UNM HEALTH SCIENCES | UNM HEALTH

Policy Update

August 16, 2024
Jason Galloway

Policy Changes effective July 1, 2024

- **UAP 3210: Recruitment and Hiring**
- **UAP 3260: Career Development**
- **UAP 3745: Service Awards**
- **UAP 4000: Allowable and Unallowable Expenditures**
- **UAP 4040: Employee Recruitment Expense Reimbursements**
- **UAP 6110: Safety & Risk Services**
- **UAP 2745: Cleary Act Compliance**
- **UAP 2550: information Security**
- **UAP 3220: Ombuds Services for Staff**
- **UAP 2140: Use and Possession of Alcohol on University Property**

Policy Changes - 4000

UAP 4000 ("Allowable and Unallowable Expenditures")

- Clarifies the various types of funds.

- Broadens Section 5 from "Food and Refreshments" to "Expenses for In-Person Employee Events and Meetings".

- Clarifies that expenses for business meetings are only allowable for in-person events.

- Adds "service" and "retirement" as allowable expenses for business meetings, and expands and clarifies examples for allowable hospitality events to include retirement events for employees that include external professional collaborators.

- Clarifies Section 6. Personal Benefits, Events and Gifts, and adds the allowance of purchase of recognition gifts for service awards and retirement.

- Adds a new section on Promotional Items, allowing for purchase of items that identify employees or market the University.

- Clarifies section on expenditures related to decorations.

- Aligns the section on exceptions with other policies where the University Controller is process owner.

Policy Changes - 4000

6. Personal Benefit

It is prohibited to use University Funds for any type of personal benefit, other than for salary and benefits to which employees are entitled under University policy. Common examples of personal expenses that cannot be reimbursed with University Funds are listed below:

•Events and Gifts. Expenses for events (such as holiday parties, farewell) and for personal gifts (such as flowers and other gifts expressing sympathy, bereavement, and non-business affiliated celebrations, or to faculty, staff, students, or their families) *are prohibited uses* of University Funds, unless authorized by other University published policies (such as the recognition programs discussed in UAP 3235 ("Staff Recognition Programs") and the employee service awards discussed in UAP 3745 ("Service Awards and Recognition"). ***University Funds may be used to purchase recognition gifts (not including cash) for service awards and retirement, provided that the items are not lavish or extravagant and are of de minimis value.*** The New Mexico Gift Act prohibits UNM from soliciting gifts from external entities to cover the cost of retirement gifts. Refer to Unrestricted Accounting website (https://ua.unm.edu/)

IRS Fringe Benefit Guide

IRS Definition of De Minimis Awards and Prizes

A prize or award that is not cash or cash equivalent, of nominal value and provided infrequently is excludable from an employee's wages. Prizes or awards that are given frequently to an employee do not qualify as an excludable de minimis award, even if each award is small in value. IRC Section 132(e)

"Nominal" for this purpose means small in value, relative to the value of total compensation. There is no set dollar amount in the law for nominal prizes or awards. (The IRS gave advice at least once, in 2001, that a benefit of $100 did not qualify as de minimis.)

https://www.irs.gov/pub/irs-pdf/p5137.pdf

Policy Changes - 4040

UAP 4040 (Employee Recruitment Expenses")

- Modifies the title to "Employee Recruitment Expenses", and the policy owner to University Controller.

- Clarifies the responsibility of the hiring official in relation to employee recruitment expenses.

- Adds language explaining that internal candidates should refer to UAP 4000 ("Allowable and Unallowable Expenditures") and "UAP 4030 ("Travel").

- Outlines the point in which an external candidate becomes a prospective employee, and no longer eligible for University-paid candidate expenditures.

- Aligns the section on exceptions with other policies where the University Controller is process owner.
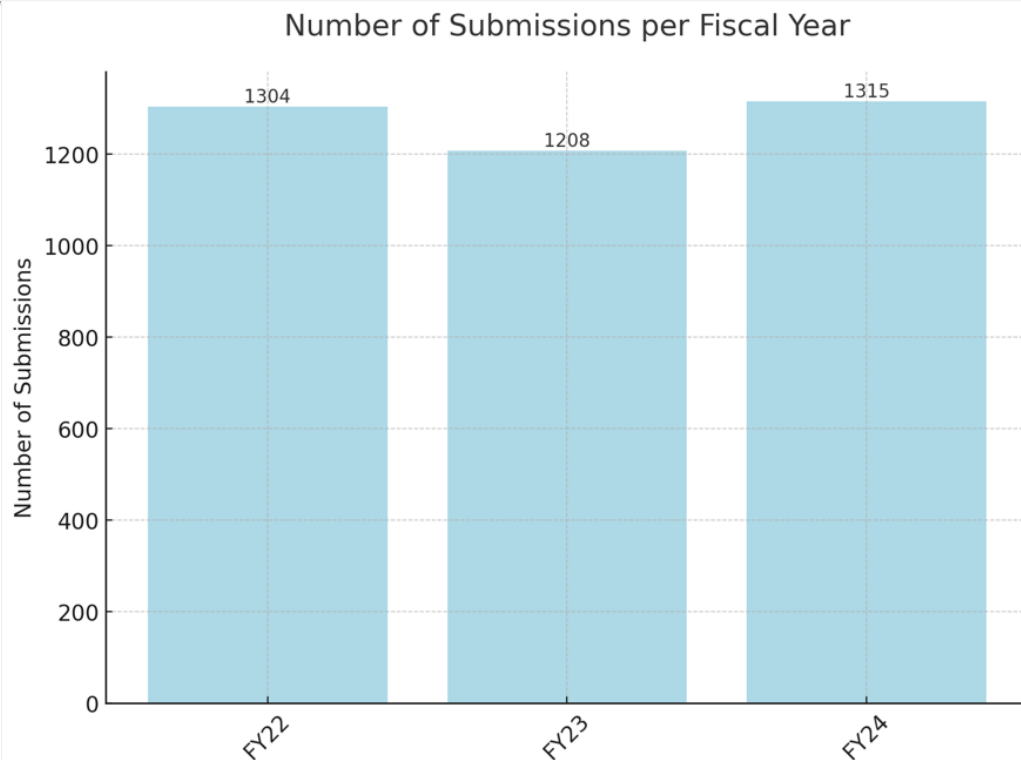
Questions

