



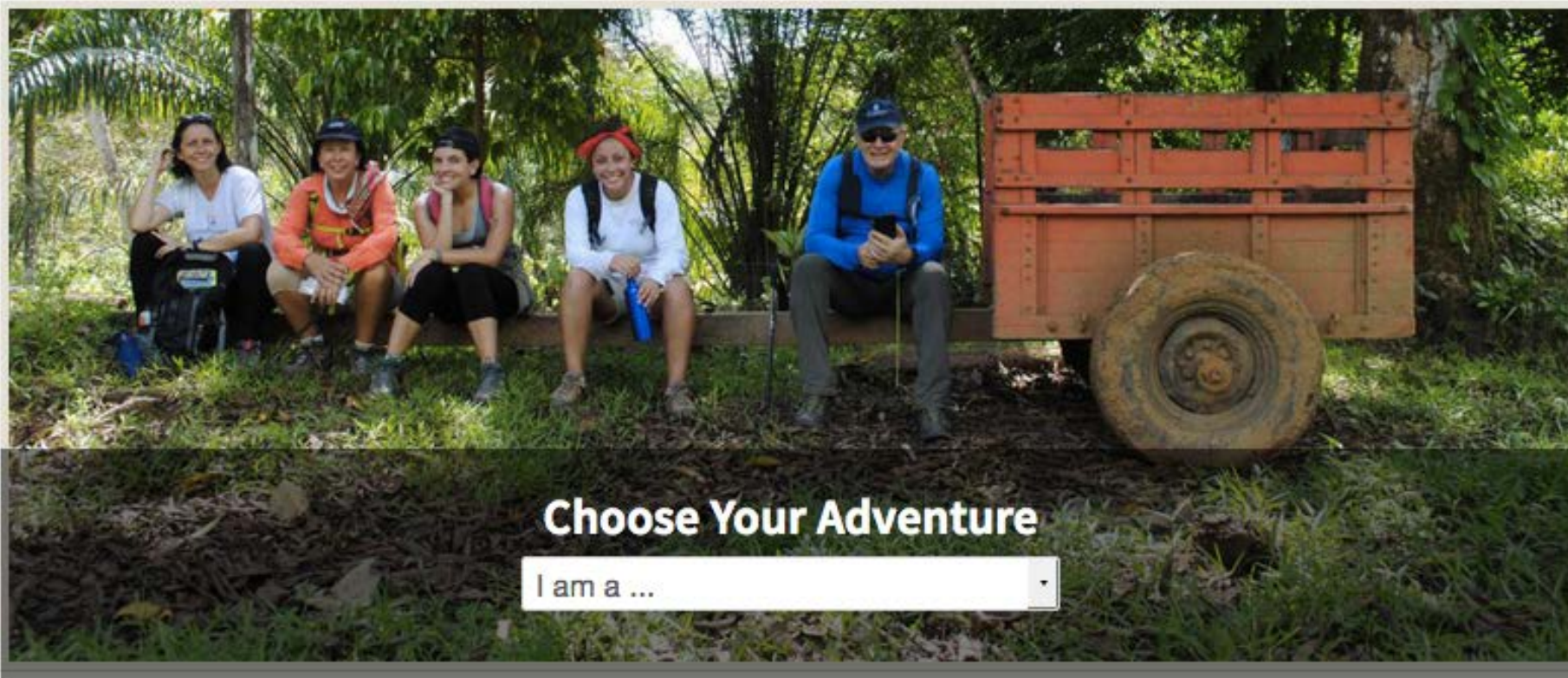
# **ABCs OF RESEARCH**

**October 10, 2017**

# Stanford | Office of International Affairs

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## Choose Your Adventure

### SPECIAL TOPIC: IMMIGRATION ISSUES AND RESOURCES

As events continue to unfold regarding federal immigration policy, this page provides resources for members of the Stanford community.

[international.stanford.edu](http://international.stanford.edu)



# Stanford | Office of International Affairs

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## For Faculty or Staff Members

### Key Travel Steps for Faculty and Staff

- Apply for a Stanford Travel Card
- Schedule a Travel Medicine Consultation
- Identify in-country challenges and develop a contingency plan
- Get a passport or check your passport's expiration date
- Determine if you need a visa for your destination country

[VIEW THE FULL TRAVEL CHECKLIST »](#)

### International Travel Registry



Register your travel so that the university can reach you in the event of emergency.

[Register now](#)

### Travel Advice and Training

We provide a university travel registry, SOLO travel steps, a DOR training module and other tools.

#### Why?

- to aggregate, curate and share widely advice on traveling internationally
- to help units deliver customized communication plans
- to better coordinate support to travelers when in the field

#### Case study:

OIA helps research team stay safe in India

### Agreements

We draft agreements and coordinate approvals for the international partnerships that are strategically important to your research.

#### Why?

### Research Consulting

We help you prepare and respond to challenges with your international research, including fine-tuned analysis of travel security, and analysis of the policies that may impact your research.

### Faculty Funding

International research exploration grants help faculty quickly demonstrate proof-of-concept and cement new partnerships for larger international research opportunities.

#### Why?

# Student International Opportunities Landscape: BEFORE



## Student Workflow

- Search department websites
- Apply for opportunities
- Write essays
- Request recommendations

