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Final Report of Human Subject Research Improvement Working Group
November 30, 2022

In February 2022, Dr. David Norton, Vice President for Research, convened a Human Subject Research Improvement Working Group ("Working Group") in response to concerns raised by faculty and senior administrators regarding the efficiency and culture of conducting human research at the University of Florida. The Working Group consisted of faculty and research stakeholders knowledgeable about conducting human research.

Working Group membership:

Dr. Lyle Moldawer, Professor, Department of Surgery, *Working Group Chair*
Dr. Azra Bihorac, Senior Associate Dean for Research Affairs, College of Medicine
Dr. Rhonda M. Cooper-Dehoff, Associate Professor, Pharmacology & Translational Research
Dr. Jennifer Fishe, Assistant Professor, Pediatric Emergency Medicine in Jacksonville
Dr. Thomas George, Professor, Department of Hematology/Oncology
Dr. Duane Mitchell, Professor, Department of Neurosurgery
Dr. Adam Woods, Associate Professor, Department of Clinical and Health Psychology
Dr. Peter Iafrate, IRB Chair, UF Research
Michael Mahoney, Director of Research Operations and Services, UF Research

The charge to the Working Group was to assess the issues and to provide a list of actionable items to improve the processes related to human research, as well as address concerns relating to efficiency and culture. The Working Group was self-governed and presented its findings, included in their entirety in the attached report to Dr. Norton. The Working Group reported eight areas of concern along with a plan to address the issues.

Several of the recommendations involve areas that are not within the direct authority of UF Research. In these cases, UF Research will engage the responsible stakeholders to ensure they are aware of the findings in the report and assist the stakeholders in meaningfully addressing the concerns.

It is important to note that the Working Group did not note any concerns regarding the protection of human subjects, nor with regulatory compliance. UF is routinely subjected to external oversight by our accrediting body, the Association for the Accreditation of Human Research Protection Programs, Inc (AAHRPP), as well as federal regulators such as the Food and Drug Administration (FDA). UF is committed to the protection of human subjects and complying with all applicable federal, state, and local requirements.

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Working Group Finding	UF Research Response
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.	1. UF Research cannot alter the reporting lines for many of the units associated with activating research involving human subjects. 2. However, UF Research will realign resources to create a Human Research Program Office (HRPO). The HRPO will: a. Provide a single point of contact for researchers engaging in human research, helping researchers to quickly identify and engage units needed to initiate and conduct research. b. Create a Human Research Program website which will include: i. A comprehensive and concise listing of all units related to human research, with phone numbers and emails for assistance. ii. Workflows showing how the process works, and how/when units contribute to the process. iii. An interactive tool that asks researchers concise questions (yes/no or multiple select answers) and identifies what units the researcher needs to work with, what training is needed, links to resources, and connects researchers with the units. iv. Training materials/opportunities will be clearly visible, with new on demand training materials (concise videos, step-by-step guides, etc.) continuously developed and published by the HRPO.

	v. FAQs will be hosed and routinely updated/adapted based on feedback from the research community and other stakeholders. c. Will coordinate with other units engaged in human research (e.g., Scientific Review and Monitoring Committee, Institutional Biosafety Committee, Research Conflict of Interest, Research Billing, etc.) to: i. Assess common needs, ii. Build centralized metrics with publicly facing reports such that: 1. The research community is informed on the time to initiate new research and perform other responsibilities 2. identify and address areas in need of improvements iii. Collaborate on communication and training initiatives d. Solicit and assess community feedback 3. Per the Working Group's request, UF Research will engage an external consultant with experience assessing large programs to assist with assessing and improving UF's Human Research 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. a. The software will identify which regulatory and activation entities need to review the protocol. b. 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. c. The clinical research enterprise should develop a real-time	1. UF Research endorses providing a single point of entry software system for activating, conducting, and tracking research. Many, but not all, of UF's research units (e.g., DSP, OCR, IRB, IBC, etc.) already utilize separate systems (UFIRST, Oncore, myIRB, Gatortracs, etc.). There are a variety of approaches that can facilitate integration of these systems. UF Research will convene a group to (a) work with research stakeholders to identify their needs, common data elements, and how systems can be integrated to improve efficiencies, and (b) benchmark how peer

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. • 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.). • 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.	institutions address this issue, assess potential options, and propose possible solutions. a. In the interim, as mentioned above, the HRPO will provide tools by July 1, 2023 to better assist researchers in navigating UF's research landscape. This will include a tool that identifies which units need to be engaged to activate research. b. The above tool can also be used to inform applicable units of the research. Those units will be encouraged to engage research teams to better facilitate their process. c. UF Research is already warehousing research data from numerous systems and is evaluating how to deploy dashboards and reports for the research community and others. 2. UF Research and the HRPO will work with research entities to routinely collect and publish operational metrics. Existing metrics will be published on the new Human Research Program website by March 2023. Additional metrics will be identified with projected times for publication. Research community feedback will be solicited for desired metrics. 3. In FY 23, UF Research has added 2.0 FTE to its metrics reporting team and will continue to provide infrastructure and support as needed.
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.	1. UF Research and the Human Research Program Office will work with units and applicable leadership (including the Senior Vice President of the Health Science Center, Research Deans, unit supervisors, and others) to establish and publish defined goals for activating research with objectives including but not limited to: making the activation process easier, faster, less resource intensive, and more researcher friendly. These goals and metrics will be available on the Human Research Program website.