Research Administration Forum & Training Session
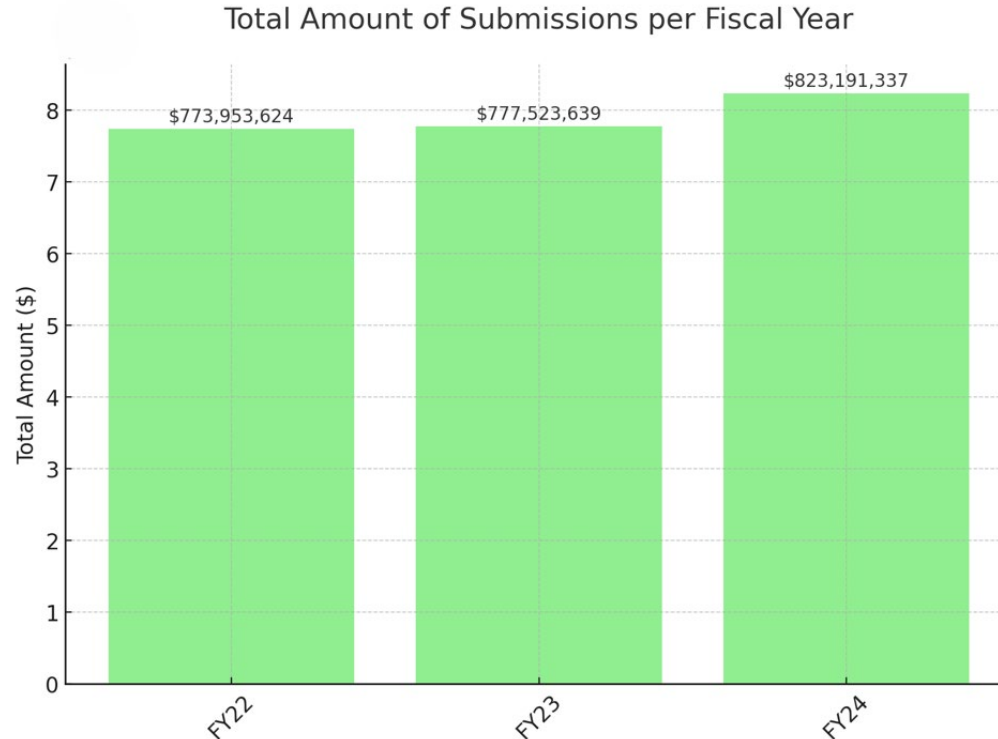
Sponsored Projects Office
August 16, 2024