on **multiple** tools & websites

Freeman Spogli Institute

Global Studies

Global Engineering

Haas Center

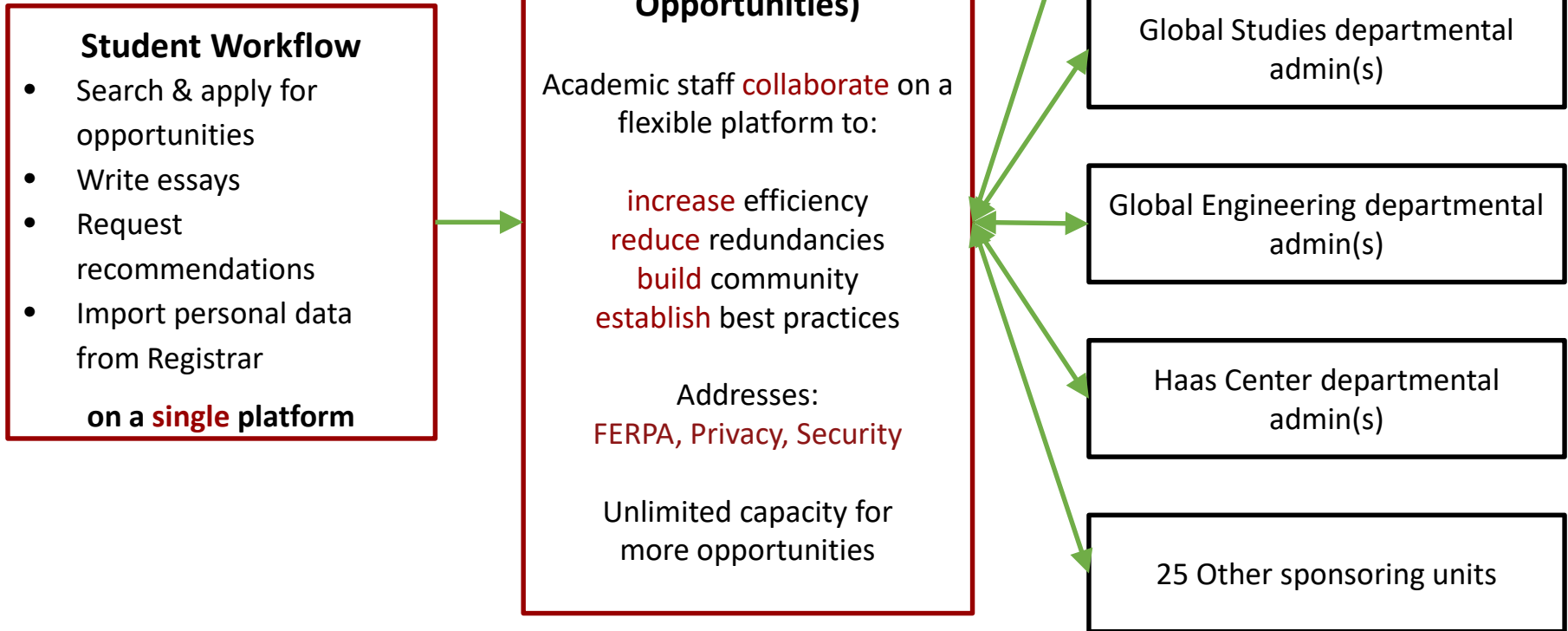
East Asian Studies

## Departmental administrator workflow

- Select platform
- Create, post and manage application
- Research application deadlines for other units
- Coordinate the review process for applications
- Notify and award applicants
- Follow-up on pending applications
- Create pre-travel requirements

replicated on **multiple** tools & websites

# Student International Opportunities Landscape: AFTER





Some things can't be learned on the Farm!

Take your Stanford experience off campus.

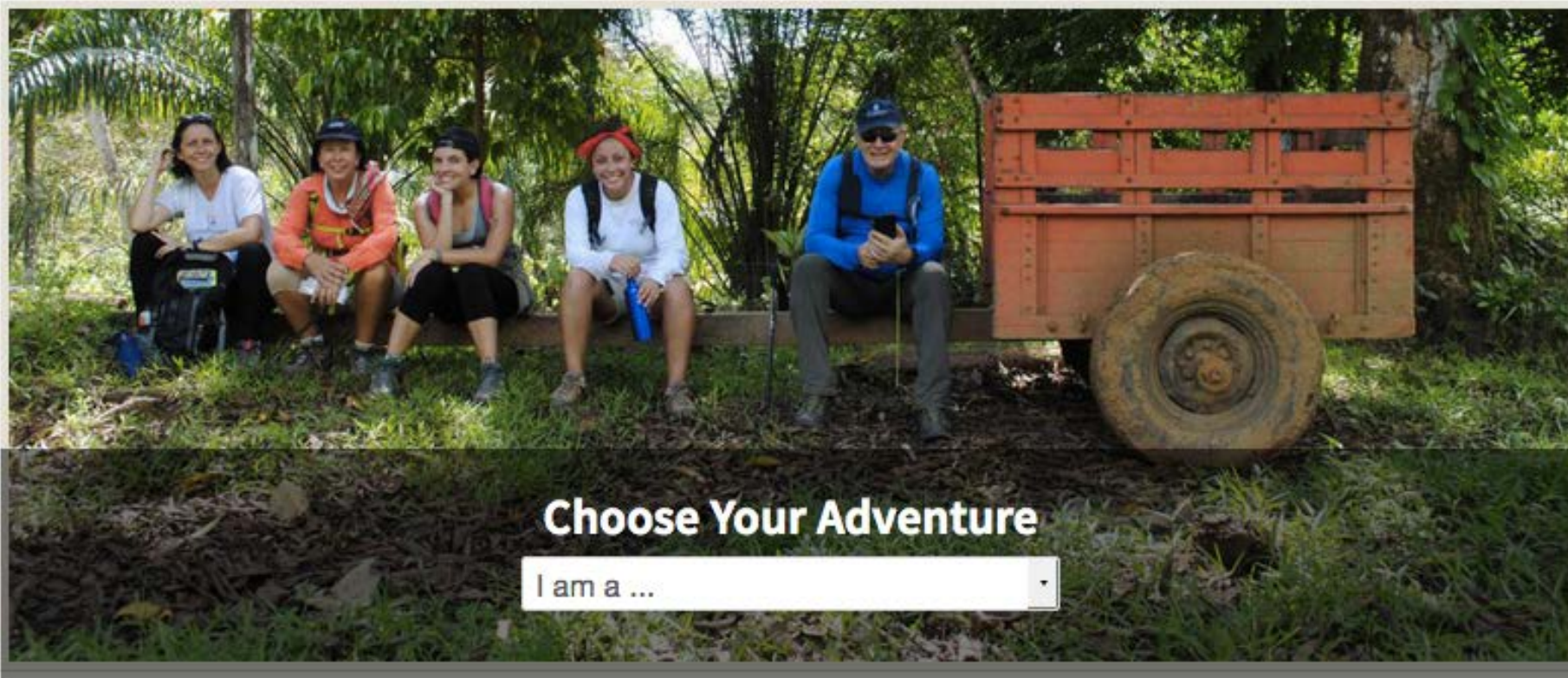
- Provide academic benefit to students
- Collaborative approach to “Best Practices”
- Solve problems and share solutions widely
- 30 units managing 300+ opportunities in SOLO
- 2,130+ unique student users
- Over 2,100 applications submitted to date



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## Choose Your Adventure

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The background features a large, light green watermark of the Stanford University seal. The seal is circular and contains the text "LELAND STANFORD JUNIOR UNIVERSITY" around the top edge and "1891" at the bottom. In the center is a tree with a banner that reads "LUFT DER FREIHEIT WEHT".

Office of the Chief Risk Officer  
(OCRO)

# Privacy Office Overview

ABC

OCTOBER 10, 2017

Pegah Parsi

Privacy Program Manager

Lily Chaskelmann

Privacy Specialist



# THE UNIVERSITY PRIVACY OFFICE

## GOALS

- TO PROTECT THE PRIVACY OF UNIVERSITY, EMPLOYEE, PATIENT, AND OTHER CONFIDENTIAL INFORMATION
- ENSURE THE PROPER USE AND DISCLOSURE OF SUCH INFORMATION
- FOSTER A CULTURE THAT VALUES AND PROMOTES PRIVACY

