

# 60 ANNUAL MEETING



Demonstrating *Resilience* and Advancing the *Profession*

August 5 – 8, 2018 | Washington, DC

## NIH Update

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*Office of Policy for Extramural Research Administration, NIH*



# NIH FY 2018 Budget News

- NIH is funded under the Consolidated Appropriations Act, 2018 ([P.L. 115-141](#)) signed on March 23, 2018.
- 2018 Legislative Mandates posted [NOT-OD-18-181](#)



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# NRSA Postdoctoral Stipends FY 18

Career Level	Years of Experience	Stipend for FY 2018	Monthly Stipend
Postdoctoral	0	\$48,432	\$4,036
	1	\$48,804	\$4,067
	2	\$49,188	\$4,099
	3	\$51,324	\$4,277
	4	\$53,184	\$4,432
	5	\$55,308	\$4,609
	6	\$57,528	\$4,794
	7 or More	\$59,736	\$4,978

See [NOT-OD-18-175](#) for more details



# Guidance on Salary Limitation FY 18

- Limited to Executive Level II – increased from \$187,000 to \$189,600, effective as of January 7, 2018.
- Rebudgeting to accommodate the current salary cap is allowed
  - if adequate funds are available in active awards, and
  - if the salary cap increase is consistent with the institutional base salary
- No additional funds will be provided to these grant awards.

See [NOT-OD-18-137](#)



# Reminder – FORMS-E

- Effective for due dates on/after January 25, 2018.
  - “Forms-E” grant application should be used ([NOT-OD-17-023](#))
  - Includes new Human Subjects and Clinical Trials Information Form
    - Consolidates information from multiple forms
    - Incorporates structured data fields
    - Collects information at the study-level
- All applications involving one or more clinical trials must be submitted through a FOA specifically designated for clinical trials ([NOT-OD-18-106](#)) – *Note any new review criteria!*
- Multi-site studies involving non-exempt human subjects research funded by the NIH, are expected to use a single Institutional Review Board (sIRB)
  - Additional implementation guidance ([NOT-OD-18-004](#)) and information on exceptions ([NOT-OD-18-003](#)) is now available.



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# Policy Updates



# Prospective Basic Science Studies Involving Human Participants

*Studies that meet the definition of clinical trials **and** the  
Federal definition of basic science*

- Delayed enforcement of registration and reporting in ClinicalTrials.gov for prospective basic science studies involving human participants.
- New FOAs specifically for prospective basic science studies involving human participants.
- Leniency for incorrect FOA submission.
- Request for Information to be released in August. Will request input from stakeholders on how best to implement the NIH CT policy for this subset of trials.

See [NOT-OD-18-212](#)



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# Federal Policy for the Protection of Human Subjects

- The Final Rule ([45 CFR part 46](#)) is intended to enhance protections for human research participants, facilitate valuable research, and reduce burdens for investigators, research institutions, and Institutional Review Boards (IRBs)
- HHS has issued a Final Rule delaying the implementation until **January 21, 2019**
- Recipients have the ***option*** of implementing 3 burden-reducing provisions during the delay period
  - The 2018 Requirements' definition of “research”, which deems some activities not to be research
  - Removal of the requirement for annual review for certain categories of research
  - Removal of the requirement for IRBs to review grant applications related to the research
- **Note: The NIH policy on the use of single IRBs in multi-site studies took effect in January 2018.**

See [NOT-OD-18-211](#)





# FCOI: Investigator Disclosures of Foreign Financial Interests

- Reminder that 42 CFR Part 50, Subpart F, Objectivity of Research, applies to each institution, domestic and foreign, that applies for or receives NIH research funding in the form of grants or cooperative agreements
- Regulation applies to:
  - Prime Recipients
  - Subrecipients
  - Domestic and Foreign
  - Each investigator who is planning to participate in, or is participating in, such research
  - *Does not apply to Phase 1 SBIR/STTR awards*
- Investigators must disclose all financial interests received from a foreign institution of higher education or the government of another country

See [NOT-OD-18-160](#) and the [FCOI Website](#)



# Inclusion Policy Changes

- **Individuals of all ages, including children, must be included in all human subjects research conducted or supported by NIH, unless there are ethical reasons not to include them.**
- Applies to all competing grant applications for due dates on or after **January 25, 2019.**
- Policy has been expanded to include individuals across the lifespan.
- Clinical research studies are expected to submit individual level data on sex/gender, race, ethnicity and age at enrollment with annual progress reports.

