core offices contact PIs but do not include coordinators. Use of acronyms in emails from central offices can be confusing/frustrating. Employees in the central offices are so focused in their specialty they often don't recognize they are working with coordinators who wear multiple hats. Communication is fragmented/lacks empathy.
- Clinical research has a strong regulatory process but the fiscal management side (reporting capabilities) needs improvement.
- Biosafety submissions - As a coordinator, it is difficult to answer the complex basic science questions. Even faculty struggle with answering the questions. Also, the electronic submission asks questions that are clearly noted in the protocol. I like the fact that it is on online system but not that I have to regurgitate the protocol to them.

Office of Clinical Research

- The contracting team are great. They communicate, copy us on every email with the sponsor. When contacted they provide educated answers.
- Sandra Smith and her team are strong, too. They respond quickly and provide support when needed.
- OnCore – if you are not in the Cancer Center and not using it for a cancer study it is a waste of time and resources.
- Calendars and other steps in the start-up process were transferred to OCR but the staff have no clinical experience. They argue over services and processes that they do not have a full understanding of. New staff in OCR request things that have already been submitted and ask questions that are not relevant.

- The Office of Clinical Research hires entry level employees for positions that are complex and require experience. It is an impossible task to do the job without prior experience. Training is lacking. Seasoned coordinators often feel like they are teaching staff how the system works.
- The lack of expertise in OCR creates constant change. The office uses a task list in OnCore but the list isn't helpful for coordinators. OCR staff want to use the automated process (task list) rather than emails. This creates delays. The system is more of a hinderance than a benefit.
- The review process is too lengthy. One study was submitted last October and still is pending.
- It is difficult to know where things are in the approval process. Other institutions have an integrated system with a dashboard that displays various stages.
- Contracting out work to Advarra rather than working with coordinators seems like a waste of funds and resources. Coordinators have the knowledge but are not included in the process. How much money has been spent to build calendars for COG or ECOG trials where everything is SOC? We are supporting a company outside of UF when things could be done in house by seasoned coordinators.
- Notification of changes to required documents or steps in the process needs improvement. Changes are discovered after submission. Website isn't updated, etc.

Research Billing Office

- Bill review for patients who are off study still show up in the coordinator's buckets. There was no testing for the new featured in OnCore intended to discontinue bill review and it doesn't work.
- Epic and OnCore still don't talk to each other well. We need IT support who is dedicated to work on these issues and find solutions. UF and UF Health need to work together to make this happen.

IT Security

- The electronic submission process for software that is needed for our trials is problematic. As a coordinator, it is difficult to answer some of the questions. Even faculty struggle with answering the questions. It's difficult to speak with someone for support with the submission.

IRB

- Continuity of IRB reviews - The same screening form was submitted for 4 studies. The fist time it was approved, second time there were issues with questions 2 and 3, third time questions 4 and 5, etc. IRB reviewers do not interpret regulations in a consistent manner.

Additional Comments

- There are no regulations at UF classifying positions or pay for research coordinators. There are no guidelines or qualifications before individuals are hired or promoted. An internal university certification program may be beneficial.

- IDR Review process is lengthy – Working on a simple submission that was submitted 8 months ago and is still not approved for laptop use. The employees in the IDR office only communicate via email.
- To train someone to be a research coordinator takes years. Not sure if this has to do with how complex the system is or how convoluted the UF system is.
- Since the systems don't communicate with one another we are required to enter the same information (study title, PI, etc.) again and again. It is repetitive and time consuming. Resources are scarce and it's not going to get better. Covid had an impact on employees working in office vs. at home. We need to find a way to streamline processes so the job can be performed with the reduced resources we have.
- UF and the Cancer Center are pushing for these complex consortiums and studies but we don't have the infrastructure (centrally – OCR, IT, etc.) to support them.
- Staff is going to work for the industry sponsors because the pay is better, they can work from home and they can travel.
- The right hand doesn't know what the left hand is doing. If we don't start streamlining this and look to other universities where it works we will fail.
- Need an onboarding process with specific contacts, research front door. Seasoned coordinators end up being navigators and trainers.
- We want leadership to know they have dedicated staff who are willing to help and want to work together to create positive change.

Summary of Focus Group: Friday, June 9, 2022….. Kris Wynne, Facilitator and Jennifer Lanz, Note Taker. There were 7 participants.

One Word Impressions

Challenging

Agree challenging

Fragmented

I like fragmented.

Process changes frequently and it isn't done in real time

Difficult to orient people to the system….hard to bring new people in.

Any place where you are generally satisfied? What works well and what isn't working?

Oncore and OCR are not working well….a lot more work on our end as coordinators. Overall the IRB isn't terrible. You get different responses from one person to the next.

The interactions with the IRB are pretty good. Integrating with UF health is our biggest problem.

The interfacing of Oncore with EPIC…the way it was sold to us did not pan out and did not reduce the workload for us. It has just made more work for us.

I second that it is the main problem along with RBO. Research billing for patients and the timelines in EPIC don't work. We have to adhere to a protocol and take care of the patients. We don't have time to go back and be compliant with billing when the timelines in EPIC don't work. This all started with the change in the Oncore calendar build. A lot of Indians in the kitchen and nobody is the lead chef at OCR.

My concern is OCR, Oncore and RBO. I just think the way they interact with one another is terrible. The bill review takes a lot of time away from the coordinator doing patient care. We take a lot of time triaging bill review. Sometimes we have to review stuff that was from years ago. The whole system was supposed to alleviate work for the coordinator.

I 100% agree with OCR and Oncore and RBO. I also have an issue with REDCap. So much repetition, so much redundancy. The integration was supposed to help, but we have to triple our effort now that OCR implemented Oncore.

I left in 2018…Oncore was underdeveloped…now I am back and I do think people are trying to make it better. The EPIC integration is so frustrating. It took such a long time to integrate my nursing view and my coordinator view. UF health is very difficult to work

with. Blood processing and the core lab. For research purposes, maybe they need to collaborate research labs and places to store samples, etc.

Another challenge is the nursing Impact committee. I am struggling to truly understand the purpose of this committee. Are they there to support the research team?

I can speak to that…if a research team wants the bedside nurse to draw PK samples, they decide if it is feasible.

The length of time that it takes to get through the nursing impact committee is forever. It took 10 months for our last study.

I am not seeing how the clinical nurse group is supporting the bedside nurse. Extra work on the bedside nurse.

IRB

The IRB is falling apart. There are only a few people left.

I don't understand why I get one response from a reviewer and a different response from another. Only established PIs get a fast response. It is inconsistent. If I ask a question, they send me to the IRB website. You have to beg them to get on the phone with you. You only get things done if you know someone.

It would be great if the IRB could create a standard process for junior faculty. They are the ones that suffer.

We need people to have a person that has consistency in the responses. We need more training. What happens to the places that have single coordinators? There needs to be a better system for new people. We need more infrastructure.

A liaison could be helpful with all of the different entities.

Agree that IRB reviewers have different responses. It is inconsistent.