# WHAT WE DO

GOVERNANCE AND OVERSIGHT

EDUCATION AND OUTREACH

ASSESS REGULATORY ENVIRONMENT

INCIDENT RESPONSE MANAGEMENT

POLICIES AND PROCEDURES

MONITORING

PRIVACY RISK ASSESSMENTS

SPECIAL PROJECTS

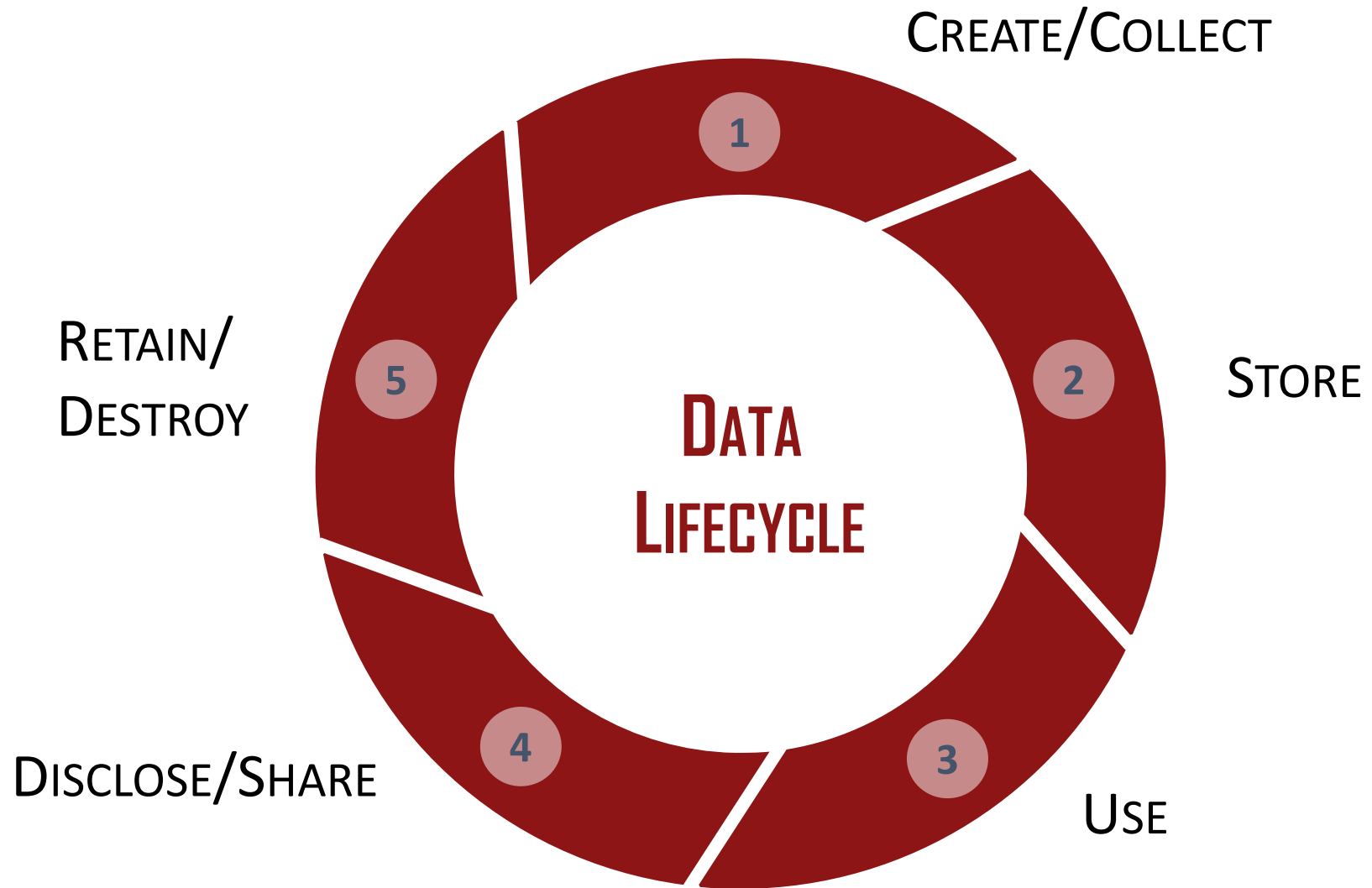
# WHAT IS PRIVACY?

**INFORMATION PRIVACY DETERMINES WHAT, WHEN, HOW, AND WHY AN INDIVIDUAL'S PERSONAL DATA IS COMMUNICATED TO OTHERS, SPECIFICALLY RELATED TO:**

- **RESTRICTIONS ON THE COLLECTION, STORAGE, PROCESSING, AND TRANSMISSION OF PERSONAL DATA**
- **ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS FOR DATA PROCESSING**
- **CONFIDENTIALITY OF SENSITIVE INFORMATION, SUCH AS FINANCIAL AND HEALTH DATA**
- **PREVENTION OF INAPPROPRIATE DISCLOSURE OF PERSONAL DATA**



# INFORMATION PRIVACY 101



# WHAT GOVERNS INFORMATION PRIVACY?

- **PRIVACY LAWS ARE NEW AND CONSTANTLY CHANGING, AND VARY BY STATE, COUNTRY, AND INDUSTRY**
- **PRIVACY LAWS MAY PROTECT DIFFERENT TYPES OF DATA**
  - **HEALTH INFORMATION (HIPAA; CMIA)**
  - **STUDENT DATA (FERPA)**
  - **EMPLOYEE DATA (STATE LAWS)**
  - **EU DATA (GDPR)**
  - **MARKETING DATA (CAN-SPAM)**
  - **INTERNATIONAL DATA (COUNTRY-SPECIFIC)**
  - **DATA FROM CHILDREN UNDER 13 (COPPA)**
  - **ELECTRONIC DATA (CA STATE LAW)**
- **OTHER THINGS THAT AFFECT PRIVACY**
  - **DUAs AND CONTRACTUAL TERMS**
  - **NOTICE OF PRIVACY PRACTICES**
  - **FTC CASES AND GUIDANCE**

# DATA RISK ASSESSMENT OVERVIEW

- **DATA RISK ASSESSMENT (DRA) PROCESS IS A JOINT UNIVERSITY PRIVACY OFFICE AND INFORMATION SECURITY OFFICE PROCESS**
- **FOCUSED ON HIGH RISK DATA AND HIGH DATA VOLUME PROJECTS**
- **EVALUATE THAT PROPOSED PROJECTS CAN ADEQUATELY PROTECT THE CONFIDENTIALITY AND SECURITY OF THE DATA INVOLVED**
  - **ENSURE THAT STANFORD HAS PERFORMED ITS DUE DILIGENCE**
  - **OPPORTUNITY TO ENHANCE CONTROLS, WHERE NEEDED, AND LEVERAGE INTERNAL BEST PRACTICES**
- **A PROJECT MAY BE RELATED TO RESEARCH, A VENDOR, DATA SHARING, DATA LICENSING, INTERNAL PROCESSES, EVALUATION**
- **AUTOMATED DRA FORM COMING SOON!!!**



