UCI Office of Research
Research Administration

Quarterly Research Administration Meeting

August 25, 2021

Welcome and Housekeeping

- This is our 3nd virtual!
- We will be “spotlighting” our speakers
- All participants are on mute, but please feel free to unmute during the Q&A periods in between topics.
- You can also enter questions and feedback into the chat
  - Or, send directly to Jonathan Lew in the chat
- We will be facilitating questions at relevant times during presentations and in between topics
- We will record this meeting and post along with the materials afterwards

Agenda

- ***FY21 Funding Data***
- RA telecommuting
- Federal Update
- Subaward Monitoring
- C&G Accounting Updates
- ERA Updates

UCI Office of Research
Research Administration

FY21 Funding Data

Barbara Inderwiesche

Access to funding data

- UCI receives record $592 million in research funding for fiscal 2020-21
- $ 591,589,221 +11.7% over last year
- Demo of Reports
  - Awards by Campus Area
  - Awards by Source by Campus Area

Questions?

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Research Administration is Working Remotely

Bruce Morgan

For How Long?

Indefinitely.

Our space at 141 Innovation, Suite 250 is one of the leases that UCI will not renew, which will save ~$1.2M per year.

How do I Contact RA Staff?

The same way you have throughout the pandemic.

- Phone
- E-mail
- Zoom – one-to-one and group meetings, including office hours for human research protections staff
- Teams – messaging/chat

Will RA staff be available for in-person meetings?

Because RA staff work from home, traveling to campus isn't an efficient use of their time. We ask that our clients be flexible to accommodate and facilitate our remote participation.

What Can I Do to Help RA Staff be Successful Remote Workers?

Being flexible and using the previously noted communication modes will help us be successful.

Also, please consider the timing of your communications. Our homes are now workplaces, and effectively balancing our work and life responsibilities is vitally important to our well-being, work-life satisfaction, and remaining a highly engaged workforce.

Questions?

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- SPA Update
- ***Federal Update***
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Federal Update

Nancy Lewis

NSF Update

Proposal & Award Policies & Procedures Guide (PAPPG) Implementation Schedule

Effective October 4, 2021

https://www.nsf.gov/pubs/polcydiocs/pappg22_1/nsf22_1.pdf

- Addition of Planning Proposal as a new proposal type
- New Travel Proposal Certification requirement
- Addition of Career-Life Balance Supplements
- Increased visibility of Research.gov

NSF Update (cont.)

- PAPPG Highlights: Planning Proposal

- Chapter II.E.1
- Mechanism used to support initial conceptualization, planning and collaboration activities that aim to formulate new and sound plans for large-scale projects in emerging research areas for future submission to an NSF program
- NSF is especially interested in activities that would catalyze new collaborations that broaden the participation of individuals or organizations underrepresented in NSF award portfolios

NSF Update (cont.)

- PAPPG Highlights: Travel Proposal

- Chapter II.E.11,
- Has been supplemented with new language which specifies Authorized Organizational Representatives must certify that prior to the proposer's participation in the meeting for which NSF travel support is being requested, the proposer will assure that the meeting organizer has a written policy or code-of-conduct addressing harassment

By signing the Cover Sheet, the AOR is certifying that prior to the proposer's participation in the meeting, the proposer will assure that the meeting organizer has a written policy or code-of-conduct that addresses sexual harassment, other forms of harassment, and sexual assault, and that includes clear and accessible means of reporting violations of the policy or code-of-conduct. The policy or code-of-conduct must address the method for making a complaint as well as how any complaints received during the meeting will be resolved.

NSF Update (cont.)

- PAPPG Highlights: Travel Proposal

- Compliance is required in all cases where UCI is submitting a travel proposal to NSF regardless of whether we are the meeting organizer or not

- NSF Supported Events-Code of Conduct Policy:

https://research.uci.edu/sponsored-projects/contracts-grants-admin/post-award-admin/nsf-supported-events.html

NSF Update (cont.)

- PAPPG Update: Career-Live Balance Funding Requests and Grant Closeout
- Chapter II.E.8, Career-Life Balance (CLB) Supplemental Funding Requests, has been added as a new "Other Proposal Type"
  - Primary dependent care or other family considerations that pose unique challenges for the stem workforce
  - Research awards, post doctoral fellowships and Graduate Fellowship Research Program(GFRP) awards qualify for the supplement
- Chapter VII.D.5, Grant Closeout, incorporates new requirements specified in 2 CFR §200.344(i). If a grantee does not submit all required reports within one year of the period of performance end date, NSF must report the grantee's material failure to comply with the terms and conditions of the award with the OMB-designated integrity and performance system

NSF Update (cont.)