Inconsistency of reviews, each CR the reviewer finds something that should have been addressed at the initial review not 4 CRs later....example ICF template language.

UF Health/Shands

I had a study that all MRIs were missed by the staff. Nobody at Shands cares about research. How can we create a better relationship?

We had trouble getting MRIs as well and we told them that we are going to get them off site and that got them to pay attention and they did the MRIs.

There is no incentive at Shands to do research. We are a nuisance.

Disconnect between UF and Shands. We are on the back burner and it is our responsibility to create a work around.

It would be worth it for Shands to introduce research in the training at Shands. All employees have a week-long training.

They need to realize their mission statement.

Office of Clinical Research

As far as OCR, the lack of clinical knowledge when they are requesting billable services. They don't understand clinical practice. We have to redo coverage analysis and redo We need people from the study team to help them. They are reinventing the wheel.

IT Security

Very time consuming. They don't understand research. It is UFs way. They lost an iPad.

IT is horrifying….it takes forever to work with an iPad. You have no idea who you have to talk to. The risk assessment has gotten a little bit better. There is mandatory training now.

The flow chart is insane. I am not an IT person. My PI isn't an IT person. The process is too long. Months and months. The privacy office gets involved. You never know who to talk to. The only good thing about the process is the new training. Need more guidance. They have lost our iPads too.

I agree. A sponsor will bring in platforms that we need to be downloaded to our computers. The process can take months. There are a lot of delays.

There is no guidance for non-IT people.

Other departments

Human research payment: Previous way and current way…now it is way better. Before it was a nightmare. People respond to questions and help you through the process.

What One Thing Would You Want to Address?

Oncore epic interface for research billing office……research billing is the biggest problem….

Everyone in the group agreed with this statement.

I agree 100% especially RBO…from the chat section.

The Oncore calendar is always wrong. I spend hours of my week to do trying to resolve my issues.

We should have a better overall intake of new employees whether it be by the department or college wide. As a new employee, it is very difficult to see the big picture. All of these services for research services for us, but it feels like we are serving them. All of the changes in the last few years have increased our workload. I understand there our compliance issues and that is why these entities exist.

There is an expectation that we should understand everyone else's language. We have to understand IT. We have to understand billing. There is a very low tolerance for us when we don't understand their job. Our job is to make the protocol work with the subjects…yet we have to understand their job. We are very siloed.

IRB needs HUGE restructuring….from the comment section.

Additional Comments

I spoke to people from the IRB and OCR. People are extremely underpaid. That is why everyone is leaving. You go to try to get an SPI. The only way to get an SPI is to get a counter offer. People can't pay their bills.

That was going to be my closing argument. You just stay in your position…we feel devalued…we are involved in patient care, we are bringing change in science. We are air traffic controllers. I have been here for 15 years….when they changed the salary range and job titles nobodies salary changed.

Hard to get people the raises they deserve. Academia cannot compete with big industry. You can earn twice as much in industry. People are leaving in droves. Nobody thanks you for your dedication or anything.

Summary of Focus Group: Tuesday June 14, 2022
Alison Ivey, Facilitator and Kim Wollard, Note Taker
There were 9 participants.

One Word Impressions

- Complicated
- Frustrating x2
- Disconnected
- Multi-faceted
- Mayhem
- Confusing x2
- Problematic

Areas of Satisfaction

- Appreciate the staff's willingness to work with you.
- Once I can get ahold of someone, I have good conversations. Very helpful.
- Contracting in OCR goes very well. They are on top of things and easy to work with.
- Communication with other departments with similar issues is helpful. Collaborating with other coordinators who have similar issues/studies is great.
- UF staff is helpful and cares about research.

Areas that could use improvement

- Disconnect between the studies we are doing and the understanding staff in central offices have on these studies. Ex, Coverage analysis. Information is not correct, learning as they go.
- Device agreements with UF Health/Shands. Length of time, Little understanding of the CMS approval letter or how research works.
- Lack of process guidance for study set up in general. No communication between IRB, OCR and ancillary committees. Sending same info to 2-4 various groups. I don't understand why there can't be a central place for submissions. Coordinators feel like they are the point of contact that connects everyone.
- Conflict of Interest office – Received grant in February it is still pending. I reach out every 3 weeks and get a general response that isn't a conclusion. Research community was never told about the changes in the COI office. Need to be more forthcoming.
- Core offices (and research staff in general) are understaffed and overworked. Nature of Covid and how funding is going. UF's reluctance to work from home models, etc. If a central office can't manage expectations, they need communicate this with the coordinators.
- As an employee in Jax who left UF and came back, there were many changes but no guidance on how to navigate the system. There are no timelines, there is no checklist or source document citing the various offices that you have to get approval from. This is no specific process or order.
- New coordinators are hired weeks or months after the previous coordinators left.
- Order of operations and who to contact is a need. Possible solutions: 1. Mock trials for hands on training. 2. Improved timing and accessibly with training.
- UF is losing funding and study opportunities because the processes take so long.

- It would be helpful to have navigators who worked in OCR to help work through complicated studies. Consultations with staff who understand the systems, providing wait times for various offices, etc.
- I know it would be expensive but it would be so helpful if systems communicated with one another. Entering the same information in various systems is time consuming.
- Onboarding new coordinators with no background in research is difficult. Training takes away from studies and other important activities. This is not something unique to UF.

Office of Clinical Research

Lack of expertise.

OnCore was supposed to streamline things and make work easier but has actually created additional work.

Jacksonville is taking training for OnCore, but are told many things will not be active in Jax. The system just doesn't work for Jax. Ex. Jax is also limited with access to MyChart, outreach, etc.

OCR is understaffed for the amount of work. Everyone is very nice but working with the staff is very time prohibitive. Lack of communication or response. It takes weeks or months to get any movement back.

"They bit off more than they could chew." They have tried to centralize too much. There is not the staff or expertise to manage the things they are responsible for.

There needs to be more qualified staff. Retention is also a big issue, not just in OCR but across campus.

Not a lot of processes in place. Links on the website are broken, processes change but the research community is not informed. New forms are created but you don't know until you submit to OCR.

Research Billing Office

No Comments.

IT Security

Ughhh….

Didn't even realize they were an ancillary.

IRM review – takes forever to get it through. On the website it says on average it takes 2-12 weeks.

UF should be more proactive and list pre-approved EDC platforms to provide to sponsors rather than trying to get approval for a new one.

EDC and App submissions – have been told by other institutions that UF is overstepping their boundaries. In one example, UF found issues with things that other institutions didn't have issues with to the point where NIH almost pulled funding.

UF IT Security does not allow one iPad for more than one study. It makes no sense.

The questions are complicated and the language they use is confusing. You have to be an IT expert to complete the paperwork.

In Jax, the IT group works directly with the sponsor. This is much more efficient and productive.

I've had studies that are closed before UF IT attempts to address the issue.

I was told that I could not use out of date software because "I would take down the entire UF network."

IRB

Website is not user friendly.

Understaffed.