# FREQUENTLY ASKED QUESTIONS FROM UPO/ISO

- IS YOUR APPROVED IRB PROTOCOL CONSISTENT WITH THE SCOPE OF WORK PROPOSED IN THE DRA? WITH YOUR INFORMED CONSENT? WITH YOUR CONTRACT?
- WHAT DATA ELEMENTS AND HOW MANY RECORDS ARE INVOLVED?
- HOW MANY USERS (STANFORD AND EXTERNAL) ARE INVOLVED?
- IS ANY DATA BEING MOVED (INBOUND OR OUTBOUND) INTERNATIONALLY?
- IS THE DATA INVOLVED LIMITED TO WHAT IS NECESSARY FOR THE PROJECT (I.E., DATA MINIMIZATION AND MINIMUM NECESSARY CONCEPTS)?
- HOW AND WHERE (LOCAL VS CLOUD) WILL THE DATA BE SECURELY COLLECTED/STORED?
- HOW WILL YOU PROTECT PHI/PII IN PAPER FORMAT?
- WHAT DATA ELEMENTS WILL BE DISCLOSED TO THE VENDOR/COLLABORATOR/PARTNER?
- WILL THE VENDOR/COLLABORATOR/PARTNER WANT TO USE THE DATA FOR ANY OTHER PURPOSES?
- DOES THE VENDOR/COLLABORATOR/PARTNER SUPPORT SAML?
- WHAT SECURITY FRAMEWORK AND 3<sup>RD</sup> PARTY AUDITS/CERTIFICATIONS HAVE THE VENDOR EMPLOYED?

# QUESTIONS/SUGGESTIONS?

# UNIVERSITY PRIVACY OFFICE

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CHIEF PRIVACY OFFICER

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650-725-1828





# New NIH Forms-E and the Clinical Trial Identifier on FOAs

ABC Meeting

Sonia Barragan, Associate Director

October 10, 2017

## New NIH Forms-E Grant Application Forms

- Forms-E: Use for NIH application deadlines on or after Jan 25, 2018.
- Forms-D: Use for application deadlines prior to Jan 25, 2018.
- Question: If my proposal has an NIH due date of January 25, 2018 but I plan to complete my proposal by Dec 18, 2017, before winter break, what forms package will be required?
  - The required forms package is determined by the application deadline and not by the application submission date. Forms-E will be required because the sponsor's deadline is on or after Jan 25, 2018.

## What New In Forms-E?

- Text has been edited to add clarity.
- Fields have been renumbered.
- The human subjects section and following attachments
  - Protection of Human Subjects
  - Data Safety Monitoring Plan
  - Inclusion of Women and Minorities
  - Inclusion of Children

has moved to a new section called the

**Human Subjects and Clinical Trials Information Form.**

★ Watch 9 min You Tube video: [PHS Human Subjects and Clinical Trial Information Form Walk-through](#)



### PHS Human Subjects and Clinical Trials Information

[View Burden Statement](#)

OMB Number: 0925-0001  
Expiration Date: 03/31/2020

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved?  Yes  No

Is the Project Exempt from Federal regulations?  Yes  No

Exemption number:  1  2  3  4  5  6  7  8

#### If No to Human Subjects

Does the proposed research involve human specimens and/or data?  Yes  No

If Yes, provide an explanation of why the application does not involve human subjects research.

[Add Attachment](#) [Delete Attachment](#) [View Attachment](#)

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

#### If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

#### Other Requested Information

[Add Attachment](#) [Delete Attachment](#) [View Attachment](#)

[Click here to extract the Human Subject Study Record Attachment](#)

#### Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1  [Add Attachment](#) [Delete Attachment](#) [View Attachment](#)

[Add New Study](#)

#### Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
<input checked="" type="checkbox"/>		<input type="checkbox"/>	<input type="text"/> <a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>

[Add New Delayed Onset Study](#)



Check Form for Errors

Save

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001  
Expiration Date: 03/31/2020

\* Always required field

Section 1 - Basic Information

1.1. \* Study Title (each study title must be unique)

[Text input field]

1.2. \* Is this Study Exempt from Federal Regulations?  Yes  No

1.3. Exemption Number  1  2  3  4  5  6  7  8

1.4. \* Clinical Trial Questionnaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

- 1.4.a. Does the study involve human participants?  Yes  No
- 1.4.b. Are the participants prospectively assigned to an intervention?  Yes  No
- 1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?  Yes  No
- 1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?  Yes  No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

[Text input field]

Add New Condition

2.2. Eligibility Criteria

[Text input field]

