iRIS Multi-Site Enhancement: Overview and Implementation

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NIH OHSRP EDUCATION SERIES

FEBRUARY 2, 2021

NIH Office of Intramural Research
Office of Human Subjects Research Protections

Learning Objectives

- Provide an overview of the **iRIS Multi-Site Module** when the NIH IRB is reviewing protocols involving more than one institution

- Outline changes in the **iRIS workflow** for the NIH Study Team and external Participating Sites

- Review tentative timeline for implementation of the **iRIS Multi-Site Module**

Key Terms – iRIS Multi-Site Module

TERM	DEFINITION
Core Site	Term used to describe the NIH Study Team led by the NIH Principal Investigator (PI). The core site has ultimate responsibility for the conduct and integrity of the research. It serves as the main study point of contact for the NIH IRB and serves as the conduit for communication to and from Participating Sites. The core site can also be referred to as the 'Lead Site' or 'Main Site.'
Participating Site	A research site involved in multi-site research that relies on the NIH IRB to provide oversight for the site. The Participating Site can also be referred to as the 'pSite', 'local site', or 'relying site'.
Relying Institution	An institution participating in multi-site research that cedes IRB review to the NIH IRB for human subjects research consistent with the terms of a reliance agreement. The Relying Institution may involve more then one participating study site, e.g. one healthcare system may have multiple hospitals and/or clinics.
NIH IRB	The NIH IRB will serve as the Reviewing IRB. It will be responsible for reviewing human subjects research and determining that the research meets the required criteria for approval under the regulatory requirements at 45 CFR 46 and, as applicable, 21 CFR 50; 312; 812. As the reviewing IRB for a multi-site study, the NIH IRB can also be referred to as the 'single IRB (sIRB),' 'IRB of record' or 'Central IRB.'

iRIS Multi-Site Module

What is the reason for the change?

- Facilitate collaborations between NIH (serving as Core Site) and Participating Sites (pSite) relying on the NIH IRB for IRB oversight
- Provide a better mechanism for the NIH IRB to manage multi-site studies
- Promote communication and efficiency between Core Site and pSites(s)
- Distinguish Core Site actions and documents from those of the pSites
  - Core-specific and pSite-specific submissions
  - Model Informed Consent/Assent templates vs pSite-specific consents/assents

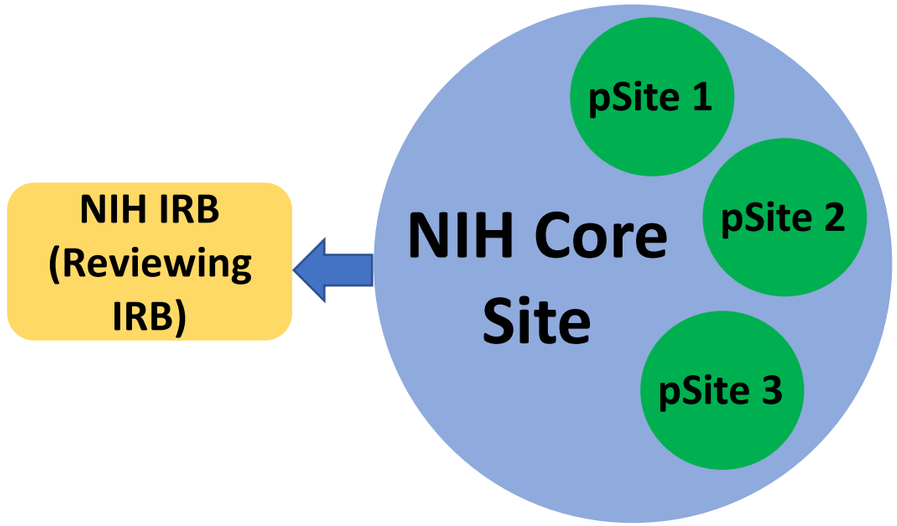
iRIS Multi-Site Module

What changes with the iRIS Multi-Site module?