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. • 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. • 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.	1. UF Research will continue to engage UF Health Shands leadership to address the institutional infrastructure that supports human subjects research, ensuring they are aware of the issues identified by the Working Group. The Human Research Program Office will assist by a. serving as the conduit between UF and UF Health Shands, b. providing guidance and assistance to UF Health Shands on issues such as their FWA, ceding review to sIRBs, and other areas as requested/appropriate. c. benchmarking how peer institutions with comparable university-hospital relationships operate d. soliciting feedback from the research community e. communicating status/progress to the research community via the Human Research Program website.
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.	1. UF Research will convene a working group including the CTSI along with veteran and early career research faculty to benchmark and establish an effective mentorship and education program to address more effective and efficient activation of research, navigating the UF research landscape, and conducting compliant research. 2. The Human Research Program Office (HRPO) will develop and publish on demand training resources including instructional videos, workflows, and tip sheets, as well as Brown Bag seminars, Boot Camps, attend departmental faculty meetings, and other instructional/communication events as requested by researchers. 3. The HRPO will solicit feedback on the effectiveness of the materials as well as requests for additional topics/resources. 4. The HRPO will publish and communicate updates and additional information.
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	1. UF Research will convey the request of the Working Group to collegiate leadership and offer our support in helping facilitate in this space.

respective tracks. Potential suggestions include: • Clarifying how much and what type of research should clinical-track faculty be required to conduct as part of their academic mission. • 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. • 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.	1. UF Research will work with the Research Deans to identify what types of research should be prioritized. For example, should priority be given to: a. Locally authored, externally funded research b. Pilot studies whose data will be used to pursue future funding c. Studies identified by Research Deans as significant to the field of study d. Other criteria established with faculty input 2. UF Research will work with research stakeholders to identify how their processes might give priority to research based on these criteria. 3. UF Research will communicate efforts and outcomes in this space to the research community.
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	1. The Vice President for Research will convene a new working group consisting of faculty, CTSI, and IT stakeholders who have expertise in this area to: a. Promote the use of existing tools such as the IDR, Consent2Share, Open Access Database, and the upcoming OMOP database.

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.	b. Assess existing needs and proactively project upcoming needs in order to recommend prioritization of existing resources and/or request & justify additional resources to address to those needs.

The Working Group also provided the following Research Entity-Specific Recommendations, along with my proposed responses:

Finding	Response
Institutional Review Board (IRB-01)	
♦ Prioritize review process	
➢ Several individuals suggested that funded (IDC-generating) research should be expedited through the system.	• As identified above in Enterprise Level recommendation #7, UF Research will partner with the Research Deans to identify what types of research should be prioritized. This could include IDC generating research.
➢ 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.	• Once a priority system is established, UF Research will coordinate with research stakeholders to facilitate prioritization across the research enterprise. HRPO staff can be tasked to facilitate and track prioritized studies, as well as to monitor timeliness and future opportunities for improvement.
♦ Streamline the IRB process for exempt\non-human and chart review studies.	• In October 2022, UF Research deployed three new web-based tools though which researchers can automatically determine if their research meets nonhuman, quality improvement, and select exempt categories. As of 11/29/22, 143 studies have received exempt approval, 62 studies have received nonhuman approval, and 7 have received quality improvement approval. UF Research representatives identified the top 10 departments that submit the most studies in these categories and have been meeting with their researchers to promote the use of the tools. The effectiveness of the tools continue to be evaluated and improvements based on feedback have already been made. There are plans to expand what types of research can be approved via this method, including chart reviews. UF Health is also deploying a new database called OMOP whose use should not require any review and approval, meeting the needs of many