2.3. Age Limits Minimum Age   Maximum Age

2.4. Inclusion of Women, Minorities, and Children  Add Attachment Delete Attachment View Attachment

2.5. Recruitment and Retention Plan  Add Attachment Delete Attachment View Attachment

2.6. Recruitment Status

2.7. Study Timeline  Add Attachment Delete Attachment View Attachment

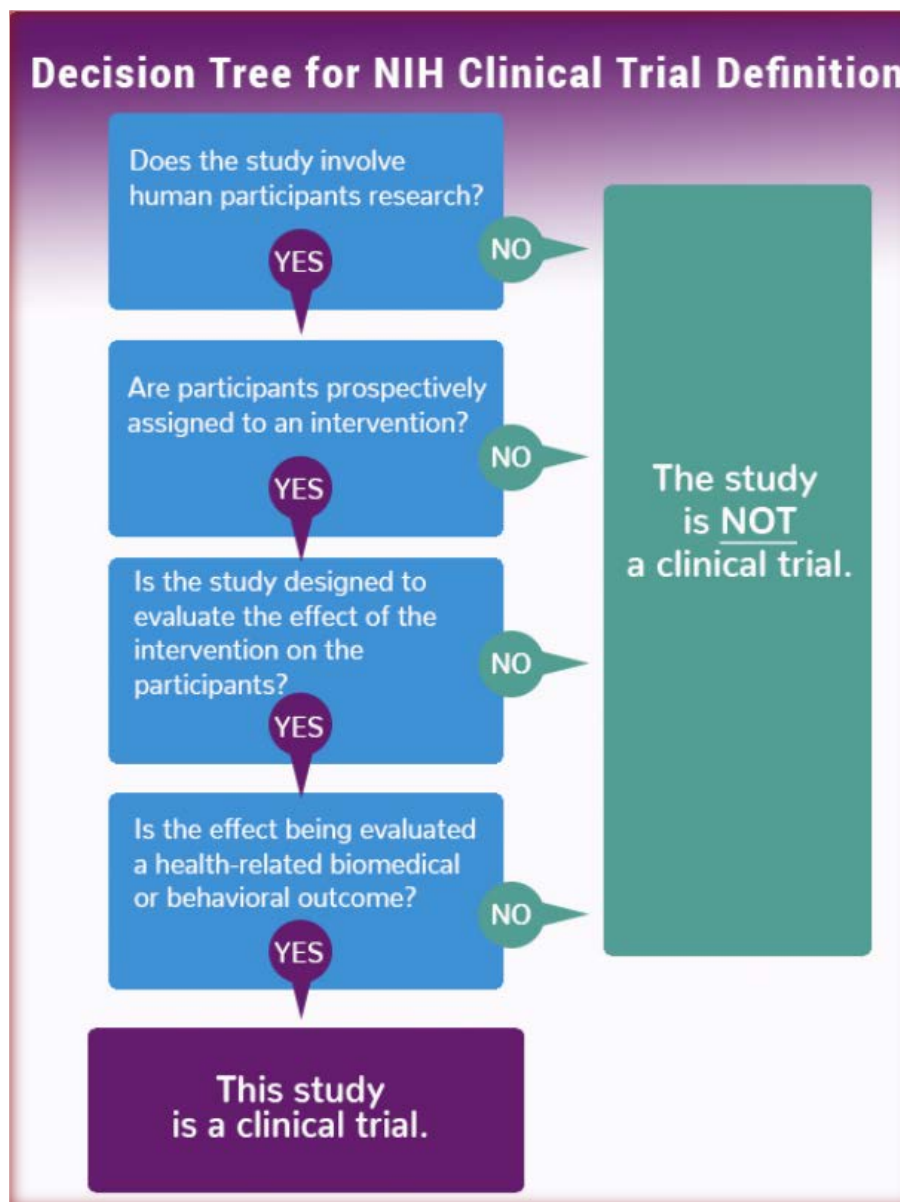
2.8. Enrollment of First Subject

Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report



# Decision Tree



# Application Instructions Available:

- <https://grants.nih.gov/grants/how-to-apply-application-guide.html>

Application Form Instructions					
Need help selecting the right instructions?					
Application Instructions	Description	SF424 (R&R) - Version D Use for due dates on and before January 24, 2018	SF424 (R&R) - Version E Use for due dates on and after January 25, 2018		
<b>G</b> General Instructions	Comprehensive guidance for research, training, fellowship, career development, multi-project, and small business applications	HTML / PDF	HTML / PDF		
Filtered Application Instructions					
<b>R</b> Research Instructions	Guidance for research only	PDF	PDF		
<b>K</b> Career Development Instructions	Guidance for career development only	PDF	PDF		
<b>T</b> Training Instructions	Guidance for training only	PDF	PDF		
<b>F</b> Fellowship Instructions	Guidance for fellowship only	PDF	PDF		
<b>M</b> Multi-Project Instructions	Guidance for multi-project only	PDF	PDF		
<b>B</b> SBIR/STTR Instructions	Guidance for small business only	PDF	PDF		

# Funding Opportunity Announcements (FOA)

How will NIH differentiate FOAs that support clinical trials from those that do not?

- Look at the title of the FOA. Imbedded in the title you will find:
  - Clinical Trial Optional  
~ or ~
  - Clinical Trial Not Allowed

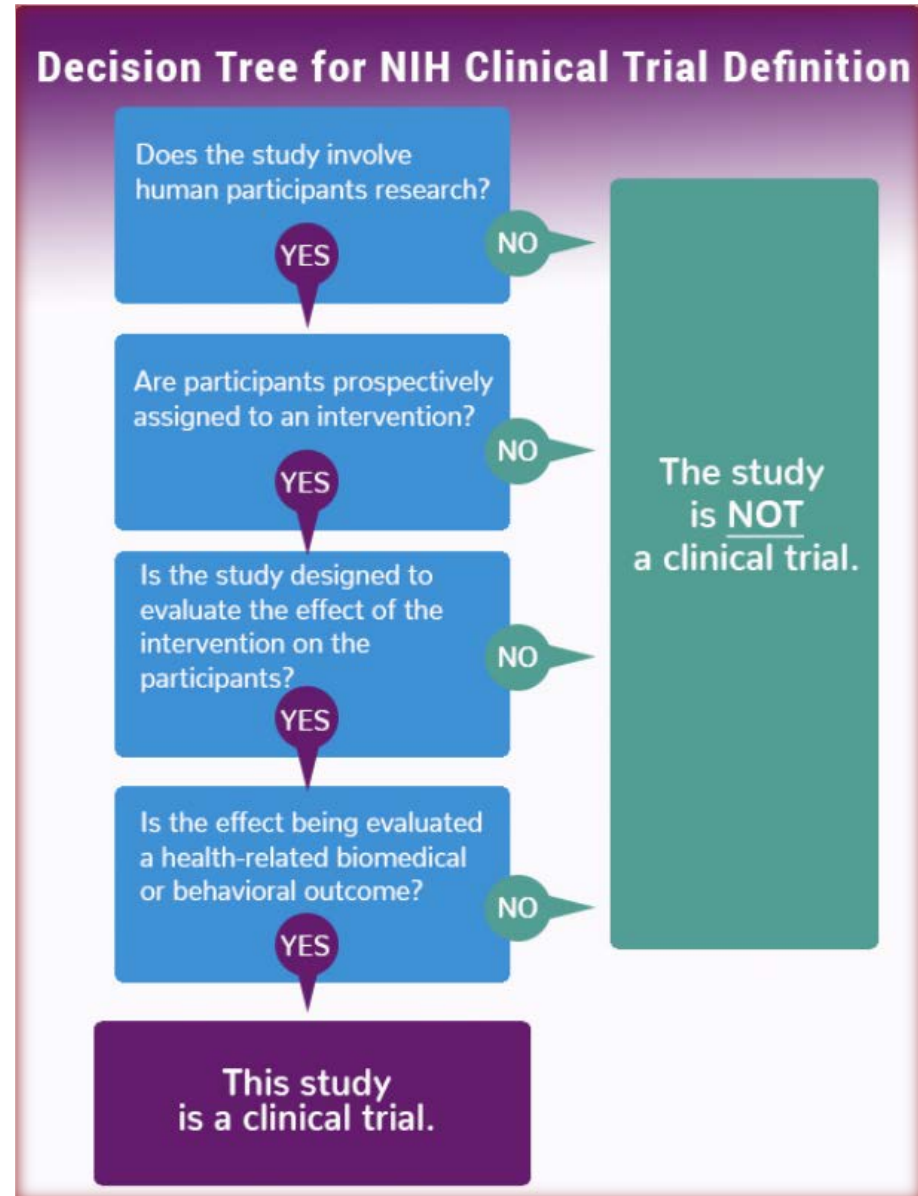
## Examples of FOAs

- PA-17-487 New Onset Depressive Symptoms in Acute Illness (R21 **Clinical Trial Not Allowed**)
- RFA-DK-17-016 Lymphatics in Health and Disease in the Digestive System (R01- **Clinical Trials Not Allowed**)
- RFA-AG-18-013 Continuation of the AMP-AD Target Discovery and Preclinical Validation Consortium (U01 **Clinical Trial Optional**)
- PA-17-492 Addressing Chronic Wound Trajectories Through Social Genomics Research (R01- **Clinical Trial Optional**)



# How to prepare for these changes?

- If the project involves human subjects research, use decision tree to determine whether study meets the NIH definition of a clinical trial.
- These case studies may be helpful in determining whether CT = Yes.
- If CT = Yes, make sure the FOA to which the PI is responding supports clinical trials.
- If CT=Yes, make sure researchers on the study complete GCP training before the award arrives.
  - CITI - Group 7 for medical research or
  - CITI - Group 2 for non-medical researchers.