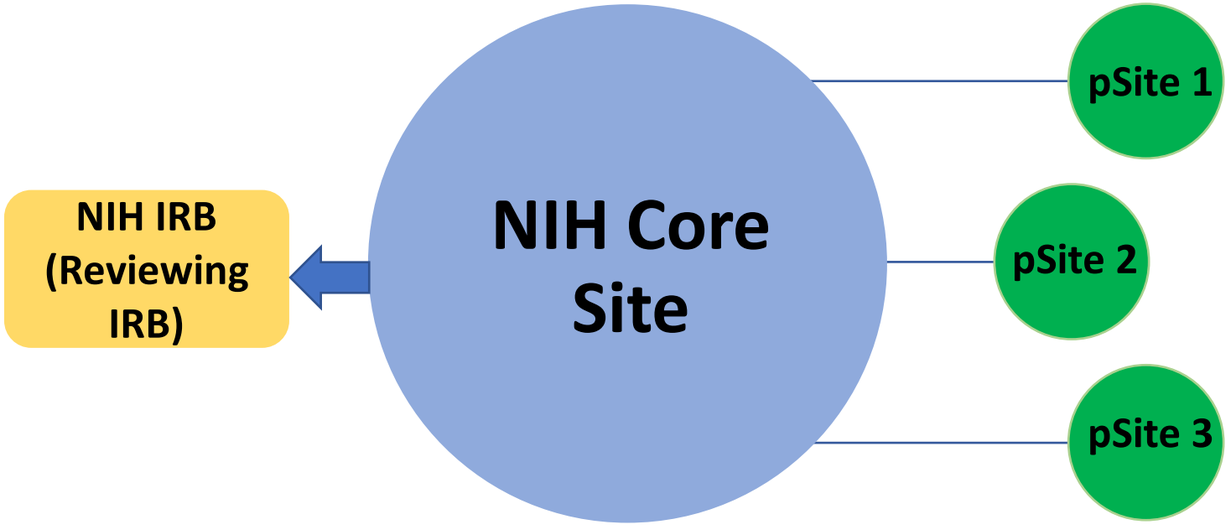
- Changes the workflow of how Participating Sites are reviewed and approved
- Introduces specific forms for the pSites
- Requires pSites to assume greater responsibility for submissions to the NIH IRB
- Facilitates Core Site PI's management of pSite submissions

Multi-Site Module Enhancement Structure

Current Approach



Planned *Future* Approach



iRIS Multi-Site Module

When should it be used?

- NIH serves as the Core Site and the Reviewing IRB for Participating Site(s)

- Does not apply when NIH:
  - Relies on an external IRB for oversight e.g., Advarra or WIRB provides IRB oversight
  - Serves as the Coordinating Center and is not the Reviewing IRB for pSites, e.g. each pSite's has local IRB review

- Legacy studies: currently no plan to convert to the iRIS Multi-Site module

iRIS Multi-Site Module

What continues to be the same?

- Initial Review of multi-site studies continues to require a two-part submission process

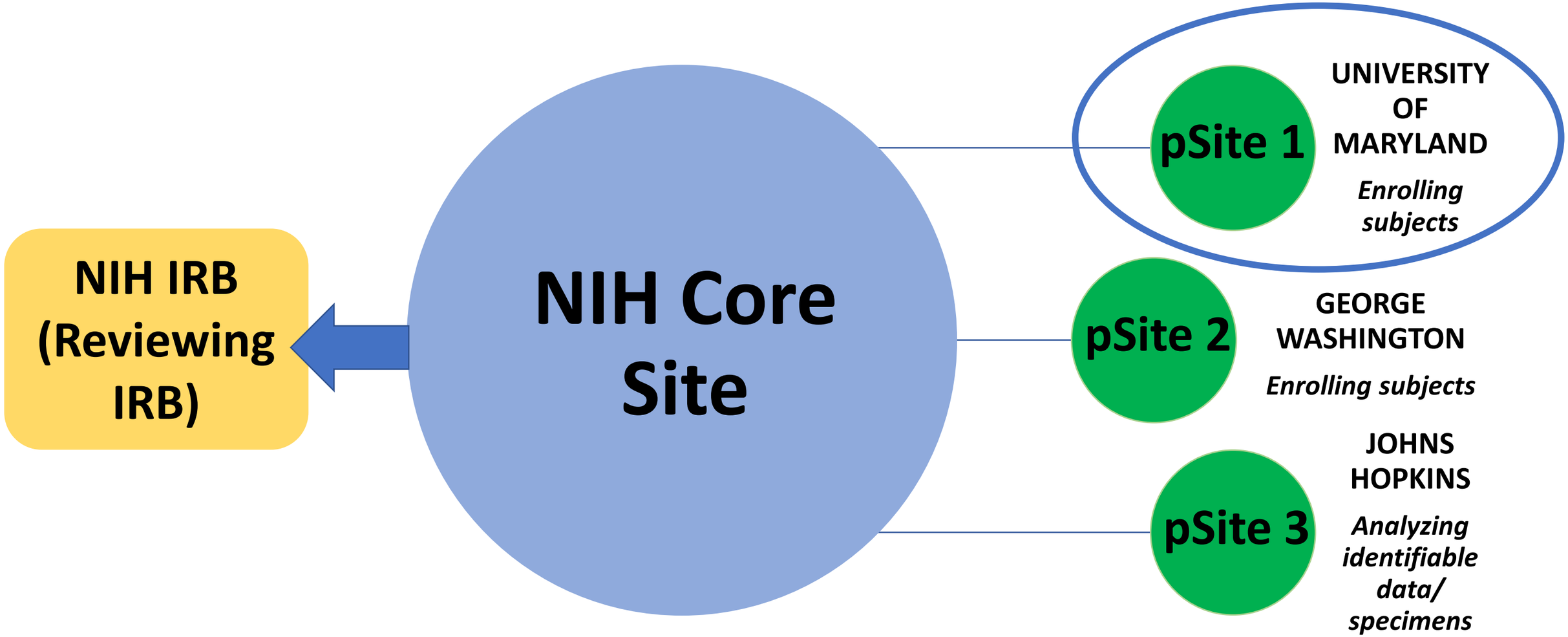
- NIH IRB reviews and approves the Initial Review submission per usual process
  - Core Site submission will be very similar to a Single Site Initial Review submission