See [NOT-OD-18-116](#)



# Closeout Enforcement

- **NIH is strengthening enforcement of longstanding closeout requirements.**
- Recipients must submit timely, accurate closeout reports
- Reports are LATE after 120 calendar days
  - NIH may allow late submission with prior approval (i.e., acceptable written justification)
  - Cash transaction data is submitted directly to PMS
  - Recipient responsibility to reconcile FFR and FCTR data
- **When recipients fail to submit timely reports NIH will initiate unilateral closeout.**
- When no FFR is submitted, HHS policy directs NIH to close the grant using the last accepted FCTR
- This could be considered a debt or result in disallowed costs

See [NOT-OD-18-107](#)



# Documentation of Personnel Expenses

- **NIH has clarified the applicability and flexibility of the requirements for documentation of personnel expenses for its grants and cooperative agreement recipients.**
- Charges to Federal awards for salaries and wages must be based on records that accurately reflect the work performed.
- Budget estimates alone do not qualify as support for charges, but may be used for interim accounting purposes.
- Records may reflect categories of activities expressed as a percentage distribution of total activities.
- When recording salaries and wages charged to Federal awards for Institutes of Higher Education, a precise assessment of factors that contribute to costs is not always feasible, nor is it expected.

See [NOT-OD-18-108](#)



# 21<sup>st</sup> Century Cures Certificates of Confidentiality

- Section 2012 of the 21<sup>st</sup> Century Cures Act – Requires the Secretary of HHS to issue Certificates of Confidentiality (CoCs) to investigators or institutions engaged in:
  - Biomedical
  - Behavioral, or
  - Other research in which identifiable, sensitive information is collected
- CoCs protect researchers from being forced to disclose their research information in response to subpoenas or other legal requests

See [NOT-OD-17-109](#)



# Certificates of Confidentiality

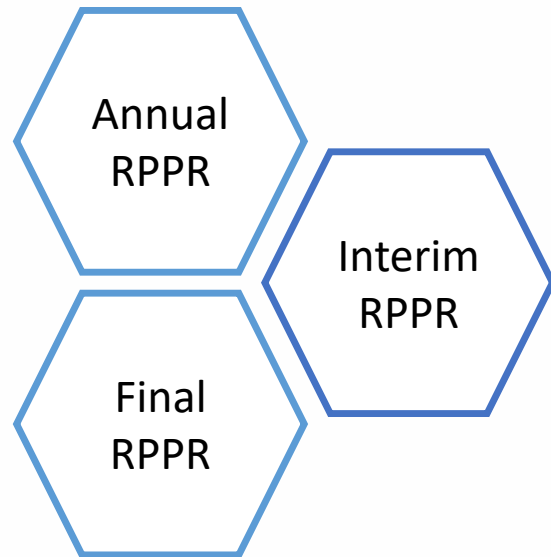
- 21st Century Cures Act required changes to NIH CoC Policy

Issue	Previous Authority	Current Authority
How to get one	Issued upon approval of application	<ul style="list-style-type: none"><li>• NIH-funded – <b>automatic</b></li><li>• Non-NIH funded – upon application</li></ul>
Disclosure	PI/ Institution could voluntarily disclose	Disclosure is prohibited unless specifically allowed by statute or with consent
Admissibility as evidence	Information protected by a CoC could be used in a legal proceeding if disclosed	Protected information cannot be used in a legal proceeding even if it is disclosed elsewhere
Copies of information	Unclear; typically advised to amend or extend	All information, including copies, is protected

See [NOT-OD-17-109](#)



# RPPR Implementation



- **Annual RPPR** – describes a grant’s scientific progress, identifies significant changes, and describes plans for the subsequent budget period
- **Interim RPPR** – use when submitting a renewal (Type 2) application. If the Type 2 is funded, the Interim RPPR will serve as the annual RPPR for the final year of the previous competitive segment. The data elements collected on the Interim RPPR are the same as for the Final RPPR, including project outcomes.
- **Final RPPR** – Use as part of the grant closeout process to submit project outcomes in addition to the information submitted on the annual RPPR, except budget and plans for the upcoming year.