Nursing Committee

There is a lack of expertise in clinical research. Nurses don't seem to be trained in research and don't consider research to be a priority.

Can submit to the committee but never get a response. No approval letters. We don't let this hold us up, we just move on without their approval.

Additional Comments

We appreciate that our voices are heard.

Human Subjects Enterprise – Focus Group Summary, 05-31-22, 1200

Participants: Dr. T George, moderator, Dr. L Moldawer, scribe and co-moderator

Six participants, three from COM, three from PHHP.

This summary is laid out thematically, rather than in the order that was discussed. Initial comments were the most pronounced or professed by the participants.

The moderator asked each of the participants what their 'one word summary' of the enterprise be and the responses were as follows: "difficult (2)", "overbearing", "barriers", "it's going to be a while". The sixth participant joined after the question was asked. In general, the participants thought the process took too long. Not enough was done in parallel and most of the processes were serial where issues were not addressed until prior issues were resolved. Although most issues are ultimately resolved, it takes too long and places too much menial work on faculty. Two examples were given where programs were lost because of the duration of the process. This was especially problematic for small grants where the process is the same, but the timelines are much shorter.

The repeating theme throughout the discussion was that the process seems to be operated by "gate-keepers" rather than "facilitators". There were several individuals who reiterated that the priorities of the enterprise were not in helping the investigators, but rather in maintaining the bureaucracy or meeting some other objective that was not evident to the faculty. Lack of collegiality, unwillingness to help. "No, we cannot do that" in response to novel, new approaches employed in clinical studies. Innovation is too risky when UF precedent is not evident. It is difficult to blame any one entity in particular because the system works serially and not parallelly, and the investigators are not aware often of hang ups. In general, there was also the comment (and agreement by others) that there was over-reach by the enterprise into issues that they should have no concern. For example, OCR or IRB recommending changes to the study design of multicenter clinical trials: thinking they had greater expertise than the investigator or other key leaders in that space. The "culture" of research at UF was noted to be one of risk aversion rather than faculty achievement.

In general, the focus by this group was on the IRB activities rather than other aspects of the enterprise, although as discussed below, there were comments targeting OCR and IT Security.

The general comments about the IRB were equivocal. The majority of individuals expressed the opinion that the IRB tried to be helpful and facilitative. Organizations that had codified pre-review processes at either the College or Center level had better experiences. Two individuals commented that IRB prereview was beneficial, but there was general consensus that it was inefficient. One participant stated that UF IRB were more "sticklers" than their previous IRB and that there were issues with the IRB reviewers having adequate expertise in certain topic areas (e.g., qualitative research). Issues did not appear until the IRB met and concerns were vocalized. This necessitated an almost uniform need to resubmit and that added an additional month. One solution offered would be to have the reviewer's reach out to investigators with any concerns and learn more about their research if they were unfamiliar with the methods or techniques applied. Also, to consider having written critiques available to the PI prior to the IRB

meeting so responses could be developed or additional data prepared, with the meeting then serving as a confirmation, shortening the review process.

Another criticism was the need to jump through numerous hoops to get non-UF personnel access to myIRB, needing a UFID and other measures which was simply to “check the box and agree to participate”. There was also one comment about the variability of the review depending upon the assignment. One recommendation would be to have reviewers and facilitators assigned to certain groups or individual investigators so that over time, they become more familiar with the research mission, and developed a better understanding of each other’s issues. Inconsistencies in decision making were felt relevant to both the IRB and risk review processes.

Two people commented on the IRB software being difficult and overly complex. One mentioned another software (Kuali) which was much simpler to use.

Considerable criticisms of IT Security were raised. They were felt to act arbitrarily, variably and without the investigators’ interest in mind. One particular item was undergraduates and non UF personnel getting access to the EHR. One investigator mentioned that an undergraduate could not access EPIC, but if he/she were paid under OPS, then they could get access to EPIC, which actually didn’t minimize risk and only added bureaucracy at the investigator’s expense. Process slow and convoluted. This group was roundly criticized as being overly bureaucratic, unhelpful and ‘tedious’, and requiring ‘all the boxes be checked’ before approval.

OCR was generally viewed unfavorably, although to this reviewer, it appeared that many in the group did not use OCR frequently. The criticisms came from one reviewer doing a lot of industry or foundation-sponsored clinical trials and their concerns were focused on the time required to complete contracting of clinical trials. ‘Slow’ was the term repeatedly used by many. An example was one RCT which was still being discussed nearly a year later, while it was activated at UMiami long after UF was first offered participation as a site.

After the meeting was completed, we received the following email from one of the participants (taken verbatum):

While it is true that a cultural shift may be required, the various agencies tasked with supporting research at UF are nonetheless responsible for ensuring that all regulations and policies are followed. As one of the senior folks on that call, I was remiss to point out that junior faculty can at times be unaware of the importance of those regulations and policies. (Certainly the same applies to some senior investigators, but that problem needs to be handled differently.) It might be useful to have a cadre of senior folks available who could diplomatically help guide the junior faculty through the necessary steps of research involvement, ensuring that all necessary safeguards are in place without the junior faculty feeling demeaned or threatened.

Summary of Focus Group: Friday, June 3, 2022…. Lyle Moldawer, Facilitator and Roger Filingim, Note Taker.

One Word Impressions

- Outstanding
- Very good to outstanding (focused on IRB)
- Overregulated, grossly understaffed and supported, parts work extremely well (IRB), the rest needs a lot of work, training requirements for investigators excessive, OCR is causing delays and losing grants
- Centralized structure is good is some ways, but takes more time and effort to jump through all the hoops

What is IRB doing well?

- Response time, receptiveness to discussions to reduce response time has improved greatly over the years – In contrast, dealing with the Cancer Center was overly burdensome & waste of time for a study that would not be enrolling here
- IRB staff incredibly responsive and supportive
- IRB software was very self-explanatory, staff was very helpful
- Click is a bit rigid and not well-suited for multicenter trials and S-IRB, need IT resources if UF is to be nimble, especially if we want to be Data Coordinating Center. Institutional investment is inadequate, leaving investigators to develop systems themselves. We talk the talk of top 5, but we don't walk the walk. Need forward thinking in a business model way.
- Faculty member recently left and inability to get IRB approved was the nail in the coffin. This was a large multicenter study, and the IRB insisted on all sites including the UF language. Only one example, but not the only. IRB does good work but sometimes they are too rigid.

Office of Clinical Research

- OCR was really helpful with first industry contract – helped with budget, patient recruitment…
- No issues, several projects have gone through
- Have gotten better with time
- In the process of losing a project, because OCR took so long to complete the documents for the budget. They are understaffed. Issues with getting cost of services from Shands. Don't have the expertise to get it done. Brian has been fabulous signing contracts, but understaffed and don't have ability to manage complex trials. Difficulties with patient care costs and patient billing. Nobody on either side (Shands vs. RBO) who has the authority to make a decision. Project on hold for a year because of this.