Agenda

- FY24 Submissions & Awards

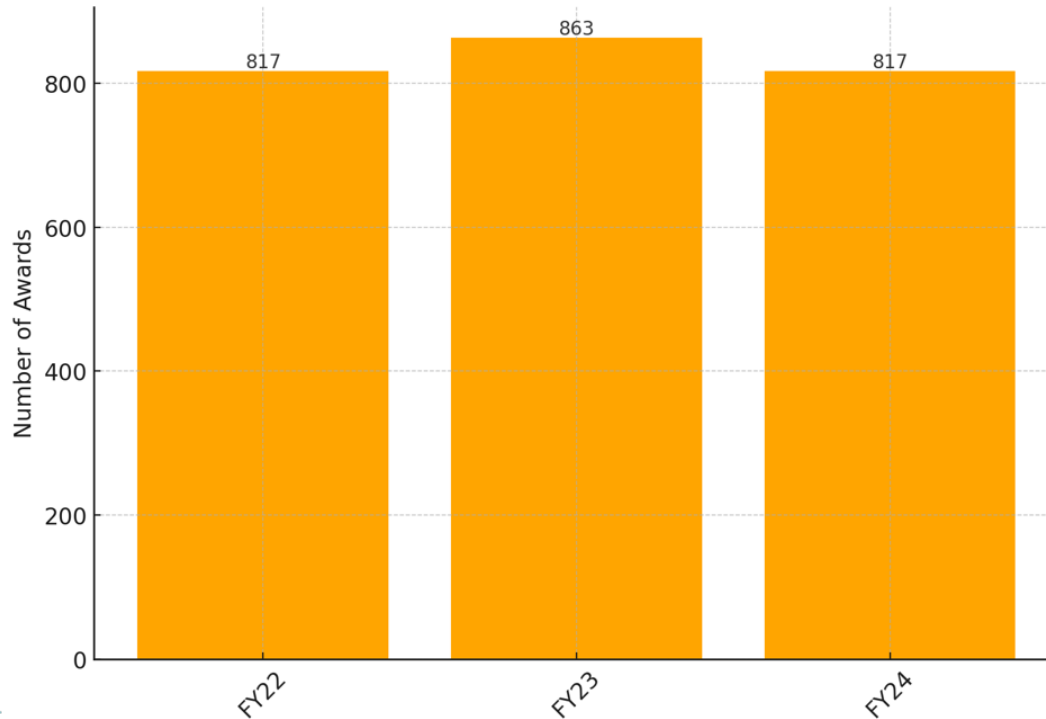- SPO General Updates

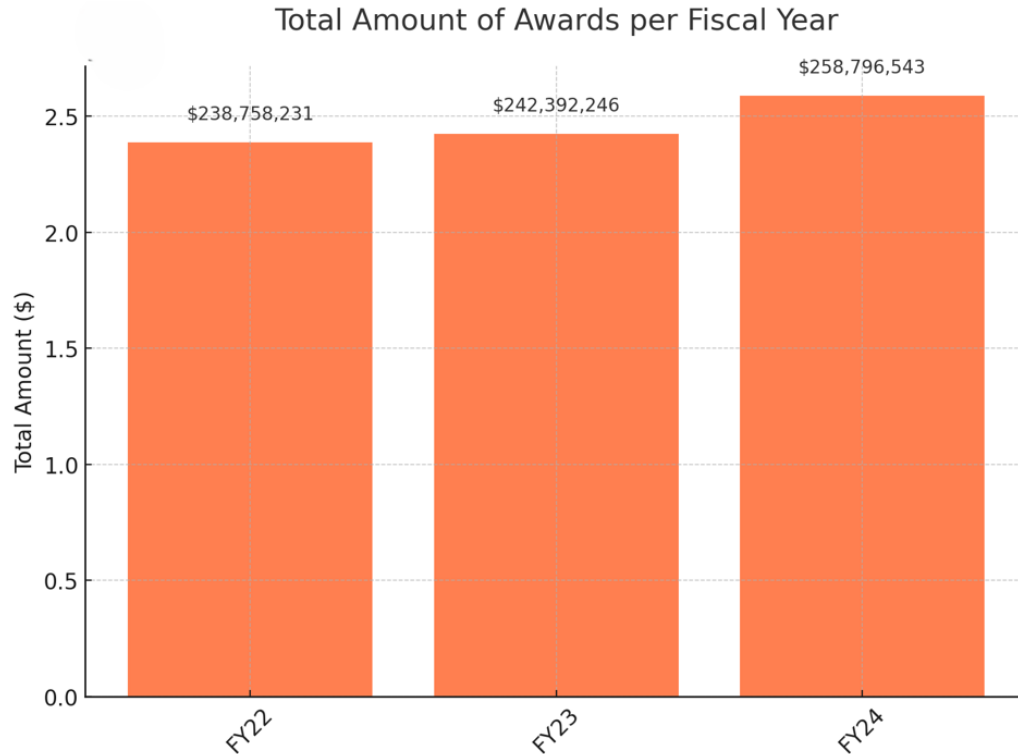# FY24 Submission #s

Number of Submissions per Fiscal Year

FY24 Submission #s Continued

Total Amount of Submissions per Fiscal Year

FY24 Award #s

Number of Awards per Fiscal Year

FY24 Award #s Continued

Total Amount of Awards per Fiscal Year

SPO Updates

- Recent vacancy in the Unfunded Agreement area possibly filled soon

- New SPO Grade 13 position opening soon

- Research Administration Dashboard coming soon (11-30-24). Please be sure to provide your input.

SPO Updates Continued

- SPO helpful documentation/aids provided in our weekly newsletter

- SPO included in QuikStart (New Faculty Orientation) starting in September

- Website Updates – F&A Decision Trees, F&A FAQ, PI Eligibility & Pre-proposal Stage

Questions

Contract & Grant Accounting Update

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August 16, 2024

Audit Update

- Audit Requests or Desk Review from Sponsoring Agencies

  - Please make sure to contact HSC Contract and Grant Accounting

    - Forward email to Kate Charleston or Jason Galloway kcharleston@salud.unm.edu or jgalloway@salud.unm.edu

Regent Policy - Audit

- In addition to the annual audits conducted by external auditors, other parties, such as federal and state agencies, may conduct financial audits and compliance or regulatory reviews of the University's projects and programs. In the event that a University department becomes aware of such an audit or review, the department must notify the Director of Internal Audit and provide the Director with a copy of the final report issued to the University for the audit. The Director of Internal Audit will notify the Audit and Compliance Committee of any significant risks or deficiencies noted in the report.

- https://policy.unm.edu/regents-policies/section-7/7-3.html

Labor Redistribution Updates

- Labor Redistribution will be returned to the originator for the following reasons

  - Transaction Date of the LR is after fund termination date
  - If the pay period is after the Budget period end date
  - If the fund is closed

  - If you have questions, please contact your fiscal monitor for assistance.

Labor Redistributions Returned

- Transaction Date of the LR is after fund termination date
  - Email Example:
  - Please work with your Contracts and Grants Office to determine next steps.

    Employee ID: 999999999
    Employee Name: Lobo, Lucy
    Pay Period: 2023 5R5 SEQUENCE: 2

    Fund: 35678
    Budget Period End Date: 03/31/2024
    Fund Term Date: 04/30/2024
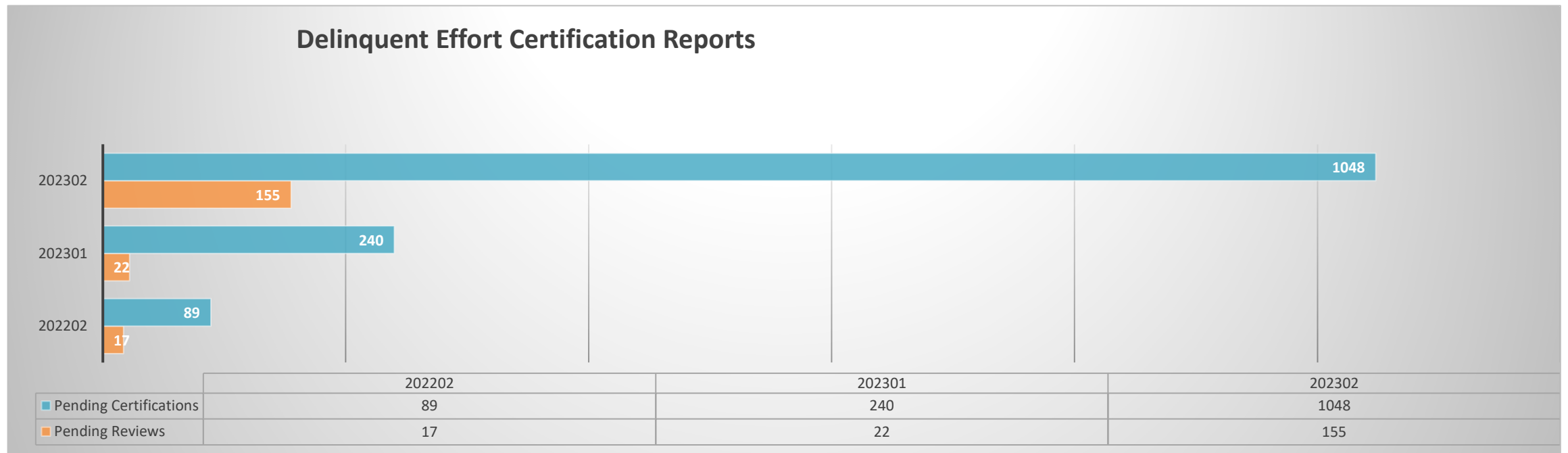   Fund Status: A
    Trans Date: 06/24/2024
    Issue: **Fund Terminated**

Labor Redistributions Returned

- If the pay period is after the Budget period end date
  - Email Example:
    - Please work with your Contracts and Grants Office to determine next steps.

      Employee ID: : 999999999
      Employee Name: Lobo, Louis
      Pay Period: 2024 5R5 SEQUENCE: 2

      Fund: 34321
      Budget Period End Date: 12/30/2023
      Fund Term Date: 02/28/2025
      Fund Status: A
      Trans Date: 06/21/2024
      Issue: **Pay Period falls after Budget Period**

Labor Redistributions Returned

- If the fund is closed
  - Email Example:
    - Please work with your Contracts and Grants Office to determine next steps.