See [NOT-OD-17-022](#) and [NOT-OD-17-085](#)

**Reminder – Final RPPRs are now required for all grants. NIH is no longer accepting the Final Progress Report format!**



# “Type 2” Policy Change

- In order to maximize transparency, NIH has updated its renewal application policy.
  - **NIHGPS Chapter 8.6.2** no longer states that “whether funded or not” the progress report contained within the renewal application may serve in lieu of a separate final progress report.
- This change aligns NIH’s final performance reporting requirement with the requirements of other Federal research awarding agencies.





# Project Outcomes

- NIH will publish the Project Outcomes Section of all Final and Interim RPPRs submitted on or after October 1, 2017.
- Will be available to the general public via the NIH RePORTER.
- Reviewed and approved by NIH staff to ensure the narrative is written for the general public in clear and comprehensible language.
- Should not include any proprietary, confidential information or trade secrets.
- Allow recipients to provide the general public with a concise summary of the cumulative outcomes or findings of the project.

See [NOT-OD-18-103](#)



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# Electronic Submission & eRA Commons



# RPPR -Institutional Delegations and Decimal in Effort Reporting

- Institutional delegations for Interim and Final RPPRs now align with delegations for annual RPPRs
  - PD/PI may delegate initiation to a program assistant
  - SO may delegate authority to PD/PI to submit an RPPR\*
- Data fields for effort reporting will be modified to enable use of decimals rather than a whole number

\*if consistent with institutional policy

See [NOT-OD-18-202](#)



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# Advance Notice of Transition to the xTRACT System for Preparing Research Training Data Tables

- NIH anticipates mandating that required training data tables submitted with applications and progress reports for the following activity codes be created via the xTRACT system:
  - T32
  - TL1
  - T90/R90
  - T15
- In late FY 2019, NIH will provide further guidance about the implementation of this expected requirement. At this time, applicants who have not yet taken advantage of the xTRACT system to create training data tables are encouraged to begin exploring its functionality, and may wish to start by using the system to create Data Table 8, to accompany an RPPR.

[See NOT-OD-18-133](#)



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# Diversity Supplements

- Effective January 25, 2018, all applications for (single and multi-project) diversity supplements must be submitted electronically.
- Options available to submit electronically include NIH ASSIST, Institutional system-to-system (S2S), Grants.gov Workspace and streamlined system through eRA Commons
- Within Section D.1 of the RPPR, recipients are required to identify whether an individual that has worked on the award is supported by a Diversity Supplement.
  - Institutions with a non-competing continuation award that includes diversity supplement support will be required to identify at least one participant that is supported by the diversity supplement.

See [NOT-OD-18-111](#)



# Automated Post Award Changes

Recipients of NIH awards can submit the following prior approval requests electronically through eRA Commons:

- **Prior Approval Request for Change of PD/PI**
- **Prior Approval Request for No Cost Extension (NCE)**
- **Prior Approval Request for Carryover**

For additional details please see [eRA Commons Online Help](#)



# Tips for e-Submission Success

- Register Early!
- Required registrations
  - System for Award Management (SAM)
  - Grants.gov
  - eRA Commons
  - DUNS
  - SBA (for small business applicants only)
- Submit early, and correct any errors before due date
- View your application in Commons
  - If you can't **VIEW** it, NIH can't **REVIEW** it!





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# Policy Reminders





# Timely Progress Reports

- Annual Progress Reports = RPPR Format
- Due Dates
  - Non-SNAP: Approximately 60 days before the start of next budget period
  - SNAP: Approximately 45 days before start of the next budget period
  - Multi-Year Funded: on or before anniversary date

***Searchable list to determine which progress reports are due:***

***<https://public.era.nih.gov/chl/public/search/progressReportByIpf.era>***



# Timely Financial Reporting

- Federal Financial Report (FFR) (SF-425) Expenditure Data
- Annual (Non-SNAP Awards)
  - FFR submitted no later than 90 days after the end of the calendar quarter in which the budget period ended
- Final (SNAP and Non-SNAP Awards)
  - FFR submitted within 120 days following the end of the project period



# Invention Reporting

- NIH recipients must file the HHS 568 at the conclusion of an NIH award
- All subject inventions reported on the HHS 568 must be reported in iEdison.
- Failure to report all inventions may result in your organization's loss of rights in the invention or other actions as appropriate.