- Cost of service request from UFHealth is the problem. Contact list is not kept up to date. Disconnect between what OCR is doing with budgeting and UFHealth understanding of the expectations. Lots of personnel turnover.
- OCR doesn't have the level of expertise needed for some protocols – investigators often have more expertise. Problem is getting the cost of services. Some investigators to it themselves.

IT Security

- UF Privacy not allowing students/volunteers EPIC access
- Using iPads to collect data never got resolved, but may have been more the sponsor rather than IT
- Slow, super-conservative – deploying 80 iPads for large grant took 6 months. Software for large CMS project took 18 months to get done.
- Social media restrictions are problematic, leaving us way behind
- UF is so risk averse, it's shocking we get anything done!

- BURRC works well – no problems

- Nursing committees have worked well/quickly

- COI office and Office of Research Integrity have been horrible – very slow. COI Office doesn't have knowledge or experience to understand the relationships and they don't seek out information from the involved faculty. Faculty get frustrated when administrators are making such important decisions without explanation.

What One Thing Would You Want to Address?

- Cancer Center delays and multiple review bodies was a problem
- Compensation for research time to allow release from clinical duties to do research. PI has done multiple trials but never given release time to support research effort. Another group member agreed.
- Have somebody with the authority and knowledge to solve investigator problems. Ombudsman or Dean-level person who has the authority to help solve problems.

Additional Comments

- We held a brief discussion of what our working group plans to do, including raising the question of whether these concerns can be addressed with increased staffing and other targeted changes or whether there needs to be greater structural change..

06/08/2022

Focus Group Feedback

Thomas George led FG

Rhonda Cooper-DeHoff served as the scribe

One word to describe your research experience

Mixed results

Burdensome (used to be “fun”)

Just “ok”

Time consuming

Collaborative/Helpful (in reference to the IRB specifically)

Collaborative/Helpful – what is working well? Based on staff/personnel/leadership is helpful (comments relate specifically to the IRB).

IRB02: Ira is extremely good and helpful

IRB01: Peter Iafrate has great leadership style (cautious but progressive which was cited as a positive virtue). Fellow submitted project that was very confusing. Peter reached out to the group and resolve the issues quickly which was appreciated.

Having Departmental Support is very helpful, when it exists. If support is from people who don’t understand what the investigator is doing, that is not helpful. If the support is not there, it really bogs down the research process since there is too much complexity with navigating the overall human subject research enterprise at UF.

Burdensome (not related to IRB) – this comment is related to other committees beyond IRB with no navigation to help get through it. Would be great if the other entities/ancillaries had systems or accessible leaders in place (similar to the IRB) that were helpful or useful. Many people agreed with this.

Concern with UF IRB wanting to go “last”, that is seeing everyone else’s approved consent forms before UF IRB will approve. This is very burdensome and time consuming, particularly for multi-institutional study approvals.

Ivana very helpful with an industry sponsored study – getting it through the IRB rapidly.

What aspects about larger enterprise is a problem in the research enterprise?

A lot of redundancy. Subjects come to CRC – PI has to submit orders to CRC, IDS, Epic, Oncore – a lot of it is repeated. Would be helpful if systems could talk to each other better.

“Process” at UF Research doesn’t exist. Seems like there is no process and no process improvement at UF Research. This comment came from a faculty member who is an engineer by training. Everything is adhoc/random/chaotic course of events. Not understanding the “process” leads to so much frustration – would be helpful if there was a “concierge” to help navigate people through the different agencies.

UF IT/IT Security is a “train wreck”. UF IT thinks they know the best way to do everything…. Unwillingness to engage. Could link UF IT to an insurance company where first response is always “no”. UF IT timelines are totally out of kilter with what happens in the real world. Adjudicating software is a complete black hole! Such a fundamental disconnect between UF IT and researchers. Took a whole year for approval of a software package that could be used for linguistics research during the pandemic. Put a post doc way behind on their project and missed important windows of opportunity it the overall research field giving UF faculty and investigators a disadvantage for publications and grants. And what they ended up using wasn’t even the best option. It set that research group behind very badly. This causes missed opportunities for funding/collaborations/etc. Asked for concrete examples that could be shared with leadership. Mind boggling that we are investing so much in AI yet we don’t have the ability to make minor changes to UF software programs or get approvals for anything that isn’t already pre-approved. Analogy given that if UF IT security oversaw equipment procurement for the operating rooms, all sharp objects would be banned from purchase because the risk of injury is too great. Much agreement was voiced.

Lots of turnover in research staff lately – this is not helpful when someone is trying to get answers. Especially when a new staff person tells someone the wrong answer. Jobs should be created at a level that would incentivize people to stay in a job and give the correct answers. Professionalize or create a career ladder/pipeline for these staff to stay in positions where their knowledge of system efficiencies can be leveraged. “Process” is highly dependent upon having successfully navigated it – and with it – institutional memory is lost with staff turnover.

Very little interest by the institution to FACILITATE the success of faculty efforts. Rather, more interest and focus on investigating the faculty. Someone wanted to buy a bottle of saline – costs $5. Staff asked….”Why do you need that saline??” Took 5 weeks to get it approved. This is just an example. Same thing happens when need to order a computer workstation. Same questions about “why do you need that”?? Faculty need to jump through so many hoops to get something to happen, as opposed to – how can I help you make this happen. Having a justification written into a grant for something isn’t

good enough for UF. Even though the grant was approved by all levels of the Department/College/UF Research. But yet when you go to actually do that grant and spend monies that are in the budget, you are not able to do that without hundreds of questions and additional justifications which makes it take longer. Makes you very behind in milestones and NIH will unfund projects based on missed milestones. Double jeopardy having to justify performing research twice (once in the original grant application; another once grant was obtained; both have tight deadlines).

Another example – took 2 years for research office to pay students who participated in a project because no one would cooperate and make it happen.

Another example – took 13 months to issue a subcontract for an R01

Another example: UF is now getting an external reputation that it takes a very long time to get anything done. What took 24 hours at every other participating research institution to start a process for a clinical trial took 6 months at UF. That funder does not want to work with UF anymore.

Selected Comments from the Chat

From P3 to Everyone

> I think IRB-01 has made a concerted effort to improve several of their processes. Staff have been very willing to try to connect researchers with questions to those who can provide some advisement.

From P3 to Everyone

> We jest about risk of sharp instruments, but have been prohibited from shaving our participants' chest at CRC, despite our need to reduce EMG/ECG artifact from chest hair. The concern of a rare risk of a minor injury was prioritized over data quality.

June 9th Focus Group: Drs. Fillingim and Woods

"One word" summary of your experiences?

- Bureaucratic, Risk averse, rollercoaster, slow, frustrating, not user friendly

- Starting with the big picture, are you generally satisfied, overall, with the enterprise?
  - YES:
    - It works most days, but the days it doesn't are severe. So, more "good days" than bad. Good experience with the clinical trials "people." DSP has been very helpful. Getting emails for grants that fit my interest are really helpful.