Research.gov Proposals: Capabilities Overview

Current Capabilities	Upcoming Capabilities	Future Capabilities
Proposal Types ✓ **Research:** Single Submissions from One Organization *(April 2018)* ✓ **Research:** Single Submission Collaborative Proposals with Subawards *(June 2019)* ✓ **Research:** Separately Submitted Collaborative Proposals from Multiple Organizations *(March 2020)* ✓ **Rapid Response Research** (RAPID) *(November 2020)* ✓ **EArly-concept Grants for Exploratory Research** (EAGER) *(November 2020)* ✓ **Research Advanced by Interdisciplinary Science and Engineering** (RAISE) *(November 2020)* ✓ **Facilitation Awards for Scientists and Engineers with Disabilities** (FASED) *(March 2021)* ✓ **Equipment** *(March 2021)* ✓ **Travel** *(March 2021)* **Proposal Features** ✓ **Withdrawal** (Single and Separately Submitted Collaborative Proposal Submissions) *(March 2021)* **Training** ✓ **Research.gov Proposal Prep Demo Site** *(October 2020)* ✓ **Initial Topic-specific How-to Guides** *(March 2021)* ✓ **Proposal Preparation Demo Video** *(March 2021)*	**Proposal Types** • **Conference** *(Targeting late summer release)* • **Ideas Lab** *(Targeting late summer release)* • **Grant Opportunities for Academic Liaison with Industry** (GOALI) *(Targeting fall release)* **Submission Types** *(Targeting late summer/early fall release)* • **Letter of Intent** • **Preliminary Proposal** • **Full Proposal related to a Preliminary Proposal** • **Renewal Proposal** • **Accomplishment-Based Renewal Proposal** **Post Award Actions** *(Targeting fall release)* • **Supplemental Funding Requests** **Training** • **Additional Topic-specific How-to Guides** *(ongoing)* • **Webinars** *(e.g., Spring 2021 NSF Grants Conference)*	**Proposal Types** • **SBIR and STTR Phases I/II** • **Center** • **Research Infrastructure** • **Fellowship** **Solicitation-specific Requirements** • **Additional specified forms or documents** (e.g., DUE Project Data Form) • **Approved deviations from the PAPPG** (e.g., Project Descriptions exceeding 15 pages)

NASA Update

Upcoming Policies

Conflict of Interest and Current Pending Support Disclosure Policy

- In response to GAO-21-130, NSPM 33, and the 2021 NDAA, NASA will be updating its COI and current and pending support disclosure policies.
- The forthcoming policy will require award recipients to disclose non-financial COC, such as participation in a foreign talent recruitment program, as well as financial COI.
- Additionally, NASA's current and pending support disclosure policy will be expanded to require the disclosure of all resources made available to certain individuals in support of their research regardless of:
  - Whether the support is foreign or domestic,
  - Whether the resource is made available through the entity applying for a research and development award or directly to the individual, or
  - Whether the resource has monetary value.
- NASA's draft policy is currently with the Office of Science and Technology Policy for review, and NASA will post the draft policy to the Federal Register for public comment this summer.

Please visit the new Grants Policy and Compliance Branch External website:
https:www.nasa.gov/offices/ocfo/gpc

NIH Update

NIH Implementation of the Revised Federal-wide Research Terms and Conditions (RTCs)

- OMB mandated awarding agencies adopt recent revisions to 2 CFR part 200 effective November 12, 2020.
- Accordingly, the Federal-wide RTCs have been revised by the participating agencies, including NIH, for harmonization of regulatory practices across Federal research agencies with the revised 2 CFR §200.
- The National Science Foundation hosts and maintains the RTC website on behalf of all the participating agencies.
- NIH implementation of these Federal-wide RTCs is also outlined in the NIH Grants Policy Statement, Section 3.1
- Please make note of the NIH Agency Specific Requirements.

Learn more: NOT-OD-21-029

NIH Update (cont.)

Expanding Requirement for eRA Commons IDs to All Senior/Key Personnel

- NIH, AHRQ, FDA, and ORD/VA will require all individuals listed on the R&R Senior/Key Person Profile (Expanded) Form to have an eRA Commons username (Commons ID) for due dates on or after **January 25, 2022**.
  - This will facilitate better data collection, assist in disambiguating data on applications, and facilitate the identification of conflicts of interest in peer review.
  - An eRA Commons ID will need to be entered for all Senior/Key Personnel (as defined in NIH GPS 1.2) listed on the R&R Senior/Key Person Profile (Expanded) Form.
    - For multi-project applications, this requirement also applies to the individual components of the application.