ClinicalTrials.gov and the NIH Policy on the Dissemination  
of NIH-Funded Clinical Trial Information

SPECTRUM CLINICAL RESEARCH QUALITY (CRQ)

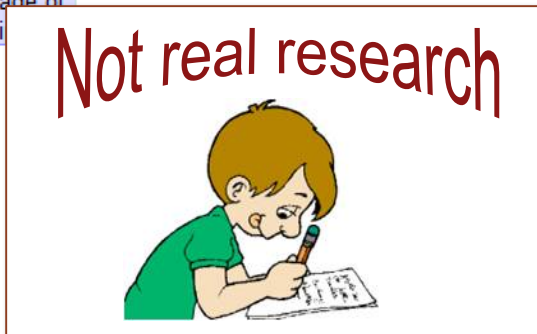
*ABCs OF RESEARCH, OCTOBER 10, 2017*

# Outcome Measure for This Session

- Percentage of participants with more questions about ClinicalTrials.gov after a ClinicalTrials.gov presentation compared to prior to the presentation
- Time frame: Baseline to end of presentation (approximately 15 minutes)



Arm/Group Title	All Participants
▼ Arm/Group Description:	Participants enrolled in the Administrators Building Competencies (ABCs) in Research meeting to get quarterly updates to research policy and procedures, including a 15-minute introductory overview of ClinicalTrials.gov.
▼ Analysis Population Description	15 participants who left in the middle of the presentation were not included in this analysis.
Overall Number of Participants Analyzed	167
Number (95% Confidence Interval) Unit of Measure: percentage of partici	100 (99.9 to 100)



# Background

- 2000: ClinicalTrials.gov registry (FDA Modernization Act)
  - › Basic registration information – for lay audience
- 2005: Publishers require registration of interventional studies prior to enrollment<sup>1</sup>
- 2008: Results database (FDA Amendments Act)
  - › Basic summary results
- 2017 Developments
  - › ClinicalTrials.gov regulations
    - Clarification/expansion of legal requirements
  - › NIH Policy on Dissemination of Clinical Trial Information
    - Expands ClinicalTrials.gov requirements to all NIH-defined, NIH-funded clinical trials

<sup>1</sup> International Committee of Medical Journal Editors (ICMJE) [Clinical Trial Registration Policy](#)

# ClinicalTrials.gov & Protocol Registration and Results System (PRS)

- [ClinicalTrials.gov](https://www.clinicaltrials.gov)
  - › The Public Site
  - › Research here – study design, statistical methods, has it been tried already?... etc.
- PRS: [register.clinicaltrials.gov](https://register.clinicaltrials.gov)
  - › The interface that researchers use for data entry
  - › CRQ helps manage access



## Who's Responsible?

- Each ClinicalTrials.gov study record has a *Responsible Party*
  - › Sponsor by default
    - ClinicalTrials.gov defines sponsor as the individual or entity that initiates the project – **not related to external funder**
  - › The sponsor can designate a principal investigator

*In general at Stanford...*

Study Type	Who is the Responsible Party?
IND/IDE Study	The investigator holding the IND or IDE
Non-IND/IDE Study	The investigator who wrote the protocol



# Applicable Clinical Trial (ACT)

- Registration and Result Reporting required
- Applicable device clinical trial
  - › A **prospective** clinical study of **health outcomes comparing an intervention** with a device product **against a control** in human subjects (excluding device feasibility studies)
- Applicable drug clinical trial
  - › A **controlled clinical investigation** of a drug or biologic (excluding phase 1 studies)
- Controlled
  - › If there is  $\geq 1$  study arm (group) and  $\geq 1$  pre-specified outcome measure it is controlled for purposes of ClinicalTrials.gov
  - › Some types of controls: active control, placebo, dose-comparison, historical control, participant's own baseline data

# Applicable Clinical Trial (ACT) Checklist<sup>1</sup>

1. Is the study interventional?
  - › ClinicalTrials.gov definition: Participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health related outcomes
  
2. Is at least one of these true?
  - › ≥ 1 US location... OR conducted under IND/IDE... OR product used manufactured and exported from US?
  
3. Is it studying an **FDA-regulated drug/biologic/device intervention**?
  
4. Is it not phase 1 or device feasibility?

<sup>1</sup> [https://prsinfo.clinicaltrials.gov/ACT\\_Checklist.pdf](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf)

# Resources for Determining Applicable Clinical Trial (ACT)

- ACT Checklist and elaborations on ACT definition
  - › [https://prsinfo.clinicaltrials.gov/ACT\\_Checklist.pdf](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf)
- ACT FAQs
  - › <https://clinicaltrials.gov/ct2/manage-recs/faq#Content42CFRPart11>
- ClinicalTrials.gov FAQs
  - › <https://clinicaltrials.gov/ct2/manage-recs/faq>

## NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

- Registration and Result Reporting required
  - › Same as Applicable Clinical Trial
- **In Scope:**
  - › NIH-defined clinical trials that receive direct NIH-funding
    - If part of application filed on/after 1/18/2017, and initiated on or after that date
    - Requirements noted in the terms and conditions of the NIH grant award notice
  - › All interventions
  - › Includes phase 1 (drug/biologic) and device feasibility
- **Not in scope:**
  - › Observational studies (i.e., not NIH-defined clinical trials)
  - › Studies that utilize NIH-funded infrastructure but receive no direct NIH funding

# NIH Clinical Trial Definition Checklist<sup>1</sup>

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

<sup>1</sup> <https://grants.nih.gov/ct-decision/index.htm>

# Resources for Determining NIH-Defined Clinical Trial

- Clinical Trial Definition
  - › <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html>
- Online Checklist: “Does your human subjects research study meet the NIH Definition of a clinical trial?”
  - › <https://grants.nih.gov/ct-decision/index.htm>
- NIH Definition of Clinical Trial Case Studies
  - › <https://grants.nih.gov/policy/clinical-trials/case-studies.htm>
- Clinical Trial Definition FAQs
  - › [https://grants.nih.gov/grants/policy/faq\\_clinical\\_trial\\_definition.htm](https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm)

# Other Requirements

- ICMJE (publication)
  - › Registration required prior to enrollment as precondition for publication
  - › Results reporting is encouraged but not required
  
- Voluntary submission
  - › A Responsible Party can voluntarily submit registration information, or results information, or both
  - › Voluntarily submissions must be complete, the same information as if submission is required, **including study documents when submitting results**



## Study Documents – Required with Results Reporting

- New requirement
  - › Protocol and statistical analysis plan
  - › Protocol amendments
- Spectrum CRQ is developing guidance
- If you think you need to submit study documents...
  - › Please contact CRQ first ([clinicaltrials-gov@stanford.edu](mailto:clinicaltrials-gov@stanford.edu)), to understand the requirements and if they apply to your study