  - NO:
    - What about the enterprise doesn't work, and why?
      - Insiders' knowledge base required to navigate the process. If you know how to navigate, you can get through it. The process is not transparent.
      - Consent forms going from 8 to 30 pages, with increased bureaucratic language. This is no longer participant friendly.
      - There is an increasing complexity to the overall process that makes the process more difficult to navigate. The complexity is driven in part by expansion of compliance rules, but not in a user-friendly fashion.
      - Very frustrating. Process is extremely slow, preventing progress.
      - At every IRB meeting, the IRB seems to be oriented to putting obstacles in front of investigators, rather than facilitating research. In addition, the IRB often over-reaches beyond their area of expertise
      - It is impossible to execute data use agreements, which significantly undermines multi center/site trials. The process is slow and needed subject knowledge is missing from the IRB reviewers: creating additional problems.
      - The definition of a limited dataset, although defined by NIH, appears to change with whoever is reviewing the protocol. The same is true with the definition of personal identifiers/PHI.
      - Navigating multisite IRBs are often faced with conflict between the UF IRB and the other University IRB, which cycles back and forth via emails, etc. until someone finally takes responsibility and moves the process forward.
      - process is cumbersome and not easy especially for new investigator or someone new to UF
      - Inconsistency is the rule with the IRB, rather than the exception. For example, using a previously approved consent form for a similar study will not make it through review, even though it is an existing approved protocol. This is entirely illogical.
      - Meeting with the IRB ahead of time seems to grease the wheels more times than not (insider info needed), but even this can lead to inconsistent outcomes at the point of review.
      - There are also inconsistencies across the University. Even single procedures, such as grant based purchasing (possibly dept or college specific issue) are extremely inconsistent.

- There is little to no clear and accessible information available online to provide guidance for any of these common clinical research processes. Lack of clarity on which ancillary reviews are required and what each ancillary actually does is not clear and guidance documents are scarce.
- People who have peripheral experience with content sitting on IRB, are unwilling to accept papers and clear documentation of safety for procedures, overruling this evidence and requiring the investigators to jump through hoops that are both unnecessary or even interfere with the science itself.
- Can't add personnel when another revision is in place. It can take a month to add a new person to an existing study, delaying the science/work.
- Also, cannot revise the protocol in a continuing review, which is an obvious place to make a revision – but is not allowed.
- Overall human clinical research approval process is cumbersome and lacks transparency, especially IRB and OCR.
- IT security/UF IT. Was prevented from putting Excel on a computer because "databases" could be emailed.
- Survey studies prohibited from being posted to Twitter by IRB. Instead, often pushed through payment-oriented channels for posting. This is prohibitive to researchers that are not funded, it creates a situation where we as researchers cannot access on obvious and central medium for soliciting a diverse array of responses needed for the science. No PHI, no patient groups. Forbidding use of twitter or other social media formats to UF researchers is both archaic and interferes with modern scientific process.

- **If you could change one thing about the system to make it better or more useful, what would it be?**
    - Make the process more transparent. Better training/documentation. Not everyone can afford a research coordinator that has been in the system a long time that has the Insider Info. A dedicated "navigator" to help move through the process from inception to approval and beyond would be hugely helpful

    - Checklist to tell me what kind of research I am considered to be doing and which ancillary entities I need to go through. While there is a basic version on the IRB website, it is not detailed

    - A formal onboarding process for research staff/faculty would be important for demystifying the process. Even though there is technically an IRB process for this available, few people are aware of this resource (including multiple people on the call).

    - Simply the process: there are too many ancillary pieces that do not communicate. There also too many different electronic systems that do not cross communicate.

    - The leadership of the various groups are very friendly but are resistant to change, wont attempt to think differently, and hearing what other institutions do. Thus, change in leadership is needed.

- myIRB, UFolio, Myinvestigator, UFIRST, etc. need to be linked rather than operating almost entirely independently.

- **Our Qualtrix survey identified two entities where there may be room for improvement. Would you be willing to comment on your own experiences with the Office of Clinical Research and the Office for IT Security.**
    - OCR: Guidance documents for how to navigate this process is not clear and very hard to find. OCR has changed so much that. we don't even try anymore—we rely on my coordinator who knows everyone and can find the person to ask in the OCR office.
    - IT Sec: non-clinical research that software necessary to conduct research - that is the "industry standard" - are prohibited, and/or the time it takes to get software installed and/or updated is prohibitive to conducting the research. This may be COM specific. The COM Faculty Council is currently administering a COM IT survey specific to COM research, so this might be a good resource for your process, and for those of you in COM, please strongly consider completing the survey.

Do we need tweaks or revolutionary change to the system to move forward?

Overall, the group agreed that revolutionary change will be needed to improve the human clinical research system. Stagnant leadership, fractured communication, and over bloated bureaucracy were cited as evidence.

UF has a reputation for being prohibitive in terms of research and research process. This is and has been communicated to many of our attempted faculty recruits and trickled back to us. That reputation

Chat transcript – 6/9/22 Faculty focus group

From P1 to Everyone 12:09 PM

bureaucratic

From P2 (he/his) to Everyone 12:09 PM

Rollercoaster

From P1 to Everyone 12:20 PM

the definition of a limited dataset, although defined by NIH, changes with whoever is reviewing the protocol. Same with personal identifiers

DSP does the DUAs —never clear who you contact for that though

my coordinator knows everyone so I rely on her to figure out who to contact, as it is not transparent or easy to find

From P4 to Everyone 12:21 PM

Agree whole process is cumbersome and not easy especially for new investigator or someone new to UF

From P1 to Everyone 12:25 PM

whole other discussion, OCR!!

Can talk about other bureaucratic hold ups for hours, but won't —happy to share those later.

research IT

From P4 to Everyone 12:33 PM

COI

From P3 (she) UF to Everyone 12:34 PM

Risk Assessment, specifically, or IT implementation.

From P1 to Everyone 12:35 PM

both.

one of my faculty was prohibited from buying a specialized computer for AI work because it was not standard and they couldn't encode it for clinical work. but he is not a clinician and doesn't use protected data

From P2 (he/his) to Everyone 12:36 PM

Part of that is related to legal's interpretation of federal law about privacy

From P1 to Everyone 12:36 PM

too many JDs on these committees and groups and not enough scientists

From P2 (he/his) to Everyone 12:37 PM

^^^^^

From P1 to Everyone 12:40 PM

OCR has changed so much I don't even try—I rely on my coordinator who knows everyone and can find the person to ask.

From P3 (she) UF to Everyone 12:41 PM

Though I have not (perhaps yet) experienced these IT challenges, I am hearing from faculty members that conduct non-clinical research that software necessary to conduct research - that is the "industry standard" - are prohibited, and/or the time it takes to get software installed and/or updated is prohibitive to conducting the research. This may be COM specific. The COM Faculty Council is currently administering a COM IT survey specific to COM research, so Adam and Roger, this might be a a good resource for your process, and for those of you in COM, please strongly consider completing the survey.

From P1 to Everyone 12:43 PM

this is confidential?

From P3 (she) UF to Everyone 12:43 PM

IT survey?