See [NOT-OD-16-066](#)



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# Educational Outreach



# OLAW Educational Outreach

OLAW free quarterly webinars series:

<http://grants.nih.gov/grants/olaw/e-seminars.htm>

- Recordings of past webinars:

[http://grants.nih.gov/grants/olaw/educational\\_resources.htm](http://grants.nih.gov/grants/olaw/educational_resources.htm)



Disaster planning resources:

[http://grants.nih.gov/grants/olaw/disaster\\_planning.htm](http://grants.nih.gov/grants/olaw/disaster_planning.htm)

- Disaster planning webinar & FAQs



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**2018**  
**NIH Regional Seminar**  
Program Funding and Grants Administration

**1:1 Meet the Experts**  
appointment now for a

**Building Bridges with  
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Research Community**

**October 17 - 19, 2018**

**San Francisco, California**

**Registration Now Open!**



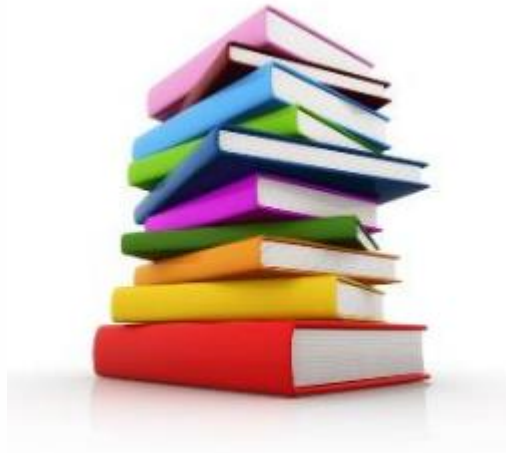


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# Helpful NIH Resources





# RPPR Resources

- RPPR Webpage: <http://grants.nih.gov/grants/rppr/>
- Includes links to:
  - RPPR Guide
  - RPPR Guide Notices
  - Frequently Asked Questions
  - Training
  - Contacts



## Policy & Compliance

[NIH Grants Policy Statement](#)

[Notices of Policy Changes](#)

[Compliance & Oversight](#)

### Select Policy Topics

[Animal Welfare](#)

[Application Submission Policies](#)

### Clinical Trial Requirements

[Clinical Trial Definition](#)

[Why the Changes](#)

[Good Clinical Practice](#)

[Specific Funding Opportunities](#)

[Clinical Trial-Specific Review Criteria](#)

[New Form](#)

[Single IRB Policy](#)

[Protocol Template](#)

[Registration and Reporting](#)

[NIH Funding Strategies](#)

[Human Subjects Research](#)

[Intellectual Property Policy](#)

[Lobbying Guidance for Grantee Activities](#)

[Early Stage and Early Established Investigator](#)

# Clinical Trial Requirements for Grants and Contracts

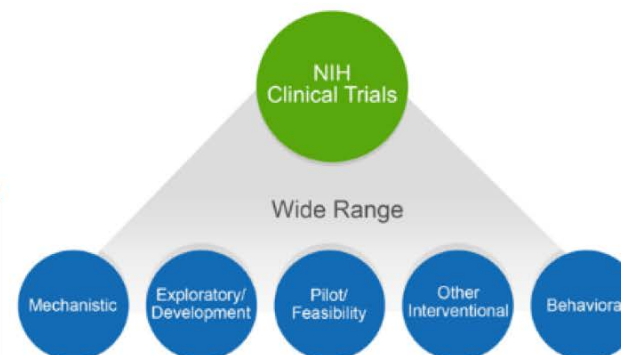
NIH is launching a series of initiatives that are rolling out in 2017-2018 to enhance the accountability and transparency of clinical research. These initiatives target key points along the whole clinical trial lifecycle from concept to results reporting. Learn more about these changes and how they will affect your research.