      Employee ID: 999999999
      Employee Name: Lobo, Louis
      Pay Period: 2023 5R3 SEQUENCE: 8

      Fund: 31234
      Budget Period End Date: 07/31/2023
      Fund Term Date: 10/26/2023
      Fund Status: I
      Trans Date: 06/24/2024
      Issue: **Fund Inactive**

- If you have questions, please contact your fiscal monitor for assistance.

Effort Certification Delinquencies

- Number of Open and Uncompleted for past periods

Delinquent Effort Certification Reports

	202202	202301	202302
■ Pending Certifications	89	240	1048
■ Pending Reviews	17	22	155

Process for Delinquent Certifiers

- System generated delinquent emails we start on Mondays and Wednesdays immediately after the certification deadline has passed. (PI and Chairs)

- Certifications that are 30 days delinquent Department Administrators (DA) and PIs will be contacted manually by HSC C&G Office.

- Certifications that are 60 days delinquent, with no response from department on previous email - DA, PI, Chair and Dean will be contacted manually by HSC C&G Office.

- Certifications that are 90 days delinquent, with no response from department on previous email - HSC C&G Office will notify the Compliance Office with the PI's failure to certify.

Finance & Admin Shared Services Resources Dashboard

We have also created a collection of additional resources. This dashboard is a resource center for new department employees, focusing on University of New Mexico Health and Health Sciences Finance and Administration services.

Onboarding Resources Dashboard

https://hsc.unm.edu/about/finance/administration/additional-services.html

Finance & Admin Shared Services Resources Dashboard

Onboarding Resources

Purpose

This dashboard is a resource center for new department employees, focusing on University of New Mexico Health and Health Sciences Finance and Administration services.

Please feel free to share this resource with others within UNM.

Smartsheet
- Smartsheet Login Page and Dashboard
- Smartsheet Onboarding Webinars
- Smartsheet University
- Formula Handbook

General Duties and Training
- Sr. Fiscal Services Duties and Trainings

Pre-Award Administration
- SPO Training Website
- SPO Available Trainings

Post-Award Administration
- Contract & Grant Training Website
- Contract & Grant Accounting
- Effort Certification: Research Administrators Symposium
- Effort Certification Training: Pre-Review Stage
- Effort Certification Training: Certification Stage
- Quick Guide for Certifiers
- Quick Guide for Pre-Reviewers

Unrestricted Accounting
- Unrestricted Accounting Training Website
- Finance Academy Certification Program Matrix
- Finance Academy PPT

IRB
- HRP 101 - Human Research Protection Program Plan
- HRP 103 - Investigator Manual
- Huron IRB Investigator Submission Guide

Human Resources
- Onboarding Dashboard
- Learning Central & BAR Roles Information Dashboard
- HR Shared Services Dashboard

Contact Us

For assistance with the Onboarding Resources Dashboard or accessing the above documents, please get in touch with **Deena Duran** at DTDuran@salud.unm.edu.

Contact Us:
Department Support Services

Questions

ClinicalTrials.gov

University of New Mexico Health Sciences Center

Office of Research

08.16.2024

What is ClinicalTrials.Gov?

- ClinicalTrials.gov is a website and online database maintained by the NIH National Library of Medicine of clinical research studies and information about their results.

- The purpose of ClinicalTrials.gov is to provide information about clinical research studies to the public, researchers, and health care professionals.

- Includes clinical trials and observational studies in all 50 states and over 200 countries.

What studies must be registered?

NIH

A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. All <u>clinical trials</u> must be registered within 21 days of enrollment of the first participant.

FDA

Trials of drugs and biologics: Controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation.

Trials of devices: Prospective clinical studies of health outcomes comparing an intervention with a device against a control in human subjects (other than small clinical trials to determine the feasibility of a device, or clinical trials to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and pediatric postmarket surveillance studies, as required under the Federal Food, Drug and Cosmetic Act.

What studies must be registered?

Clinicaltrials.gov

Any research study involving human volunteers (also called participants) that is intended to add to medical knowledge. There are two types of clinical studies: interventional studies (also called clinical trials) and observational studies.

What are the penalties for failing to register?

ICMJE

Unregistered trials will not be considered for publication in journals that adhere to ICMJE standards. In addition, since 2005 many other medical journals have begun to require prospective public registration of certain clinical trials as a prerequisite for publication. Questions about policies of a specific journal should be addressed to that journal directly. A list of journals whose editors or publishers have signed on to the ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals may be found at http://www.icmje.org/journals.html.

NIH/FDA

Penalties may include civil monetary penalties up to $11,569 fine for failing to submit or for submitting fraudulent information to ClinicalTrials.gov. After notification of noncompliance, the fine may go up to $11,569 per day until resolved. For federally funded grants, penalties may include the withholding or recovery of grant funds.

HEALTH SCIENCES

ClinicalTrials.gov Protocol Registration and Results System (PRS)

Protocol Registration and Results System (PRS)

Public site
https://clinicaltrials.gov

Organization: UNewMexico

Protocol Registration and
Results System (PRS)
https://register.clinicaltrials.gov
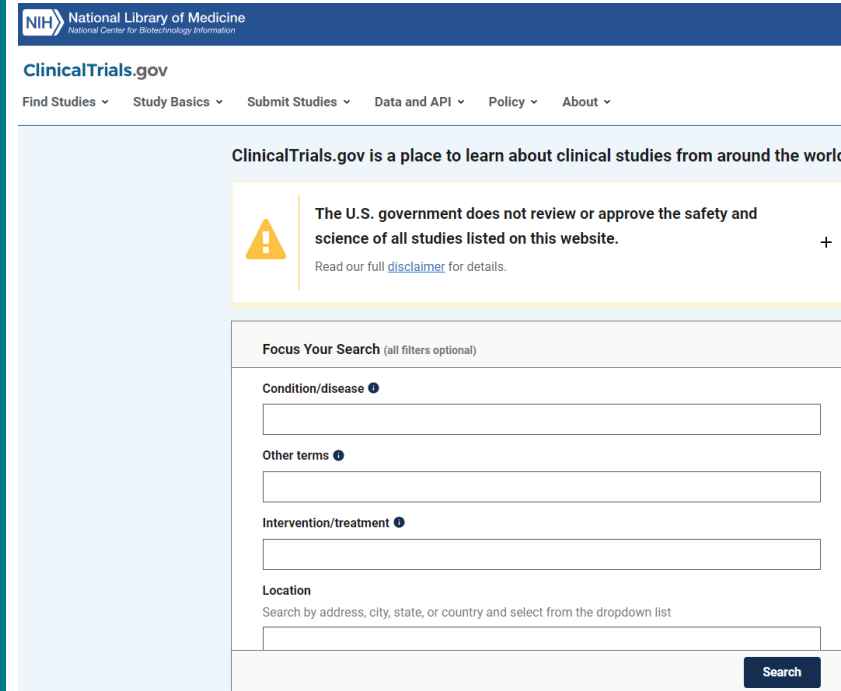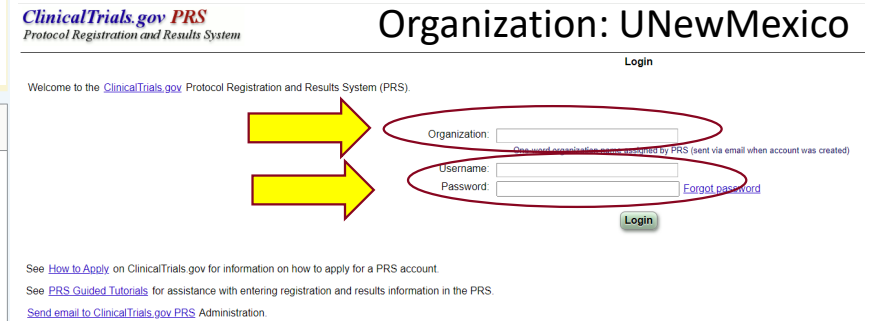
Email UNM PRS administrator for PRS account