From P1 to Everyone 12:44 PM

leadership that is open to change and improvement

I like the leadership but don't find them open to change or feedback

From P2 (he/his) to Everyone 12:45 PM

IRB01 staff will walk investigators through all the steps for myIRB

From P1 to Everyone 12:46 PM

https://irb.ufl.edu/myirb/myirb-help-selecting-the-requested-review-type.html

but not really detailed enough

From P5to Everyone 12:47 PM

status quo bias is a huge challenge

From P3 (she) UF to Everyone 12:48 PM

I cannot thumb P2's comment up enough.

From P2 (he/his) to Everyone 12:50 PM

Kuhn's paradygm shift

From P3 (she) UF to Everyone 12:58 PM

thank you for these links.

Indeed!

It *is* heartening that this process is underway.

Focus Group 06/15/2022

Duane/Linc – Moderator

Rhonda – Scribe

One-Word Impression – overall thoughts

Good (not great)

Effective – does what it needs to do

Challenging to use for QI studies

Generally satisfied?

For education/QI studies it is very challenging. Forced to send stuff to an IRB that reviews primarily clinical studies – based on how QPIR form is filled out.

Overall, pretty satisfied – the system makes sure I am doing what I am supposed to

For a clinician doing clinical studies, very satisfied, but has a lot of resources available to help go through the steps.

Change one thing?

Integration of the various entities. IRB/OCR, etc. And also being able to understand where a study stands within each entity

Build in “Domino’s pizza tracker” type of thing with “glowing arrow” to know exactly where the study stands and who has the responsibility of each step. This could include the steps of the IRB/OCR/Other ancillaries as necessary for a particular study. Everyone on the focus group agreed this would be very helpful!

For QI (QPIR / IRB) the process for this is not clear and constantly gets kicked out as research. QPIR program pushes into IRB for any time data is asked for. Suggestion made that the vast majority of QIPR projects are not actually being recorded because the faculty don’t want to go through the process knowing that it will get kicked out to the full IRB 01. Can system be adapted to be more useful/intuitive and allow for QI projects which are required for all trainees (anesthesiology)?

Forms are difficult – and it is not always clear as to what to do if you don’t understand how to complete a form properly. There is no training for junior faculty (or residents/fellows). Having training available (on-line modules) for IRB aspects (templates for protocols, including different types of protocols – clinical and non clinical, and other templates) as well as other ancillaries would be useful. This would be very helpful for young faculty and trainees.

I2B2/IRB/CTSI/REDCAP – Need for systems integration. There are three (or more) separate systems are required to do this. If these could be integrated, that would be

very helpful. If then ask for tissue, then you have a whole other form. Nothing is linked. If there was integration, it would accelerate everything. Replication causes a tremendous loss of time!

Barriers that exist in your area or the ancillaries / institution

Processes for types of studies (education based) gets bumped to IRB01. Too onerous to explain non-clinical study so not using processes

If support is not available it is a huge barrier to getting work done. Having clear paths to IRB staff would be helpful.

Jax has very few support structures available for research which is a problem.

OCR/IT Security specific comments

Most ancillary reviews are really fast. OCR review is really slow.

OCR has separate form – why the need to ask for all the information again? But overall, the process seems to go reasonably quickly.

IT Security – most people on this group have not used IT Security, not much to say about it.

If IRB could do a better job about guiding people to do what they want, that would be very helpful. Like Microsoft “clipee” used to do – “looks like you are trying to create a resume….” If IRB could do that (people better than tools) that would be very helpful!

06/17/22 Focus Group (only two people in this group)

Linc - Facilitator

Rhonda – Scribe

One Word…

Siloed

Convoluted (in a positive and negative way)

What one thing works most smoothly (the best)

Bright people in the system but may be hard to find

Built in help in the IRB forms is very useful (clicking on the ? in the smart form)

What one thing does NOT work (particularly ownerness/complicated)?

Recruiting patients for studies (as a non-clinician in a clinical department) if patients have not agreed to "consent to share".

Processes in place that create roadblocks (example: application has "100 pages" and junior faculty doesn't know what IRB is looking for. It gets submitted and not where it should be. Goes back and forth and lingers.) Onboarding training is not sufficient to get really trained in all aspects of human subjects research. While the information is conveyed to faculty, but may not be specific to meet the needs at the time it is actually needed.

Maybe Departments could have their own training that could follow up on the onboarding training.

"Regulatory Concierge" would be helpful.

Any experience with other aspects of the research enterprise:

IDR: dedicated IDR person in GNV but only works on JAX stuff. But a lot of turnover. And supposed to have 2 people for JAX but there is only 1 person, so there is a lot of backlog. Also problem in JAX that people just don't want to collaborate with GNV. Recent IDR pull took 3 months after getting IRB approvals, etc. But it was complicated – included Oncore, IDR and Tumor Registry data.

Entities at JAX are not as updated as GNV (IDR as an example).

Research Compliance, Biosafety, etc – they have great people, but the processes are very complicated. Conflict of Interest as example – multiple different levels and groups working in similar areas (Norton's office, Provost office). Not a well-orchestrated unit.

Operational weak link is the units working together.

In Jax, Department Research Staff are only employed by UF JPI and not UF COM. This is a huge problem because researcher faculty can’t share files with research staff.

Other thoughts

Should be more diversity on IRB (race, gender, geography, etc).

Need to take JAX perspective into consideration more in many matters (ie consent to share issue).

IRB Town Hall Focus Group 7/7/22
RE: Human Subject Enterprise
10 participants

Moderators: Dr. Lyle Moldawer, Dr. Roger Fillingim and Dr. Kim Wollard
Scribe: Angela Avery

<u>One Word Impressions of IRB and research process</u>

Undervalued
Misunderstood
Cumbersome
Intricate
Tedious
Training needed
Complex
Confused
Convoluted

<u>What aspects of the IRB process produce that single word response?</u>

- Complex on both ends, black box
- Would rather review a full board drug study dealing with cancer versus a study submitted by a student. No introductory system showing how things flow. No good resources for students and/or mentorship
- Smaller fraction of studies come from experienced investigators who understand system

<u>Priorities</u>

- 1st come 1st served from IRB in box, assigned in real time by order of arrival, pushed to PIs or staff
- At the height of pandemic, COVID studies were prioritized
- Generally anything at any level do not sit in staff box for more than 48 hours
- Full board will be looked at within 2-3 days before go to review
- Felt there would be too much bias to put forward a priority system. Not right to push students to the back of line because they don't have funding.
- Example. Emergency requested received today, hasn't answered any emails and requested a one-day turnaround
- PIs don't see value of submitting to us, assign a low-level person submitting that doesn't understand
- Fiscal assistants submit with no expertise, or often most junior person assigned leader on the study team

<u>Training</u>

- Vision of protocol development team
- Check the boxes of what makes a good protocol before getting to IRB and regulatory aspects

- Admin staff is not taken seriously and not valued. Turnover rate causes a lot of issues. They make detrimental mistakes to the study process (deviations, adverse events, etc.)
- Additional training for new investigators and students walking them through pages.
- Training has limited value historically
- Limited success with CTSI coordinator shared service
- Centralized workforce training, steady research infrastructure for PIs would be beneficial
- New coordinators and faculty don't have enough mentoring in department. They don't know who to contact
- Need personalized training
- IRB sends new PIs the researcher manual and ask them for specific questions
- Communication barriers, hesitant to call for help. Same as calling IRS for help. Change culture, make people freer to reach out
- Scaling up effort would require resources
- They don't realize the study is with them, don't know how to check the status of the study.
- People call to complain but haven't submitted it.