- Participating Sites are reviewed ***after*** the Core Site is approved
  - NIH IRB will review the submission to approve a Participating Site ***after*** the Reliance Agreement is in place

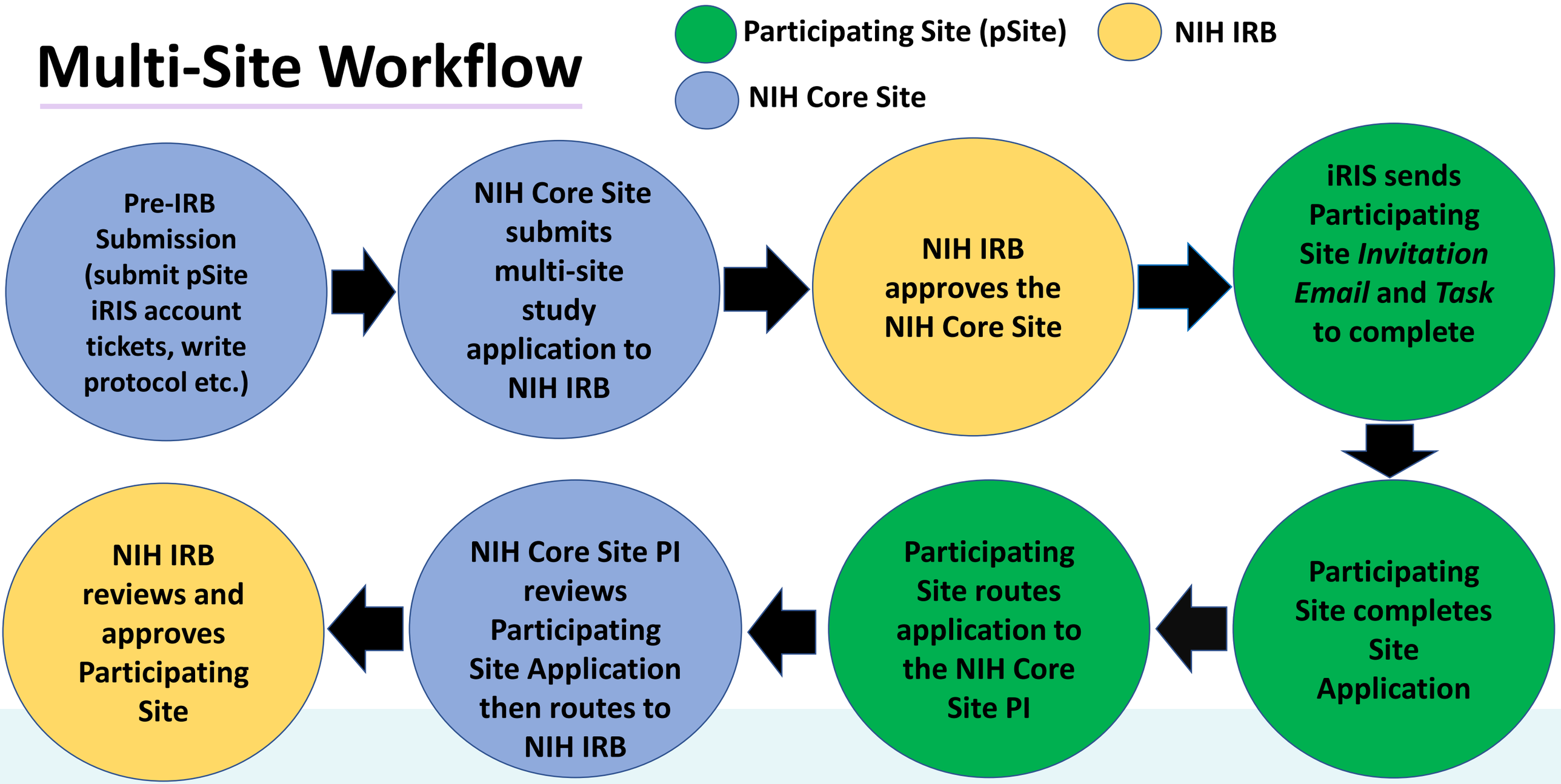
- NIH Reliance/sIRB overview available in OHSRP Education Session (August 2020)