OfficeOfResearch-ClinicalTrials.gov@salud.unm.edu

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Steps for Registering a Study in CT.gov

*Determine who is responsible for registering the clinical study →

Determine if CT.gov registration is required

https://clinicaltrials.gov/policy/reporting-requirements →

Obtain PRS account from PRS administrator

Contact: OfficeOfResearch-ClinicalTrials.gov@salud.unm.edu

↓

Register study on CT.gov using PRS

https://register.clinicaltrials.gov (no later than 21 days after enrollment of first participant)

←

Preview, Inspect and Submit Record for **PRS review

Address PRS QC review comments ← →

↓

Record (including the NCT number) available on CT.gov within 2-5 business days

- To determine the appropriate Responsible Party for registering a study and submitting results, see the See the Elaboration of Definitions of Responsible Party and Applicable Clinical Trial (PDF)
- Review of records with registration information may take approximately 2 to 5 business days. Review of records with results information may take up to 30 days.

HEALTH SCIENCES

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Required registration updates

- Responsible Parties should update their records within 30 days of a change to any of the following:

  1. Individual Site Status and Overall Recruitment Status data elements on ClinicalTrials.gov
  2. Primary Completion Date data element on ClinicalTrials.gov

- As described in 42 CFR Part 11, additional information must also be updated within 15 or 30 days of a change.
- Other changes or updates to the record must be made at least every 12 months.
- It is recommended that the Record Verification Date be updated at least every 6 months for studies that are not yet completed, even if there were no changes to the record.

Protocol Registration and Results System (PRS)

https://clinicaltrials.gov/submit-studies/prs-help/how-register-study

- The steps on this page describe the overall process of registering studies.
- If you would like step-by-step instructions for entering registration information into the PRS, see the PRS Guided Tutorials.

Protocol Registration and Results System (PRS)

Steps for Submitting Results in CT.gov

Review Requirements for submitting results

https://clinicaltrials.gov/policy/reporting-requirements

→ **Log into PRS** →

Update Protocol Section and submit record
- Overall Recruitment Status
- Study Start Date
- Primary and Study Completion Dates
- Actual Enrollment
- Arm and intervention information

→ **Enter Results** (within 12 months of the actual *primary completion date)

↓

Preview, Inspect and Submit Record for PRS review

← ****Address PRS QC review comments**

↓

Results posted on CT.gov

*Primary completion date: The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated.

**The Responsible Party must ensure major review comments are addressed within 15 calendar days (registration information) or 25 calendar days (results information) of the date on which PRS Staff sent the notification.

HEALTH SCIENCES

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Protocol Registration and Results System (PRS)

https://clinicaltrials.gov/submit-studies/prs-help/how-submit-results

- The process of submitting results information to ClinicalTrials.gov involves accurately summarizing the results information in the tabular format required by law and to ensure that the results are consistent with the ClinicalTrials.gov review criteria.

Protocol Registration and Results System (PRS)

View **Results Section**

Module Status:

Participant Flow: ✔

Baseline Characteristics: ✔ 1 Note

Outcome Measures: ✔

Adverse Events: ✔

Certain Agreements: ✔

Limitations and Caveats:

Results Point of Contact: ✔
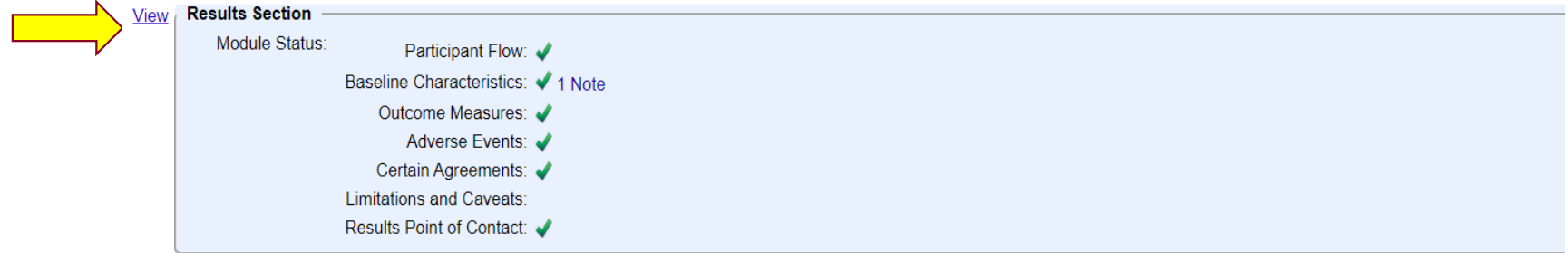
- **Participant Flow:** A summary of the progress of participants through each stage of the clinical study (by study arm for interventional studies or by group/cohort for observational studies). This includes the number of participants who started, completed, and dropped out of the study.

- **Baseline Characteristics:** Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. Examples of data include demographics, age, sex, race and ethnicity, and study-specific measures.

- **Outcome Measures:** These are tables that show the results for each of the planned measurements used in the clinical study (For interventional studies, the results of each measurement are used to understand the effects of the intervention. For observational studies, the results of each measurement are used to see how a disease changes over time or to understand the effects of an exposure).