## NIH Definition of a Clinical Trial

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. [Learn more](#)

Your human subjects study may meet the NIH definition of a clinical trial.

**FIND OUT HERE**



### On This Page:

- [Why Changes to Clinical Trial Policies?](#)
- [Good Clinical Practice Training](#)
- [Clinical Trial-specific Funding Opportunities](#)
- [Clinical Trial-Specific Review Criteria](#)
- [New Human Subject and Clinical Trial Information Form](#)
- [Single IRB Policy for Multi-site Research](#)
- [Clinical Trials Protocol Template](#)
- [Clinicaltrials.gov Registration and Reporting](#)



## Related Resources

[FAQs](#)

[Training Resources](#)

[Important Terms](#)

[Research Involving Human Subjects](#)

[Resource on Research Methods](#)

[ClinRegs: international clinical trials regulations](#)

[Clinicaltrials.gov](#)

[For NIH Staff](#)



# Frequently Asked Questions

## **FAQs –searchable websites for:**

- Application/progress report preparation, funding initiatives, policies, human subjects, sIRB, clinical trials, animals, disaster response, PMS Subaccounts, Core Facilities, FCOI, etc....

[http://grants.nih.gov/grants/frequent\\_questions.htm](http://grants.nih.gov/grants/frequent_questions.htm)



# Summary of Helpful NIH Web Pages

- Office of Extramural Research (OER) Web Page:
  - <http://grants.nih.gov/grants/oer.htm>
- NIH Grants Policy Statement (Rev. 10/17):
  - <http://grants.nih.gov/grants/policy/nihgps/>
- NIH Extramural Nexus – newsletter for the extramural community:
  - <http://nexus.od.nih.gov/all/nexus-by-date/>
- Grant Application Basics:
  - [http://grants.nih.gov/grants/grant\\_basics.htm](http://grants.nih.gov/grants/grant_basics.htm)
- eRA Training: Video Tutorials
  - [http://era.nih.gov/era\\_training/era\\_videos.cfm](http://era.nih.gov/era_training/era_videos.cfm)





# Summary of Helpful NIH Web Pages

- How to Apply - Application Guide:  
<http://grants.nih.gov/grants/how-to-apply-application-guide.htm>
- Annotated SF424 (R&R) Application Forms (General and Small Business and Multi-project):  
<https://grants.nih.gov/grants/how-to-apply-application-guide/resources/annotated-form-sets.htm>

## **How we check for application completeness:**

<https://grants.nih.gov/grants/how-to-apply-application-guide/submission-process/how-we-check-for-completeness.htm>

## **Do I have the right electronic forms for my NIH application?:**

[http://grants.nih.gov/grants/ElectronicReceipt/files/right\\_forms.pdf](http://grants.nih.gov/grants/ElectronicReceipt/files/right_forms.pdf)

## **Self Help Resources page:**

<http://grants.nih.gov/support/index.html>



# Summary of Helpful NIH Web Pages

- eRA Commons Web pages:
  - <http://era.nih.gov/>
- eRA Commons User Guides:
  - [http://era.nih.gov/commons/user\\_guide.cfm](http://era.nih.gov/commons/user_guide.cfm)
- Intellectual Property Policy:
  - <http://grants.nih.gov/grants/intell-property.htm>
- Research Portfolio Online Reporting Tools (RePORT):
  - <http://report.nih.gov>
- RePORT Expenditures & Results (RePORTER):
  - <http://projectreporter.nih.gov/reporter.cfm>



# NIH OER Listservs

- NIH Guide for Grants and Contracts:  
Official publication for NIH Grant Policies, Guidelines & Funding Opportunities  
<http://grants.nih.gov/grants/guide/listserv.htm>
- Office for Human Research Protections (OHRP):  
<http://www.hhs.gov/ohrp>
- Office of Laboratory Animal Welfare (OLAW):  
<http://grants.nih.gov/grants/olaw/references/list.htm>
- eSubmission:  
Separate listservs available for scientists and administrators  
<http://grants.nih.gov/grants/ElectronicReceipt/listserv.htm>