# Overview of Requirements and Enforcement

	NIH Policy	Law/Regulations	ICMJE Policy
Scope	NIH-funded clinical trials	Applicable Clinical Trials	Interventional Clinical Trials
Registration Required?	<b>Yes</b> (within 21 days of enrollment)	<b>Yes</b> (within 21 days of enrollment)	<b>Yes</b> (prior to enrollment)
Results Required?	<b>Yes</b> (1 year after Primary Completion Date)	<b>Yes</b> (1 year after Primary Completion Date)	<b>No</b>
Phase	All	Excludes phase 1 (drug) and device feasibility	All
Intervention Type	All (e.g., including behavioral, etc.)	All FDA-regulated drugs, biologics, and devices	All
Funding Source	NIH	—	—
Enforcement	Loss of NIH funding <ul style="list-style-type: none"> <li>• Funding for individual investigators</li> <li>• Funding for Stanford University</li> </ul>	<ul style="list-style-type: none"> <li>• Civil penalties (up to \$10,000/day)</li> <li>• Criminal proceedings</li> <li>• Loss of HHS funding to study and/or institution</li> </ul>	Refusal to publish

# Spectrum CRQ ClinicalTrials.gov Resources

- We can set up your Stanford PRS account and give access to study records
- Education
  - › 1:1 training and assistance
  - › Small group training
  - › Clinical Research Operations Program (CROP) classes
- Help documents
  - › Spectrum Website (ClinicalTrials.gov support)
  - › Registration how-to guide (by email request)
  - › Results tips and how-to guide
- *Contact Us!* Email: [clinicaltrials-gov@Stanford.edu](mailto:clinicaltrials-gov@Stanford.edu)
- *Cancer studies...* Email [ccto-website@stanford.edu](mailto:ccto-website@stanford.edu)



# Industry Sponsored Clinical Trial Project

Tim Reuter | ORA

October 10, 2017

# Project Overview

Improve business processes and systems associated with Industry Sponsored CT PTA set-up, sponsor billing, collections and closeout, in partnership with the SoM

## CRISP Improvements

- Redesign CRISP to enhance user experiences
- Provide comprehensive training and improve communications

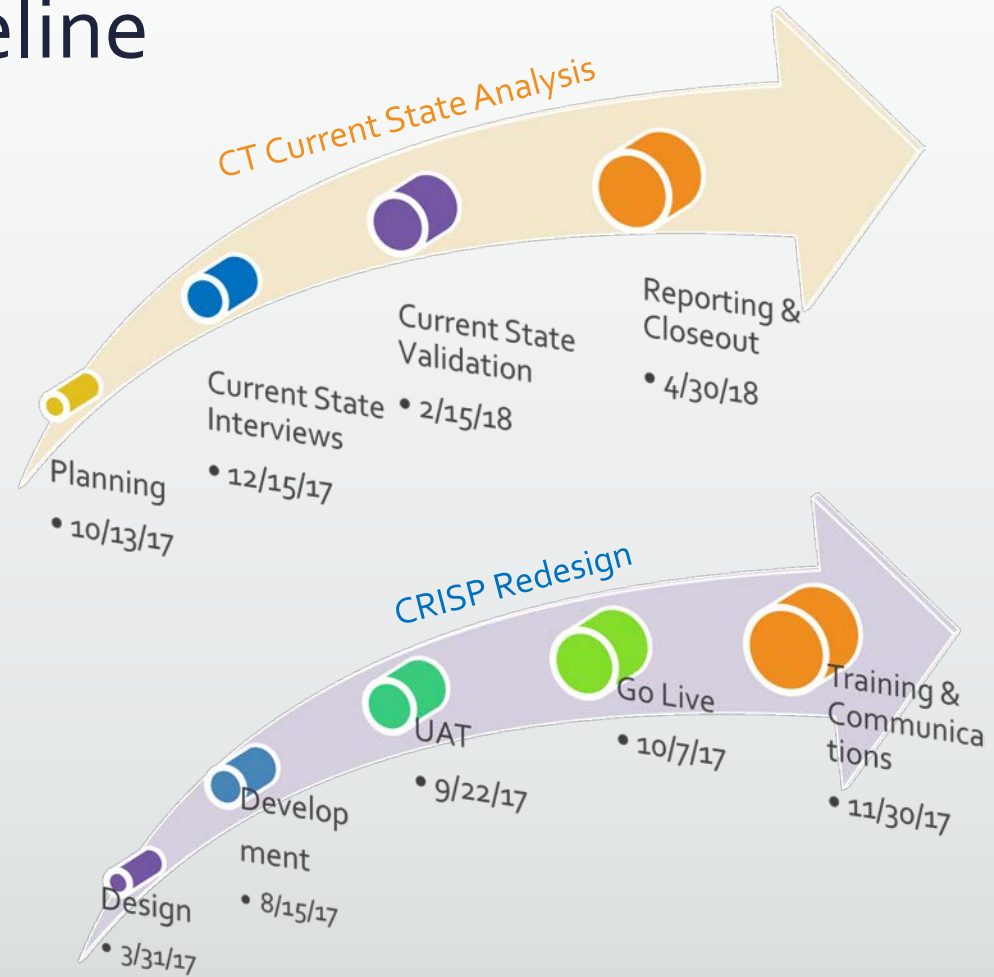
## Current State Analysis

- Understand and document CT account set-up, sponsor billing, collection and closeout
- Identify areas to focus for potential improvement efforts in the future

SMART  
Meeting  
10/17/17



# Timeline



# CRISP New Look

First Release live - 10/7/17

- All Trials are now organized in context of SPO#
- Pages have been rearranged in logical order for easier, more self-intuitive navigation, and fewer clicks
- Interactive Grid with Excel like features has been introduced for all multiple data entry pages
- Introduced a 'Global search'. Search can be performed by SPO, Award, PI, Invoice#, and Request ID
- Multiple fees and attachments can be added to an invoice request at the same time
- Invoice Requests are now separated between Per Subject Fees and Invoiceable Items
- Trial Attachments page has been added as a global repository for attachments per trial...



# Need Help?

Stanford University | CRISP

Help

User Guide

HelpSU

Contact

**CRISP**  
Clinical Research Invoicing  
System for Participants

**CRISP has a new look!** The system has been enhanced to improve user experience. A few notable changes you will see are - the trials are now organized by SPO Number, pages have been rearranged in a more logical order, and you now have the ability to add multiple fee schedules to an Invoice Request. To explore all of the new features and updates, please click on the "Help" link in the left-hand navigation column to watch a full video demo and view the updated User Guide.

Clinical Research Invoicing System for Participants (CRISP) supports communication between the School of Medicine Departments and the Sponsored Receivables Management Group (SRM). CRISP enables tracking of patient events and invoiceable items on all sponsored clinical trials, and facilitates the processing of sponsor invoices.

If you need help, please submit requests by clicking on the Help/HelpSU link on the left side of the page, or by calling (650) 725-0086.