- **Adverse Events:** The number of study participants who experienced a problem or unwanted health change during the clinical study or within a certain length of time after the study. These may include any abnormal physical exam or laboratory finding. Adverse events may or may not be caused by the intervention being studied.

Protocol Registration and Results System (PRS)

→ Documents to be uploaded (in PDF/A format) include:

- Study Protocol and Statistical Analysis Plan - only required with results information for studies with a Primary Completion Date on or after January 18, 2017.

- Informed Consent Form - optional under 42 CFR Part 11, but may be required by funder, including if study is conducted or supported by a Common Rule (45 CFR 46) department or agency.

CT.gov PRS queries?

Email: OfficeOfResearch-ClinicalTrials.gov@salud.unm.edu

Phone: 505-272-2021

HSC SPONSORED PROJECTS/ MULTIYEAR AWARD RECORD MAINTENANCE

Click Multi-year Workflow
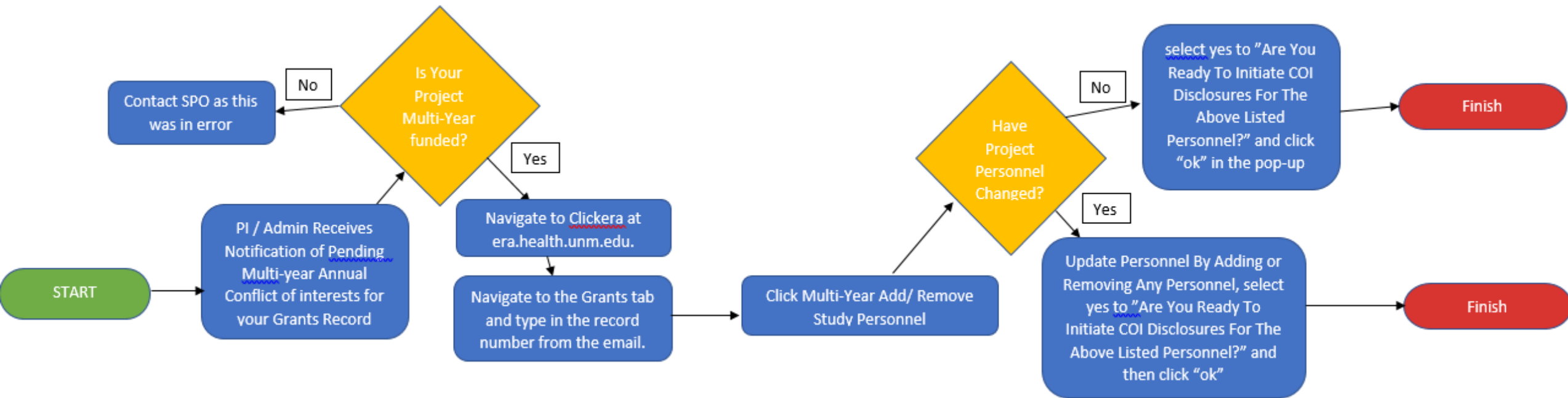
Click Generated Email
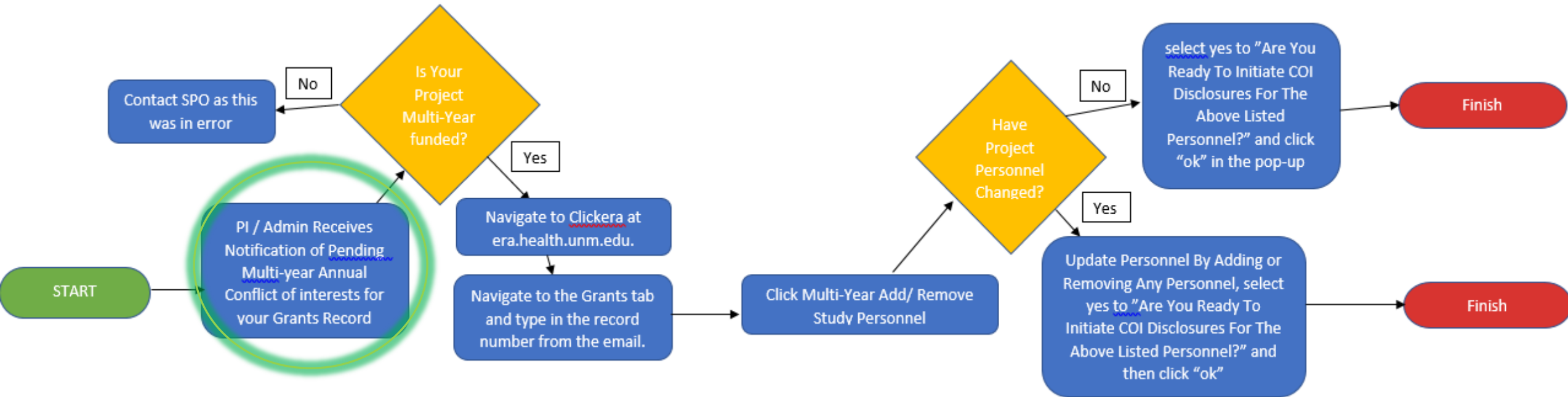
Notification to the PI and the Admin of Record

When the record has reached 11 months into the current cycle, it will send out an email notifying the PI and their Admin that they need to update personnel involved with the record.

Subject: ATTENTION NEEDED: Update Personnel for New Budget Period Beginning in 30 Days

[[-- External - this message has been sent from outside the University --]]

Grant Title: Elucidating Endothelial Injury in Alzheimer Disease

Grant Sponsor: NIH / National Institute on Aging (NIA)

PreAward #: FP00012822

Banner Fund #: 3QS40

Budget Periods:

Name	Start Date
Period 1	9/1/2023
Period 2	9/1/2024
Period 3	9/1/2025

Is Your Project a Multi-Year Project?
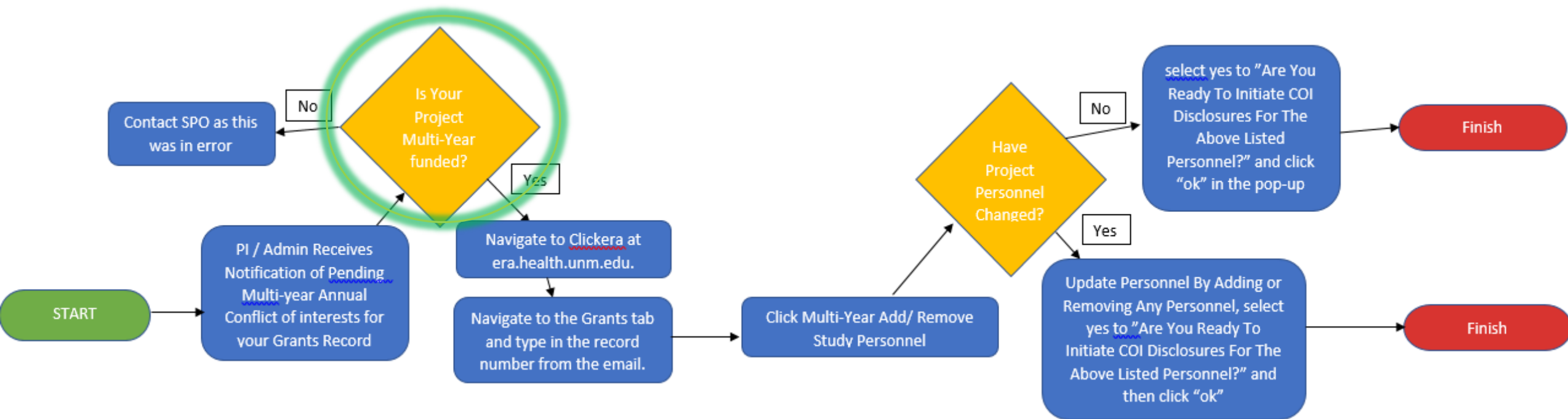
Finding Your Record
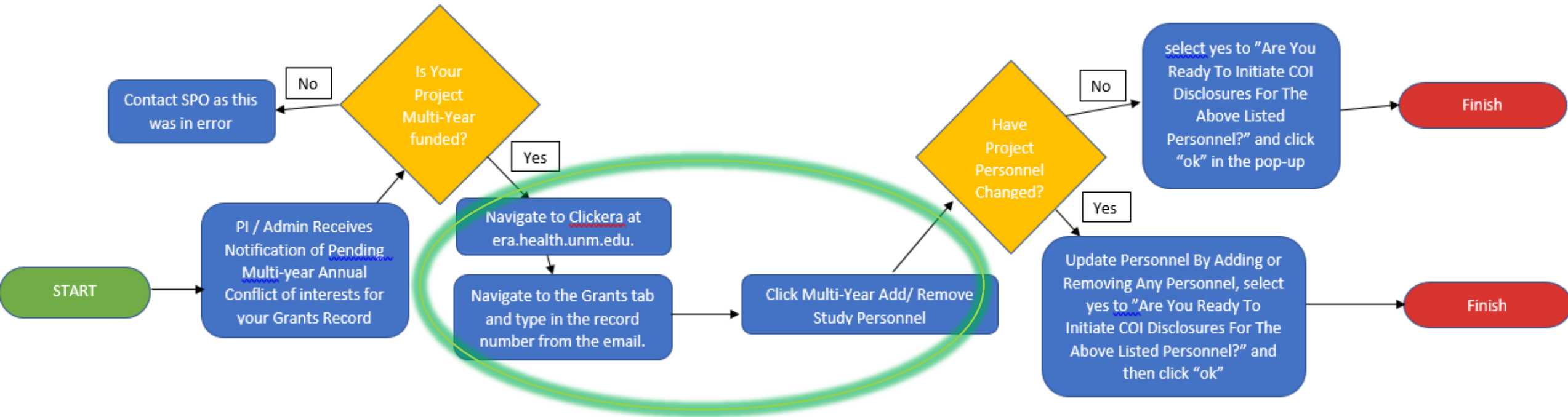
Logging In

Enter your User Name and Password here:

- This login screen can be reached directly at: https://era.health.unm.edu/
- If you have problems logging in, please contact the administrator below:
  - Sean Gonzales, SGonzales@salud.unm.edu, 505-272-3495

Finding your Record

Choose the drop down list to see your searchable fields

- To search for the record, use the search box to filter results.

"%" indicates a wildcard
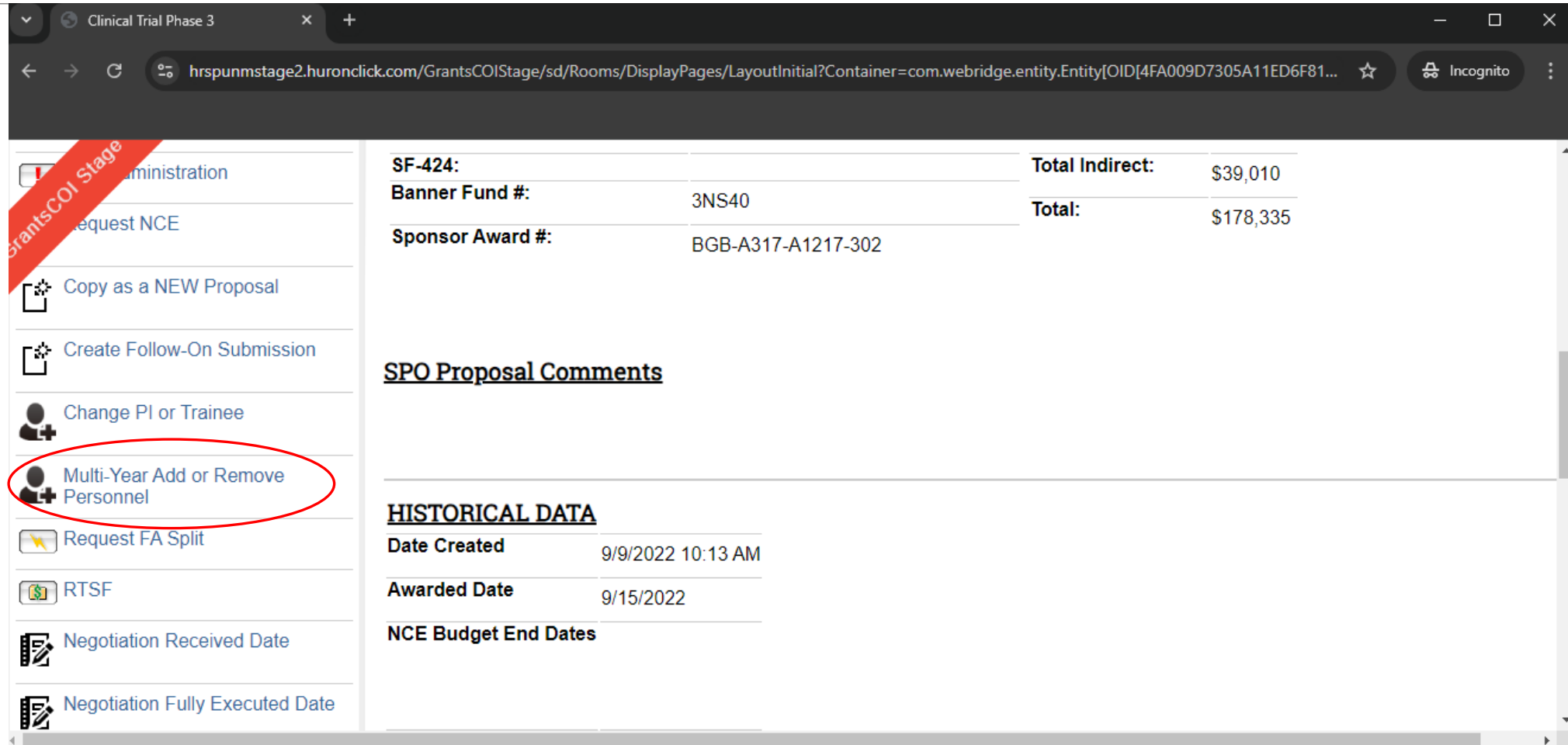
- Click on "Advanced" to add additional search fields. You can then add rows to the Advanced Search until you have all the desired search fields.