Learn more: NOT-OD-21-109

NIH Update (cont.)

Implementation of Changes to the Biographical Sketch and Other Support Format Page

- NIH expects applicants and recipients to use the updated Biosketch and Other Support format for applications, Just-in-Time (JIT) Reports, and Research Performance Progress Reports (RPPRs) as of **May 25, 2021**
- NIH will require the use of the updated format pages on and after **January 25, 2022**
  - Electronic signatures and supporting documentation will be required beginning **January 25, 2022**
  - Failure to follow the appropriate formats on or after January 25, 2022, may cause NIH to withdraw applications from or delay consideration of funding.

NIH Update (cont.)

Biosketch Format Updates

- Biosketch Form & Instructions:
  - Updated title of Section B to capture all scientific appointments (***all*** positions and scientific appointments, foreign and domestic)
  - Removed Section D: Research Support, which duplicates information provided in Other Support

    Note: Scholastic Performance will remain in Section D for fellowship Biosketch
- Page limit has not changed (5 pages)
- Updated SciENcv template is available!

NIH Update (cont.)

Other Support Updates – Highlights

- Updated form and instructions provide more structured format
- **Supporting documentation:** supporting documentation, which includes copies of contracts, grants or any other agreement specific to senior/key personnel foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support. If the contracts, grants or other agreements are not in English, recipients must provide translated copies.
- **Immediate notification of undisclosed Other Support:** When a recipient organization discovers that a PI or other Senior/Key personnel on an active NIH grant failed to disclose Other Support information outside of Just-in-Time or the RPPR, as applicable, the recipient must submit updated Other Support to the Grants Management Specialist named in the Notice of Award as soon as it becomes known.
- PI or other senior/key personnel will electronically sign submissions to certify accuracy of the information provided

NIH Update (cont.)

- **NOT-OD-21-170 Update: Notification of Upcoming Change in Federal-wide Unique Entity Identifier Requirements-Effective January 25, 2022**

The purpose of this notice is to update the applicant and recipient communities of the federal-wide transition from the DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number to a new government-owned Unique Entity Identifier (UEI). By April 2022, the federal government will stop using the DUNS number to uniquely identify entities registered in the System for Award Management (SAM).

UCI's UEI has been assigned and can be found on our Institutional Information webpage: https://research.uci.edu/sponsored-projects/institutional-info.html

NIH Update (cont.)

FORMS-G" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2022: NOT-OD-21-169

- Effective for due dates on or after January 25, 2022.
- Key changes:
  - Transition from the DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number to the new government-owned Unique Entity Identifier (UEI)
  - All Senior/Key personnel listed on the R&R Senior/Key Person Profile (Expanded) form will be required to have an eRA Commons username (Commons ID)
  - Require the use of the updated Biographical Sketch and Other Support format pages

See High-level Summary of Form Changes in FORMS-G Application Packages for a full list of form changes

Questions?

Contact your Contract and Grant Officer:

https://research.uci.edu/sponsored-projects/about/staff-dept-assignment.html

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Subaward Monitoring

Grace Park

Beata Najman

Subaward Monitoring UG §200.331

Pass-through entities must monitor the activities of subrecipients to ensure that the subaward is used for authorized purposes, subaward performance goals are achieved, and the subrecipient is in compliance with Federal statues, regulations, and the terms and conditions of the subaward.

Shared Monitoring Responsibilities

- The UG under 2 CFR §200.331 renews focus on monitoring outgoing subawards
- Successful subaward monitoring requires partnership at each stage of the project lifecycle
- We all have a part to play – the Principal Investigator, Department Administrators, Sponsored Projects, and C&G Accounting

Sponsored Projects

- Assess subrecipients prior to execution of subaward agreement
- Draft subaward agreement covering necessary risk and flowing down terms and conditions of the prime award
- Offer training and guidance
  - Subaward Management Webpage (https://research.uci.edu/sponsored-projects/contracts-grants-admin/subawards/sub-management.html)

Principal Investigator (PI)

- Monitor subrecipient throughout the period of performance
- Provide consistent and thorough monitoring and review of subrecipient's technical performance; escalate concerns to SPA if necessary
- Review reports and verify technical performance to invoices
- Approve each invoice for payment by signing the invoice or by indicating by email that the invoice may be paid
  - If the progress is in any way incomplete or unsatisfactory, the PI is encouraged to postpone approval of the invoice

Department Administrator

- Set up a mechanism to monitor subaward activities and invoice payments
- Track subaward spending by reviewing the following information:

  - Subaward amount
  - Grant/Contract dates and budget year
  - Whether a carry forward is automatic or must be approved in advance by the sponsor
  - Invoice payments and remaining balances
  - Cost sharing commitment by Subawardee (if applicable)

- Retain documentation for your grant record

Subaward Invoices – Department

- Review invoice against the approved budget and verify that all costs are appropriate and in alignment with cost principles
- Question costs that appear unusual or unallowable
- Confirm the correct indirect cost rate and the appropriate exclusions are used per the executed agreement
- The indirect costs should be separated from direct costs on the invoice, and the indirect cost rate should be clearly indicated
- Ensure that invoicing is occurring according to the schedule outlined in the terms and conditions of the subaward
- Sign or initial each invoice to confirm that expenses are allowable and that funding is available

Subaward Invoices – Department

- For Federal and Federal-flow through awards, confirm that specific certification language appears on the invoice:

  "By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729-3730 and 3801-3812)."

- In accordance with the Uniform Guidance found at 2 CFR §200.305 that approved subaward invoices are paid within 30 calendar days of receipt

Closeout Stage – Department

- Ensure that subrecipients submit a final invoice for project expenses within the time specified in the agreement, and such an invoice is marked “final”
- Confirm all project deliverables were provided
- Review and approve final invoice

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UCI Office of Research
Research Administration

Contracts & Grants Accounting Updates

Beata Najman

- Payroll Certification
- Award Closeouts and Status of Lien Form
- NSF Awards with Canceling Funds

Award Expiration Date	Canceling Amount	Non-Canceling Amount
08/31/2021	47,241.91	0.00

- PWC Audit
- Changes in CGA Workload Assignments
- Contracts & Grants Training – sign up in UCLC, search for “CGS”

- Direct vs. F&A (August 26, 10 a.m. – 12 p.m.)
- Payroll Certification (August 31, 11 a.m. – 12 p.m.)
- Ledger Reading and Award Closeout (September 2, 10 a.m. – 12 p.m.)

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- ***ERA Updates***

Login.gov

Jonathan Lew

Login.gov

- Beginning September 15th, 2-Factor Authentication will be required in order to log into the NIH eRA Commons
- 2-Factor Authentication (2FA): an extra layer of protection used to ensure the security of online accounts beyond just a username and password.
- eRA Commons is utilizing Login.gov for its 2FA

NIH eRA Commons will be enforcing 2-Factor Authentication in a phased approach

- **Phase I:** Effective September 15, 2021, 2FA will be required for all individuals that hold Scientific roles (PI, Graduate Student, Postdoc, Trainee, etc.)
- **Phase II:** By early 2022 (date not specified yet) individuals with Administrative roles need to have 2FA set up (Asst, SO, BO, etc.)