Dashboard suggestion

- IT Security isn't an official ancillary right now, make it not IRB gatekeeping
- Suggest that contact info for ancillaries is more open and easier to find. EH&S given as example
- IRB received a call that clearly was not IRB question, person said they called IRB because they were the only ones that who answer the phone
- myTraining also impossible to get help or assistance

Quality improvement

- Very important to IRB
- Try to engage the research community and are open to changes that don't sacrifice compliance
- Student research requires extra work for access to EPIC, etc
- Respect study studies, but they are not fun. There's little mentorship and they take more time
- Streamline exempt studies
- It's disheartening when students don't know how to reach out to their department for help
- Encourage chairs to have IRB reps come to departmental meetings to explain IRB process. 5-10 minutes, this type of outreach helps more
- Departments used to review IRBs first, but no longer. Some review at department level. Wasn't a priority for department chairs
- Scientific soundness of protocols falls to IRB unfortunately
- Need institutional buy in from top down that puts value on regulations and submissions so departments get help they need. When don't have that, it creates an us vs. them mentality, IRB wants to work collaboratively

Workgroup feedback – mixed review of IRB reviewers quality and consistency

- Emails and notes are impersonal, blunt and to the point. When people call us good result, personal contact with board is not there. IRB faculty members don't have that much time for the one-on-one.

LLM - What about submission concerns raised at meetings versus before hand

- IRB meetings get perspectives from different specialties
- In the past paper system, the reviewer would contact the PI before board meeting. myIRB prevents that. Three reviewers, but single reviewer can't send you questions individually. System requires them to be lumped together. Sees value if primary reviewer would be able to contact PI prior to meeting, enhancing communication.
- Agenda goes out 5 days before meetings, PIs have to be willing to respond in a timely manner
- Emails through myIRB, links to submission and stays in history. Very useful
- A lot of universities have multiple, specialize boards per subject matter. That might streamline things.

Concerns raised regarding the diversity of the IRB board

- Ethnicity, gender, stage of faculty development. Need to represent a broader scope of UF
- Could go to community events/town halls to find members that are invested. Community members do not represent larger community of Gainesville. More representative of the study populations being investigated, but IRB doesn't have much of a role in that.
- IRB doesn't recruit, chairs appoint board members.
- In favor of term limits, 5-7 years, bring in new faces on the board

Criticism that whole Human Research Enterprise is risk aversive, validity to that concern?

- Conservative is a better word
- Difficult question, some ways UF is very liberal and some ways conservative
- Vetting process for sponsors, subject compensation for injury. Perceived as IRB rule, but it is not.

Convey requests for Dr. Norton to make system work better

- Respect and collaboration
- Huge investment into research community, administrative staff and study teams. Pay accordingly and expand
- Retain really qualified coordinators
- Increased pay for IRB staff. Recently have lost three staff members to remote work location and salaries.
- All IRB staff have been working on campus 5 days/week, work from home not applied equally at UF
- Institution buy-in for protocol development. Develop protocols before IRB sees them. SRMC protocols better than most.
- SRMC type system for all, will let IRB focus on regulatory issues
- We appreciate having a voice in the discussion and we're very invested in quality improvement

Summary of IRB focus group (HSRPIWG): 7/22/22 at 12pm

Lyle Moldawer, Facilitator

Impression of the current system

It is a working system with room for improvements.

We have a premier IRB who is nationally recognized as being one of the best, but has done so with very limited resources.

Issues

Institutionally the IRB hasn't been supported with staffing and IT needs. Office staff should not be entry level. It creates too much turnover.

Better infrastructure to help the investigators navigate the process is needed. Not additional coursework but support to navigate through the process. Office of Professional Support – before it is sent to IRB investigators would have a resource.

Sometimes staff recommendations are not consistent with how a certain line of research is done. It can be very confusing for new staff. We want faculty to be successful not frustrated.

Issues are not addressed prior to the board meeting but the protocols are not received by the board members until Thurs or Friday before the meeting on Wednesday. Investigators are sent to the meeting but the coordinator is sent in place, often unable to answer questions. Hybrid meetings, multiple way of interfacing with the PIs regardless of where they might be.

Suggestions

Need both departmental and institutional support. At the very least, the dept Chair or Chief should take responsibilities of the submissions that are made.

Re-write jobs, re-evaluate salary for IRB staff. Provide staff support with availability at various hours.

Since the IRB works and is at a central level, It seems like a central resource could work, with departments having a sign off.

John Hopkins has a model that we may be able to follow.

Membership to the IRB

The IRB is diverse and complex. Consistency is important with the IRB. Rotating people in and out will increase inconsistency. There shouldn't be term limits.

IRB members who are contentious do not stay on the board. The team is pretty easy to work with, understanding and following the regulations. Board does a good job at pointing out if someone isn't doing things correctly.

Question asked: Do you think your contributions on the IRB board are recognized? Some effort but more than anything it's a personal reward. A great way to learn about what is going on, very educational and interesting.

OCR Town Hall Focus Group 7/7/22
RE: Human Subject Enterprise
Break out group #1

Moderator: Dr. Roger Fillingim
Scribe: Dr. Kim Wollard
~ 10 participants

1. Resources

Workload is far greater than the workforce. In 2019, a contracting officer 1 would manage anywhere between 20-25 projects. Generally speaking a team lead does not have projects to manage, but today currently due to workforce issues, team leads are managing around 75 projects.

Due to staffing issues and workload, team members are forced to make subjective decisions on how to prioritize work rather than taking an objective approach of first come, first serve.

No resources to recruit, retain or recognize competent staff. Our initial goal was to reduce burden for the study teams, but due to resources, this may be true in some areas but not accomplished in all.

Resources are a huge issue given the scope of what they are required to do. The initial mission of OCR was billing compliance, but is now much broader. There is not enough staff or resources to manage the workload.

OCR is a core office with no annual budget. F&A generated from 214 does not flow back to the office. It would benefit us to have our own budget like other core missions.

2. Inability to implement Policy and lack of authority.

OCR does not have authority to implement institutional policy.

We have compliance guidelines that we are supposed to follow in this office but nothing is in writing to back us up.

UF needs clearer policies in place for clinical research and billing compliance.

3. Training

Turnover with study staff impacts OCR review because processes must be explained. OCR staff spend time training on items that are not in their scope of work. This leads to timeline delays for everyone.

The current workforce issues do not allow time for beneficial training tools such as newsletters, in-person training sessions or website updates.