Updating Personnel

- Click Multi-Year Add or Remove Personnel

Updating Personnel

Do Personnel Need Updating?

hrspunmstage2.huronclick.com/GrantsCOIStage/sd/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity%5BOID%5B18B65419DC4E6F4E...

Multi-Year Add or Remove Personnel

Multi-Year Research: Add or Remove Study Personnel

Please enter <u>all</u> personnel that will be working on the project during the period of the no-cost extension. Only personnel listed on this form will have COI certifications submitted.

Principle Investigator:
Sean Gonzales [···] ✖

Trainee/Fellow:
[   ] [···]

UNM Personnel:
[+ Add]

	Last Name	Key / Other Significant	Role	Biosketch	Disclosure	
[✎ Update]	Salazar	no	Other Professional			✖
[✎ Update]	Vinyard	yes	Co-Investigator			✖

Non-UNM Personnel:
[+ Add]

Last Name	Key / Other Significant	Role	Biosketch	Disclosure
There are no items to display				

PLEASE ENSURE THAT ALL PERSONNEL ARE CORRECT ON THIS FORM BEFORE SELECTING "YES"
ONCE YOU SELECT "YES" AND CLICK "OK", COI DISCLOSURES WILL AUTOMATICALLY BE CREATED FOR THE PERSONNEL LISTED HERE.

* Are You Ready To Initiate COI Disclosures For The Above Listed Personnel?
● Yes ○ No <u>Clear</u>

[OK] [Cancel]

HEALTH SCIENCES

Updating Personnel

Updating Personnel

Multi-Year Add or Remove Personnel

Multi-Year Research: Add or Remove Study Personnel

Please enter **all** personnel that will be working on the project during the period of the no-cost extension. Only personnel listed on this form will have COI certifications submitted.

Principle Investigator:
Sean Gonzales ··· ⊗

Trainee/Fellow:
[   ] ···

UNM Personnel:
+ Add

	Last Name	Key / Other Significant	Role	Biosketch	Disclosure
☑ Update	Salazar	no	Other Professional		⊗
☑ Update	Vinyard	yes	Co-Investigator		⊗

Non-UNM Personnel:
+ Add

Last Name	Key / Other Significant	Role	Biosketch	Disclosure
There are no items to display				

PLEASE ENSURE THAT ALL PERSONNEL ARE CORRECT ON THIS FORM BEFORE SELECTING "YES"
ONCE YOU SELECT "YES" AND CLICK "OK", COI DISCLOSURES WILL AUTOMATICALLY BE CREATED FOR THE PERSONNEL LISTED HERE.

* Are You Ready To Initiate COI Disclosures For The Above Listed Personnel?
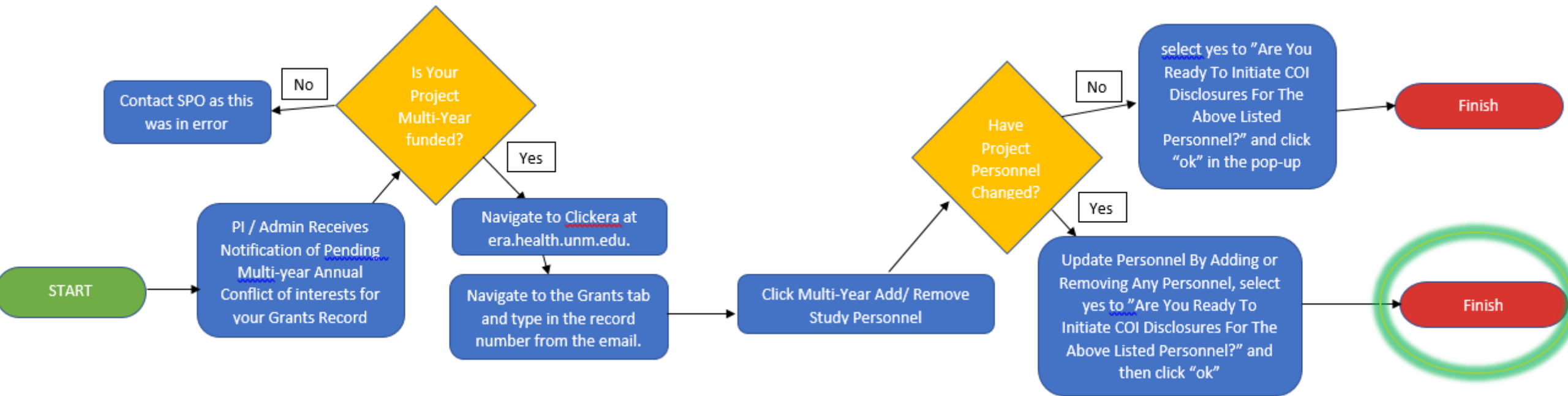● Yes ○ No Clear

OK   Cancel

To Add Personnel Click Add. HSC Personnel are added to UNM Personnel and Non-HSC Personnel are added to Non-UNM Personnel

To Remove Personnel Click the "X" on the line they're on. Your Browser will ask for confirmation

Click "ok" when you're finished with the activity

Be Sure to Click "Yes" here in order to initiate disclosures. If you don't click "Yes" here, then the activity won't complete if you click "ok"+

Updating Personnel

Questions?