- ****It's recommended that you get 2FA set up now and not wait!****

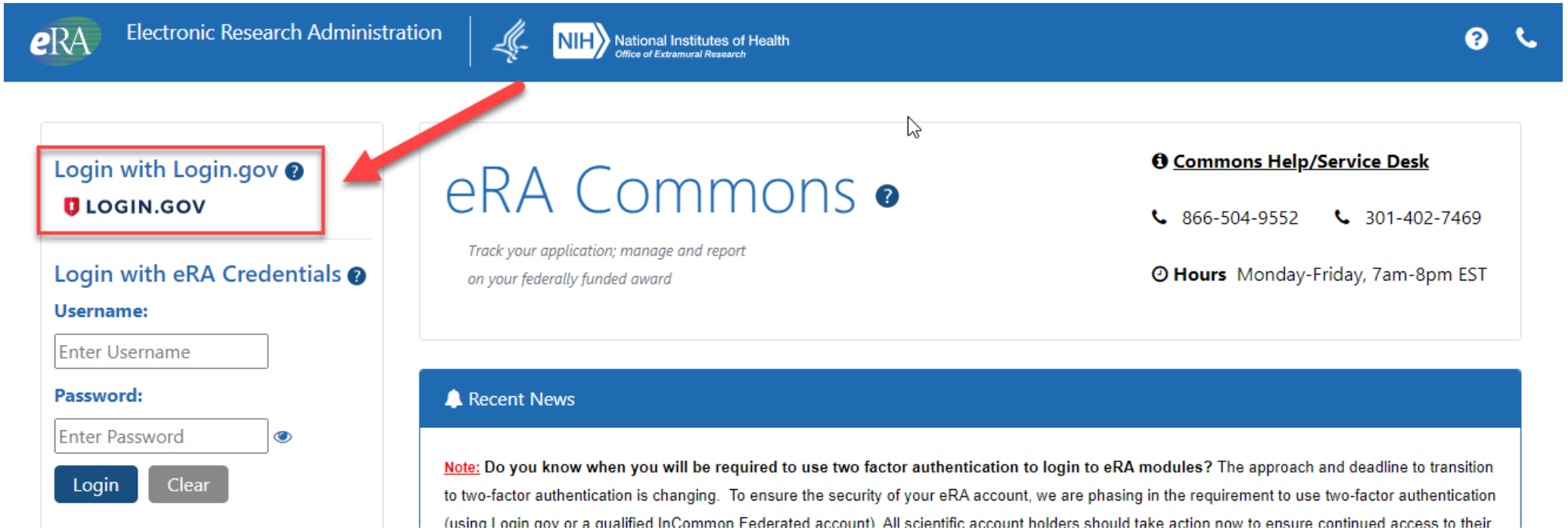
Registration & Linking

Step 1: Register for a Login.gov account

- https://login.gov/create-an-account/
- You'll need:
  - Email Address
  - Password
  - Select an Authentication Method
    - Authentication App (Google, Microsoft)
    - SMS/Text Message

Registration & Linking

Step 2: Login to eRA Commons using Login.gov to link accounts



Questions?

KR Protocols

WHAT YOU NEED TO KNOW

Go-Live Schedule

- Launch: Tuesday, ***September 7, 2021***
- IRB web applications shut-down:
  - ***5PM Friday, September 3, 2021***
- Data Migration
- Office hours (next slide)

Office Hours

- ~~Tues 08/24 – 11AM and 3PM~~
- Wed 08/25 ***(TODAY!)*** – ~~9AM~~ and 2PM
- Thurs 08/26 – 9AM and 3PM

- Tues 08/31 – 10AM and 2PM
- Wed 09/01 – 10AM and 2PM
- Thurs 09/02 – 10AM and 2PM

- Refer to listserv from HRP or CG News for Zoom info
- Adhoc as needed for groups our 1X1
- Contact ERA@research.uci.edu

IMPORTANT!
Transcription Process

- Unable to migrate data from attachments to text fields
- Transcription of protocol by ERA must occur prior to processing a transaction on existing, approved protocols.
- ERA prioritizing those protocols that are up for renewal, continuation, on an agenda
  - Contact ERA for others
  - How would you know if transcription occurred? (next slide!)

Is this your first transaction (amendment or renewal) in KR Protocols?

IMPORTANT! To verify whether Electronic Research Administration (ERA) has already transcribed the protocol, go to the Administrative Details section.

- (●) Yes, this is the study team's first time initiating an amendment or renewal in KR Protocols
- ( ) Yes, ERA has transcribed the study team's existing protocol in KR Protocols and it is now ready for the study team's first tran ction
- ( ) No, the study team has already submited a previous amendment or renewal in KR Protocols