# Grants Information: Who to Contact?

- General Application Questions:
  - E-Mail: [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov)
  - Phone: 301-945-7573
- Grants.gov Customer Support:
  - E-Mail: [support@grants.gov](mailto:support@grants.gov)
  - Webpage: <http://grants.gov/>
  - Phone: 1-800-518-4726
- eRA Commons Helpdesk:
  - Web: <https://grants.nih.gov/support/index.html>
  - Toll-free: 1-866-504-9552
  - Phone: 301-402-7469
  - Hours: Mon-Fri, 7a.m. to 8 p.m. Eastern Time



# Grants Policy: Who to Contact?

- Division of Grants Policy:
  - E-Mail: [GrantsPolicy@mail.nih.gov](mailto:GrantsPolicy@mail.nih.gov)
  - Phone: 301-435-0949
- Division of Grants Compliance & Oversight:
  - E-Mail: [GrantsCompliance@mail.nih.gov](mailto:GrantsCompliance@mail.nih.gov)
  - Phone: 301-435-0949
- Division of Extramural Inventions and Technology Resources:
  - E-Mail: [Inventions@nih.gov](mailto:Inventions@nih.gov)
  - Phone: 301-435-1986





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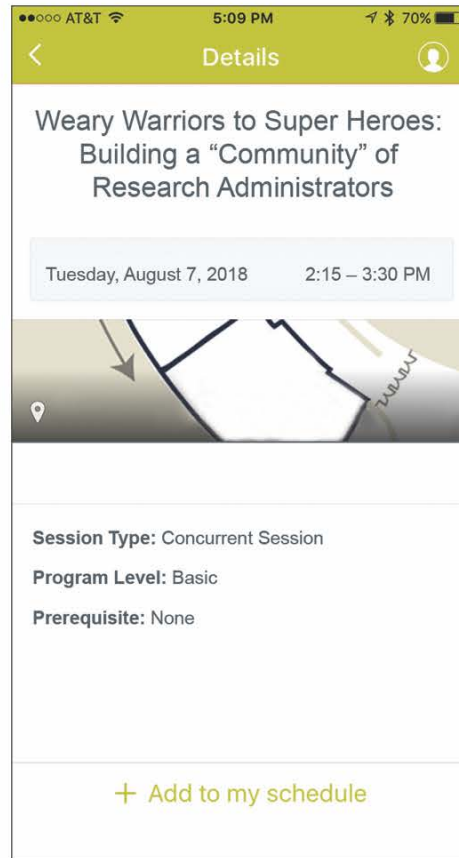
# Questions?



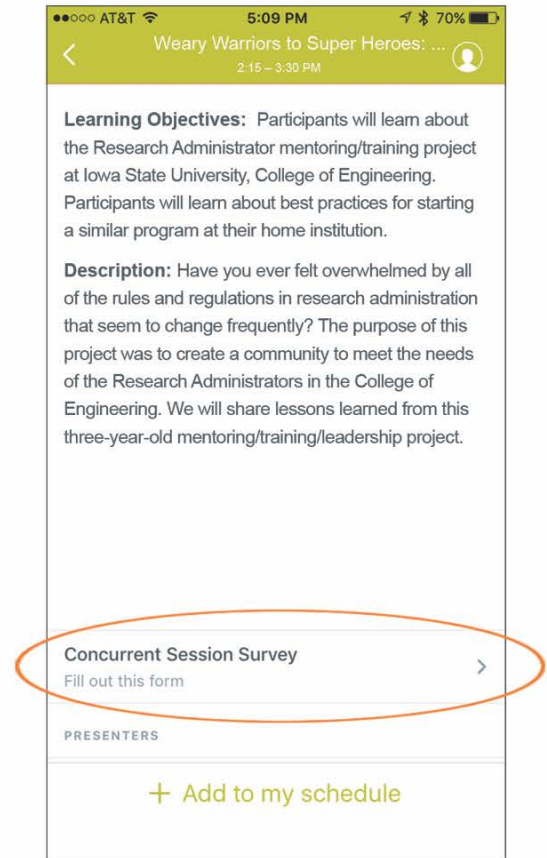
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1. In Guidebook, search the schedule and open the session you are attending.



2. Open the details of the session.



3. Scroll down to enter the session survey and answer four multiple choice questions.