Opportunity to meet expectations given the volume. One side doesn't understand what the other side is doing. Cross training between study teams and OCR could help. Education is needed across the board. Need realistic expectations.

Better communication is needed between the study teams and OCR. Goal would be for study teams to come to OCR and go through the process. Study teams are our customers, but training across the board needs improvement.

Coordinator and central office training is needed with some sort of annual exam to keep status. Checks and balances to ensure staff is proficient in their roles.

4. Leadership/Authority

Knowing about the working group has created anxiety because the staff know there are problems and don't know what will happen next. The office doesn't feel like there is a leader and it is quite "unnerving."

The staff feel like there is not adequate support from UF leadership. They are working hard every day but don't feel like there is anyone there supporting their mission in upper level leadership.

5. General issues

UF does not have one unified system. Information is listed multiple times in various systems. A more efficient system is needed.

Studies are submitted without feasibility determination. Only about 10% of active studies meet their enrollment target.

SOPs – there are no written SOPs, not just for OCR but for the study teams, as well. Each team doesn't have all of the resources they need but together they can make it work.

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OCR Town Hall Focus Group 7/7/22
RE: Human Subject Enterprise
Break out group #2

Moderator: Dr. Lyle Moldawer
Scribe: Angela Avery
11 participants

<u>One Word Impressions</u>

Stagnant
Tedious
Inconsistent
Complicated
Overwhelmed
Chaos

<u>Pressure points and challenges</u>

- Unspoken theme or narrative of OCR…trying to be all things to all people. We do not have the bandwidth to accommodate that for everyone. It's been a challenge, the pressure to be all things to all departments and teams.
    - OCR relatively new in the scope of research at UF. Taking all the different departments that have a long history of doing research and trying to bring them into one singular workflow has been a controversial process from department to department. It's been a challenge to find one way to accommodate all research processes of all departments in what OCR does.
        - Example: Incomplete information received from study teams, which creates us to take on the administrative burden for them. Requires us to get things outside our scope, e.g.: pricing
- We will grin and bear it. We have a "do not say no" culture. Don't want to negatively impact their perception of us. We say "yes" a lot. Don't have the manpower to do it all. Others on team may have to step in and take workflow from others because things weren't submitted correctly the first time around. We don't have capacity to be everything for everyone.
- LLM - How would we fix it?
    - Lack of training for study team side. COVID main source of what happened. Everyone was working from home for so long, turnover has been particularly challenging. The new staff don't understand how OCR works as a whole, the intake process, where it goes from there, how long it takes, and things get stuck for issues going back to the study side. A lot of part-time researchers, for P&T, etc. Used to meet with study teams frequently. Lacking now on both sides.
- Communication is not like it used to be, as far as study teams being willing to hear out, when they do contact us they are pretty annoyed already. They don't understand the process, perceive it as a problem when the contact us.

- Without communication what each side is doing and without adequate training people tend to go back to the old ways. If they don't understand how things should process there's a stubbornness and reluctance to change. This OCR employee is relatively new, so she's sending emails to study teams that they may not have received in the past. Study teams get annoyed, saying they know how to do their jobs. She would like to get email back with requested information and not the complaints associated with the request.
- OCR will have to shift in their process moving forward - genreate some parameters in the OCR work process. What will we accept from the study teams. Not all the study teams will like the new process to make things efficient.
- It will take support from external leadership for OCR to make sure we have the resources and people in place to facilitate the new parameters. Have been told by upperleadership that they can't return incomplete intake forms for example. They want use to go on a chase to figure out everything that should have been provided (protocols, etc).

LLM - Is there any effort to prioritize work based upon the different types of applications? Is it 1st come 1st served?

- There is an effort the prioritize certain things, but in general 1st come 1st served
- Not an official policy, but they do prioritize cancer studies, expanded access things that are critical

LLM – How to best use time, most bang for the buck? Spending a lot of time and effort on applications that unlikely to be done and unlikely to bring any reward to the University?

- Resources is one of the main things, everybody is spread thin.
- The quality of submissions received from the study team
- Emergencies and things that can be deprioritzed
- CDAs, DUAs are no financial and no returns to university, but we prioritize those because that's how we get the studies in.
- Prioritze hard deadlines from sponsors
- Emergencies are created by study teams sitting on it too long and then drop in OCR's lap. It's not possible to process a whole study in a week.
- Submissions that are not close to being ready to review, budget hasn't been started, contact not started, etc. and then study teams get mad at OCR
- Some processes are serial and some run in parallel
- We can negotiate contract while budget being negotiated to cut down on deadlines
- OCR tasked with taking analog information transferring to digitial, entering into systems, creating calendar. If gaps from study team, OCR is tasked with keeping track of that.

LLM – any open positions? Working at full staff?

- Most positions are filled, but OCR definitely needs more people
- OCR has ½ the amount of people as DSP for contracting team, but tasked with as much work
- Each person is doing the work of 1.5 – 2 people
- Every year we get communication regarding increasing research dollars at UF, but no acknowledgement of how we got there. Messaging of how we're managing dollars coming into UF.

Training challenges

- Workforce development training, there's no level of standardization for research administration people
- Study Coordinator 1 vs Coordinator 2, not standardized of training to do functions of job
- New PIs not knowing they need to use EPIC, never heard of OnCore or IDS. We should offer a service that manages study for them. Getting patients into EPIC, etc. CTSI offers services, but PIs don't want to pay for it or junior faculty don't have the resources to pay CTSI
- OCR will do portofolio reviews if study teams ask for it

Thoughts on Qualtrics survey comments from faculty and staff

- Is OnCore really necessary for non-cancer studies? Yes, it is now required for EPIC and IDS
- Shands interactions with OCR, CTSI, RBO, Nursing review committees have not been as cooperative with UF Health side.
    - We/UF can't take liability for Shands, so having to hold up process waiting for Shands.
    - There's no respect, appreciation for OCR. We're looked down upon by IRB, DSP, Innovate, etc
    - Shands is a separate entity with own review process. What we do does not make money for Shands
    - OCR has a pretty good working relationship with RBO, but study teams do not have the same experience, less than optimal. OCR ends up being the go-between of RBO and study teams
    - RBO focuses on EPIC and research billing, does not have a good understanding of study coordinator burdens, working with other systems.
    - Challenges with the number of systems each person has to deal with UFirst, OnCore, etc
    - Duplicate work and multiple systems don't work together. OCR becomes the go-between for multiple systems, not our core mission or responsibility.
    - Confirmation of services, cost of services - the study teams don't provide anymore. OCR has do to it now and not their area of expertise.

OCR leadership changes, see this as an opportunity or a concern?

- Both, we don't have a director after this week.
- But we do have a very good leadership team right now, OCR will be OK
- We have a great opportunity but depends on what leadership outside OCR does, will provide us with resources we need?
- Training of research staff
- Cancer Center Office of Professional Support model? Mandated to meet accreditation.
- Suggestion to let study staff know where things are stuck in the process. Where sitting and how long? (Dashboard)