IMPORTANT! TRANSCRIPTION INSTRUCTIONS

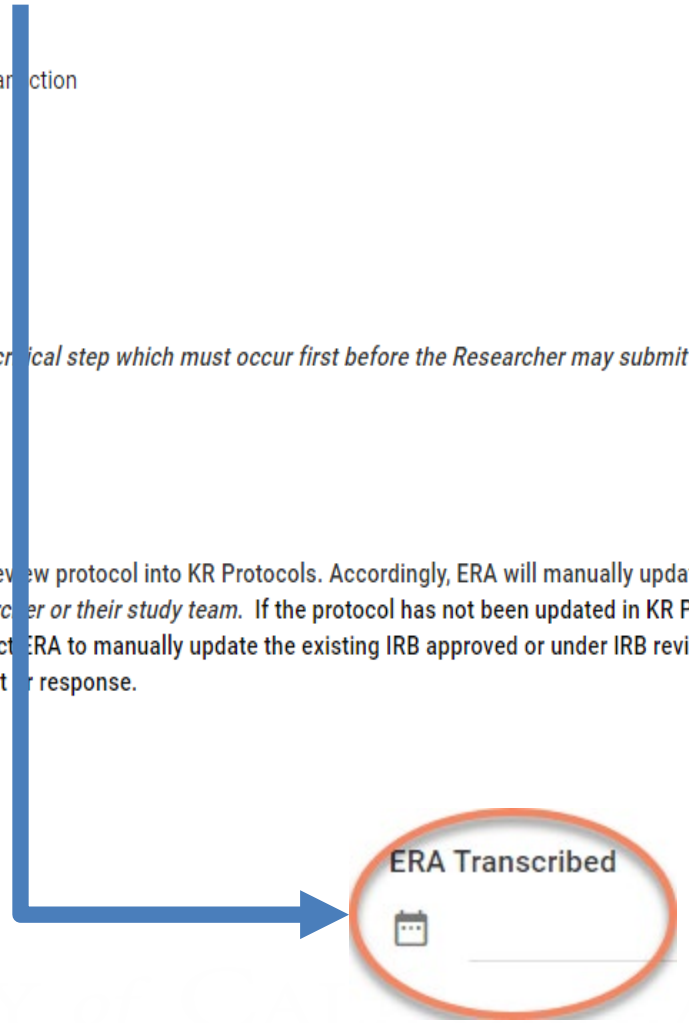
ERA SUPPORT REQUIRED

For existing protocols that were approved by the IRB or were under review by the IRB prior to September 7, 2021, there is a cr ical step which must occur first before the Researcher may submit their continuing review or amendment (protocols approved by the IRB) or response (protocols under review by the IRB).

To initiate this step, Researchers must contact ERA prior to their first transaction.

Why do Researchers need to contact ERA?

At the time of data transfer, we are unable to electronically transfer all the data points from the IRB approved or under IRB rev w protocol into KR Protocols. Accordingly, ERA will manually update KR Protocols to ensure that it is completely aligned with the last IRB approved or under review protocol submission. *ERA will do this manual update upon request by the Researc er or their study team.* If the protocol has not been updated in KR Protocols, the Researcher will encounter a series of validation errors preventing them from submitting the transaction. In accordance with ERA's Service Level Agreement, expect RA to manually update the existing IRB approved or under IRB review protocol within 2 business days of the request. Once ERA completes this task, Researchers may then begin using KR by initiating and submitting a continuing review, amendment r response.



Big Process Changes to Note

Big change #1: Lead Research Eligibility

- No longer systematically screening
  - Responsibility lies within the coordinating point to ensure eligibility
- Reference https://research.uci.edu/compliance/human-research-protections/researchers/lead-researcher-eligibility.html
- Consistent with PI Eligibility in KR Proposal Development
- Lead Researcher Certification (see next slide)

Lead Researcher Certification

As Lead Researcher, I have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to all Institutional Review Board (IRB) requirements, federal regulations, and state statutes for research involving human subjects.

I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.
2. All named individuals on this project have read and understand the procedures outlined in the protocol and their role on the study.
3. All named individuals on this project have completed the required Educational research tutorials and have been made aware of the "Common Rule" (45 CFR Part 46), applicable Food and Drug Administration (FDA) regulations (21 CFR Parts 50, 56, 312 and 812), have read the Belmont Report, and UCI's Federalwide Assurance (FWA) that are available on the Human Research Protections Program (HRP) website.
4. All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.
5. I understand that, if the study described in this IRB application is supported by a federal award or used as a basis for a proposal for funding, it is my responsibility to ensure that the description of human subjects activities in the proposal/award is identical in principle to that contained in this application. I will submit modifications and/or changes to the IRB as necessary to assure the proposal/award and application are identical in principle.

I and all co-investigators and research personnel agree to comply with all applicable requirements for the protection of human subjects in research including, but not limited to, the following:

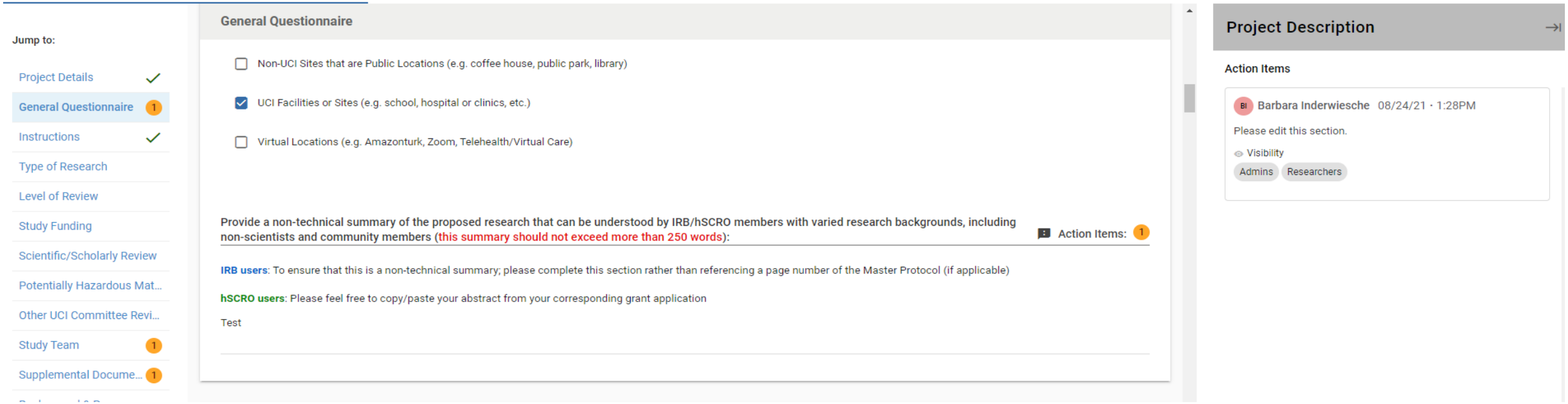
1. Obtaining the legally effective informed consent of all human subjects or their legally authorized representatives (unless waived) and using only the currently approved, stamped consent form (if applicable).
2. Per federal regulations, once a human research study has received IRB approval, any subsequent changes to the study must be reviewed and approved by the IRB prior to implementation except when necessary to avoid an immediate, apparent hazard to a subject. See Reporting of Unanticipated Problems.
3. Reporting any unanticipated problems involving risk to subjects or others, including protocol violations per UCI IRB policy. In addition, HIPAA privacy violations must be PROMPTLY disclosed to the UCI Privacy Officer. There are time requirements for reporting these breaches of confidentiality, which, if not met, may result in monetary damages to the researcher and the institution.
4. Responding appropriately to subjects' complaints or requests for information about the study; and reporting to the IRB any subject complaints that are not resolvable by the study team.
5. Promptly providing the IRB with any information requested relative to the project.
6. Assuring the appropriate administration and control of investigational test articles (i.e., investigational drugs, biologics or devices) by a qualified investigator or other appropriate individual or entity (e.g., UCI Health pharmacy), and assuring use and maintenance of an Investigational Drug/Biologic Accountability Log or Device Accountability Log.
7. Registering applicable clinical trials with clinicaltrials.gov. For more information about this topic, visit the ClinicalTrials.gov web page or the HRP webpage. The consequences of not meeting the registration and reporting requirements include monetary damages to the researcher and the institution.
8. Obtaining continuing review prior to study expiration (I understand if I fail to apply for continuing review, approval for the study will automatically expire, and all human research activities must cease until IRB approval is obtained).
9. Promptly and completely complying with an IRB decision to suspend or terminate its approval for some or all research activities.
10. Submitting to a routine review of human subject research records. The Compliance & Privacy Office at UCI Health performs ongoing routine reviews of open biomedical research protocols, in an effort to ensure in part that human subject research activities are conducted in accordance with regulations, laws and institutional policies regarding the protection of human subjects. In addition, the HRP unit of the Office of Research has developed the Education Quality and Improvement Program (EQUIP). Through EQUIP, HRP staff conduct periodic quality improvement monitoring and educational outreach.
11. For clinical trials initially approved by the IRB on or after January 21, 2019, posting one (1) IRB-approved clinical trial consent form at a publicly available federal website. The consent form must be posted after recruitment closes, and no later than 60 days after the last study visit. For additional guidance, refer to the OHRP FAQs on Informed Consent.
12. Filing a final report with UCI HRP at the conclusion of this project.

Big change #2: Department Chair Signatures

- KR Protocols does not have routing functionality
- Chair signature is not required
- ERA is adding Department Chairs in the system so they can access protocols in their departments at any time
- To make changes to department chair assignment, contact ERA

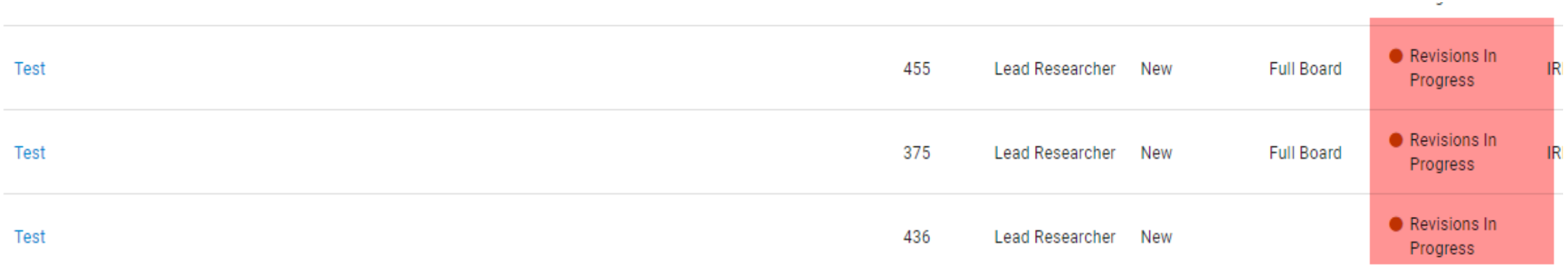
Big change #3: Correspondence and Memos

- All correspondence / communication will be in KR Protocols
  - No emails, memos, etc.
- Replaced with “ACTION ITEMS”