Proceed

For questions, please contact Chris Nodohara at (650) 725-1786, [cnodohara@stanford.edu](mailto:cnodohara@stanford.edu)

# Looking Ahead

- Engage SoM Dept. representatives in development of comprehensive training and improving communications
- Ongoing and incremental improvements in CRISP and related processes in future releases



# eCertification for Quarterly Review & Certification

Ken Schulz  
ABC 10/10/2017

# Automation of the Quarterly Review and Certification Process?

- Provide faculty and staff an efficient and effective process for reviewing & certifying expenditures on sponsored projects in order to comply with federal requirements
- Reduce administrative burden for both faculty and staff
  - Automate the Quarterly Review & Certification Process
  - Automate the Review & Certification Record
  - Eliminate need to print and store reports
  - Eliminate Annual Payroll Distribution Certification
- Provide faculty and staff an efficient and effective support process to manage sponsored projects
  - Ability to view payroll distribution
  - Ability to drill down to see account details

# eCertification

## A New System for a Familiar Process

Demo system

- <https://sera-dev.stanford.edu/apex/f?p=703>

# PI Landing Page

Stanford University | SeRA | Quarterly Review & Certification Donald, Duck [Log Out](#)

Home Certification Quarter: Oct-Dec 2015 (Due Date: 02/29/2016)

**Welcome Donald, Duck**

The information below displays the status of your certifications. The teal buttons enable you to View Accounts and Certify, View 100% Payroll for yourself and that of staff charged to your accounts, and view Pending Comments that require attention. Please complete your certification after your designated research administrator has completed their review.

Certification Due Date : 02/29/2016

### PI Certification Progress

Certified	Remaining	Cert Not Required
1	4	1

1/5 Certified Accounts

### Research Administrator Progress

Reviewed	Remaining	Review Not Required
1	4	1

1/5 Reviewed Accounts

**View Accounts and Certify**

**View 100% Payroll**

**0 Pending Comments**

**Confidentiality Statement**  
The Quarterly Review and Certification System contains personal salary information. The reports and financial information in this system shall be used in compliance with [Stanford Administrative Guide 1.1.1 University Code of Conduct: Section \(3\) Confidentiality and Privacy](#).  
In using this system, I agree to comply with all applicable federal and state privacy laws and University policies concerning confidential personal and financial data; and I understand that a breach of this agreement can be cause for disciplinary action, up to and including termination of employment.

# eCert Roadmap October-December 2017

- System Readiness – October
  - Complete pilot with PIs and Research Administrators
- Campus readiness October-January
  - Information Meetings for Sr. Associate Deans, DFAs, School Overseers
  - Roadshows for Research Administrators in each school
  - Hands-on training in labs for Research Administrators
  - PI and Research Administrator Briefing Document
  - User Guide in the eCertification System
- Rollout December 2017
- First Review and Certification of Fall Expenditures Jan to March 2018
  - Research Administrators Jan 15<sup>th</sup> to February 14<sup>th</sup>
  - PIs February 15<sup>th</sup> to March 14<sup>th</sup>



Questions?

# Grants.gov PDF Package Retirement

MEGAN DIETRICH, OSR & SONIA BARRAGAN, RMG

ABC Meeting

10/10/17

# Why are we here?

Effective December 31, 2017, the **Grants.gov** legacy PDF application, also known as the SF424 package, will be retired and no longer available for federal proposal submissions.

## Effective January 1, 2018:

- ❖ For proposals submitted by the **Office of Sponsored Research**, please use **Cayuse 424** for **Grants.gov** federal proposal submissions where the SF424 had been previously used.
  - For NSF proposals, OSR continues to support Fastlane
  - For NASA proposals, OSR can support NSPIRES or **Cayuse 424**
  
- ❖ For proposals submitted by the **School of Medicine (SoM) - Research Management Group (RMG)**, please work with your [Research Process Manager](#) for guidance on proposal submissions.
  - For NIH proposals, SoM continues to support ASSIT
  - For NSF proposals, SoM continues to support Fastlane
  - All other federal agencies currently using PDF application packages, should use **Cayuse 424** effective January 1, 2018

# What about NIH proposals that include faculty from the SoM *and* other Stanford schools?

## It Depends:

- ❖ If the lead PI is from the SoM, the application will be built in and submitted from **ASSIST**
  - Non-SoM dept. staff should coordinate with their SoM dept. counterpart(s) to provide the requisite application information & attachments
- ❖ If the lead PI is not from the SoM, the application will be built in and submitted from **Cayuse 424**
  - SoM dept. staff should coordinate with their non-SoM dept. counterpart(s) to provide the requisite application information & attachments

# How do I access Cayuse 424?

- ❖ From your <https://sera.stanford.edu> dashboard select on Navigate & then Cayuse 424
- ❖ If you do not have user access you can submit a SeRA Help Ticket or email Megan Dietrich [reymar@stanford.edu](mailto:reymar@stanford.edu)
- ❖ Firefox is the preferred browser for Cayuse 424.

The screenshot displays the Stanford SeRA dashboard interface. The top navigation bar includes a search field, a 'Navigate' dropdown menu, and a 'Help' button. The 'Navigate' dropdown is open, showing a list of options: Cayuse 424, eCertification, eProtocol, IDC Waivers, OPACS, and Stanford Profiles. A red arrow points to the 'Cayuse 424' option in this dropdown. On the left sidebar, under the 'Navigate to' section, the 'Cayuse 424' option is also visible, with another red arrow pointing to it. The main content area is titled 'My Dashboard' and features a 'My Action Items' section. Below this section, there is a search bar and a table with columns for 'Go', '1. Primary Report', 'Rows', 'All', and 'Actions'.

# Cayuse 424 Features

- ❖ Peer network
  - 150+ institutions use Cayuse 424
  - Cayuse 424 has been at Stanford since 2015
- ❖ Preloaded faculty, staff & inst. profile info for convenience
- ❖ Access Customization
- ❖ Version Control
- ❖ Easy searching for solicitations
- ❖ Real time error & warning counting/validation
- ❖ Easy printing
- ❖ Excellent customer support
- ❖ Integration with SeRA – coming soon!

# Cayuse 424 Support & Training

## ❖ Upcoming Trainings:

- Wednesday, October 18, 2017 - 11:00 am to 12:00 pm - Clark Center S361
- Thursday, November 16, 2017 – 1:00 pm to 2:00 om – Clark Center S361

## ❖ [Cayuse 424 on DoResearch](#)

## ❖ [Stanford Cayuse 424 Quick Guides](#)

## ❖ <http://support.cayuse.com/docs/cayuse-424>





## ❖ SeRA HelpTicket

## ❖ OSR – Client Advocacy and Education

- ❖ Tim Leung – 650-725-5966 [tnleung@stanford.edu](mailto:tnleung@stanford.edu)
- ❖ Megan Dietrich - 650-721-2236 [reymar@stanford.edu](mailto:reymar@stanford.edu)



# ASSIST Training Documents

- ❖ ASSIST training was held in Sept and Oct.
  - Go to the [RMG website](#) and look at “What’s New”
  - Click on the link [“Using ASSIST to Prepare Proposals”](#)
    - [Sample NIH R01 Application](#) 
    - [ASSIST Training](#) 
    - [Initiating a Proposal in ASSIST](#) 
    - [Completing a Proposal in ASSIST](#) 
- ❖ In SoM, Contact your RPM
- ❖ RMG Dept Assignments :  
<http://med.stanford.edu/rmg/rpmmaster.html>

**Questions?**