Multi-Site in iRIS

Multi-Site Module Enhancement Structure



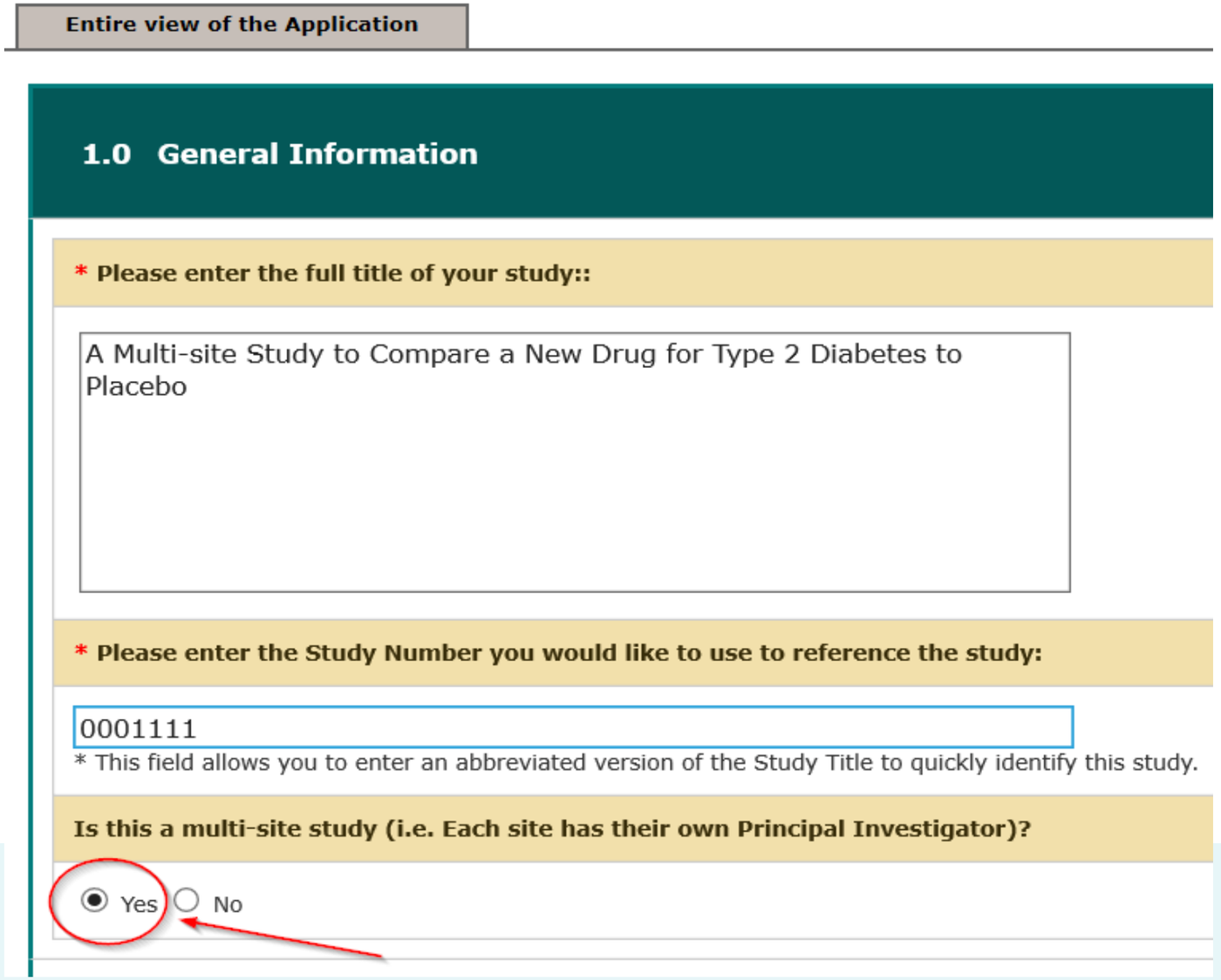
Multi-Site Workflow



NIH Core Site Completes Study Application

NIH Core Site

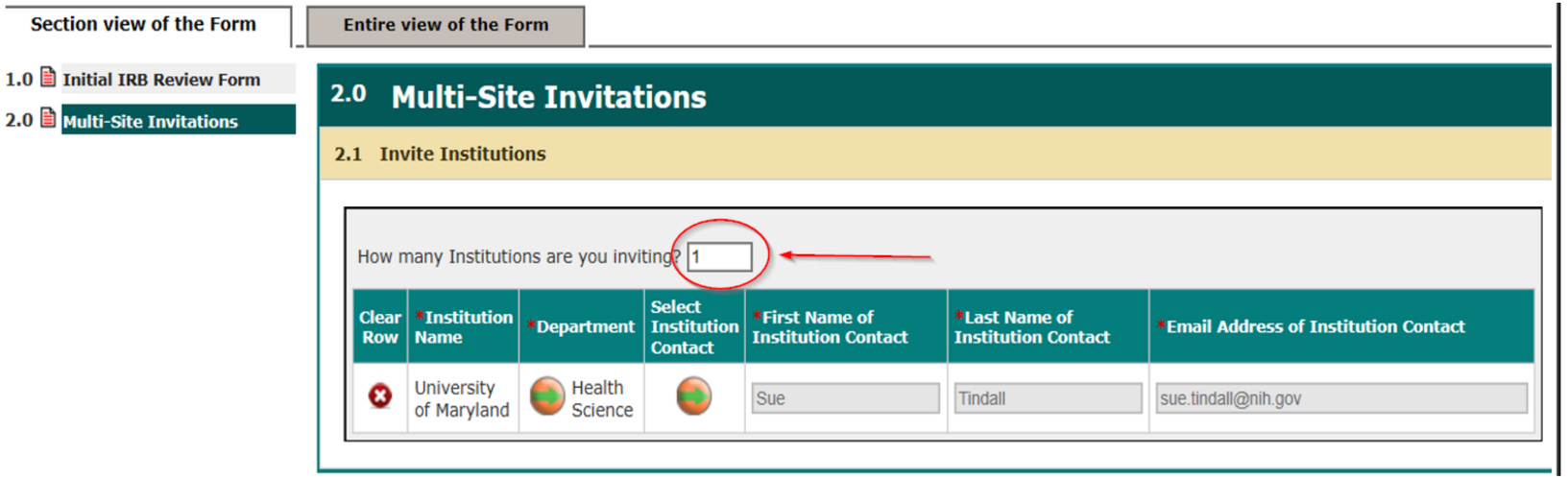
- NIH Core Site completes the Study Application.
  - Within the Initial Study Application, they will select “Yes”.
  - This triggers the multi-site portions of the Study Application going forward.



NIH Core Site Selects Participating Sites