	researchers who would have traditionally done 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?	• Educate research community regarding the current process of Board member selection, the volume of IRB work conducted at the full board (8%) and the time it takes for new members to be productive. What the mix is of new and seasoned members, and what research is conducted by Board members. Also that they are evaluated yearly. • Establish job requirements and qualifications for Board members • Both IRB Chairs felt that the benefits of retaining board members for multiple terms—for their established expertise in both regulatory and disciplinary aspects of effective board membership, as well as their providing models and mentoring for less experienced members—far outweighs any benefit that might be gained from an explicit limit to the number of terms any given member could serve. There are already mechanisms in place that could be, and have been, used to remove problematic members from further participation on the Boards. Both Chairs could also point to examples of long-serving Board members whose removal would have been to the detriment of Board functioning. • Evaluate how the new process for nominating and appointing IACUC members works in CY 2023. If successful, consider deploying this process for the IRBs in CY 2024.
♦ 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	♦ As it relates to new protocol submissions that require review by the full Committee, the IRB will implement a process that will evaluate a protocol's likelihood of being tabled on its initial review. If sufficient issues are identified, the HRPO will convene a pre-meeting with the Principal Investigator, research team, HRPO pre-review staff, veteran IRB Reviewers, and where possible, other applicable research stakeholders (e.g., OCR). The purpose of the meeting will be to resolve any major issues prior to review by the full Committee.

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.	• UF Research will document and recognize the effort of serving on the IRB, including participating in pre-meeting reviews to expedite approvals of full Board studies. UF Research will ensure department chairs and Research Deans are aware of the commitment prior to appointment to the committee as well as in an annual recognition of service. UF Research will engage Research Deans to assist with having department chairs recognize service to the IRB.
Office of Clinical Research (OCR)	
• 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.	• There has been turnover in the leadership of OCR. UF Research and the College of Medicine are partnering to determine best path forward to significantly improve service in these areas.

IT Security	
▪ A dedicated IT Security team for research applications should be developed. Currently the lack of such a team results in unnecessary 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 (e.g., expansion of the AI Initiative).	• IT Security reports UF Information Technology under the Office of the CIO (it does not report to UF Research). IT Security has been engaged during the Working Group assessment and is aware of the community's concerns and needs. UF Research is engaging IT Security to better educate the research community on what is required and when, when Fast Pass (previously vetted solutions) might be more advantageous, as well as to reevaluate their own processes as it relates to research needs in particular. IT Security recently restructured to add more FTE to the Integrated Risk Management team that conducts risk assessments. We are also informed that the CIO is expected to announcement an enterprise-wide policy as it relates to software utilization. • UF Research is prepared to convene a working group (including both faculty and IT Security experts) to more deeply assess this area, benchmark how our peers operate in this space, and provide a more expert assessment on how to better facilitate research that requires an IT Security assessment.
Research Billing Office (RBO)	
▪ Re-evaluate process by which billing decisions for research are made. ▪ Improve interactions with OCR.	• UF Research will convey this request to the RBO and its leadership.
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	• The HRPO will engage the SRMC to assess how to streamline the processes, eliminate duplicative submissions, and increase efficiency.

scheduling, more frequent meetings).	
Conflict of Interest (COI):	
▪ Improve accessibility and increased speed of approval of the management plan.	
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).	• The Human Research Program website will provide clearer information on who to contact, when/how to initiate HURRC review, and other HURRC related issues. • HRPO staff can help triage investigators with this ancillary.
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.	▪ The first recommendation is limited to the CTSI ancillary role in the myIRB application. The HRPO will generate new guidance and educational materials to better inform researchers on this requirement, evaluate adding help text to myIRB, as well as evaluate is there continued need to require this ancillary approval as part of the IRB workflow. ▪ The social media review and use policies were updated December 2021, just prior to the Working Group. The HRPO can help communicate current requirements as well as solicit feedback from the community for opportunities for improvement. ▪ The request to decrease service charges has been conveyed to CTSI leadership.
International Research Ancillary	
▪ Providing information about required procedures and support when the country doesn't have IRBs, and the speed of the review.	• UF Research has already taken several steps to address these issues, including developing workflows, better defining when local approvals are required, and addressing timeliness of review. Additional improvements are forthcoming, including the planned

	elimination of Addendum Q from the myIRB application, enhancing the IRIH form to better solicit information and educate researchers on requirements, providing more educational materials, and allowing international studies to be approved via the new automatic determination tools.
Environmental Health & Safety (EH&S)	
▪ Provide clearer information on protocols that need the ancillary's review, and improved training.	• The HRPO will work with EH&S to see how these objectives being met and communicate results to the research community.
ClinicalTrials.gov (CT.gov)	
▪ Making the submission less time consuming, and providing more support (e.g., on wording).	• The CT.gov team is currently part of OCR, which as mentioned above is being completely reevaluated. These recommendations will be addressed and results will be communicated to the research community.
Institutional Biosafety Committee (IBC)	
▪ Simplifying the submission requirements and improved training.	• The HRPO will work with the IBC and EH&S to see how these objectives being met and communicate results to the research community.
Nursing Impact Committee	
▪ No recommendations listed.	
DSP in Jacksonville	
▪ No recommendations listed.	