Big change #4: Returning for Edits

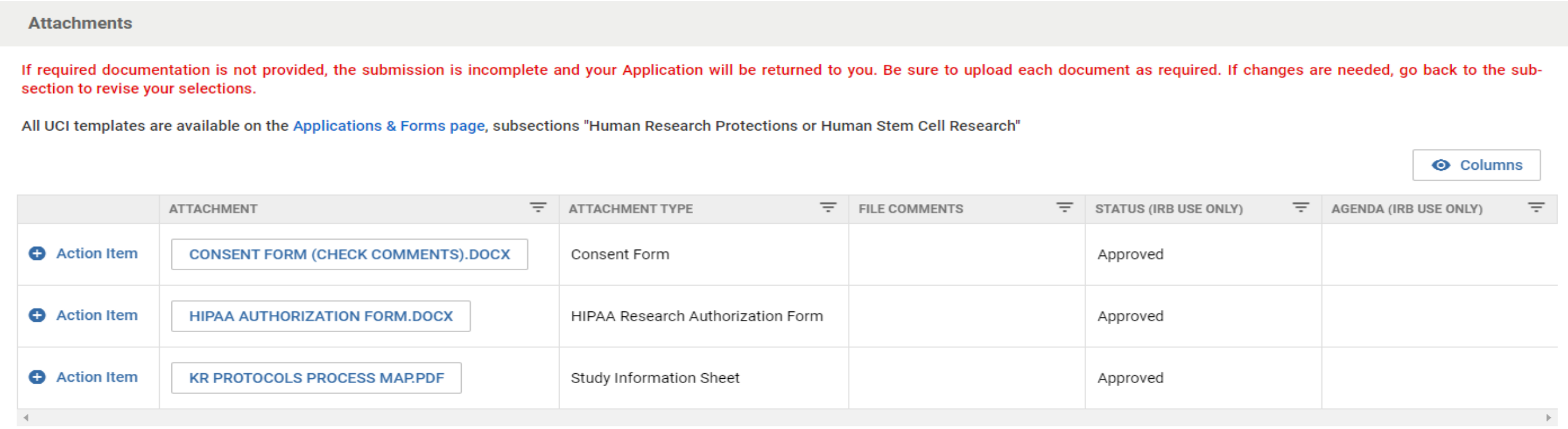
- For requested edits, the application will be returned to the researcher for revisions
- A notification will be sent
- Status: Revisions in Progress



Test	455	Lead Researcher	New	Full Board	Revisions In Progress	IR
Test	375	Lead Researcher	New	Full Board	Revisions In Progress	IR
Test	436	Lead Researcher	New		Revisions In Progress	

Big change #5: Approved Documents

- KR Protocols replaces Document Depot
- Find Approved Documents in the Protocol in the Attachments Section



Attachments

If required documentation is not provided, the submission is incomplete and your Application will be returned to you. Be sure to upload each document as required. If changes are needed, go back to the sub-section to revise your selections.

All UCI templates are available on the Applications & Forms page, subsections "Human Research Protections or Human Stem Cell Research"

Columns

	ATTACHMENT	ATTACHMENT TYPE	FILE COMMENTS	STATUS (IRB USE ONLY)	AGENDA (IRB USE ONLY)
Action Item	CONSENT FORM (CHECK COMMENTS).DOCX	Consent Form		Approved	
Action Item	HIPAA AUTHORIZATION FORM.DOCX	HIPAA Research Authorization Form		Approved	
Action Item	KR PROTOCOLS PROCESS MAP.PDF	Study Information Sheet		Approved	

Big change #6: 700U Collection

- Do not attach 700U in KR Protocols
- For Clinical Trials, submit 700U in KR Proposal Development with contract materials
- For research that is not a clinical trial, 700U collection is status quo – per request at award stage

Questions?

Wrapping up

- Join us next time!
  - Wednesday, December 8, 2021, 10AM-11:30AM
  - Virtual
- Send us your feedback, request for content, questions!
  - era@research.uci.edu