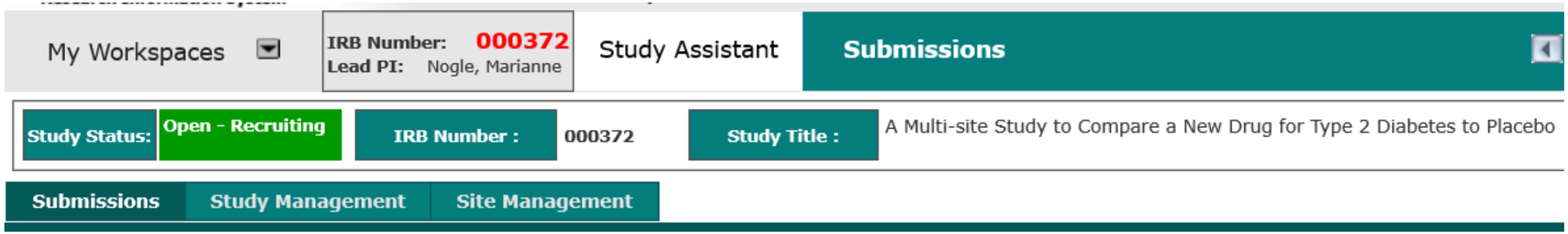
NIH Core Site

- After completing the Initial Study Application, the NIH Core Site will be directed to the Multi-Site Invitations section of the Initial IRB Review Form.
  - In this section, the Core Site identifies Participating Site(s).
  - Invitations will be issued to these sites after the initial review is completed by the NIH IRB.



NIH IRB Reviews/Approves NIH Core Site

NIH IRB

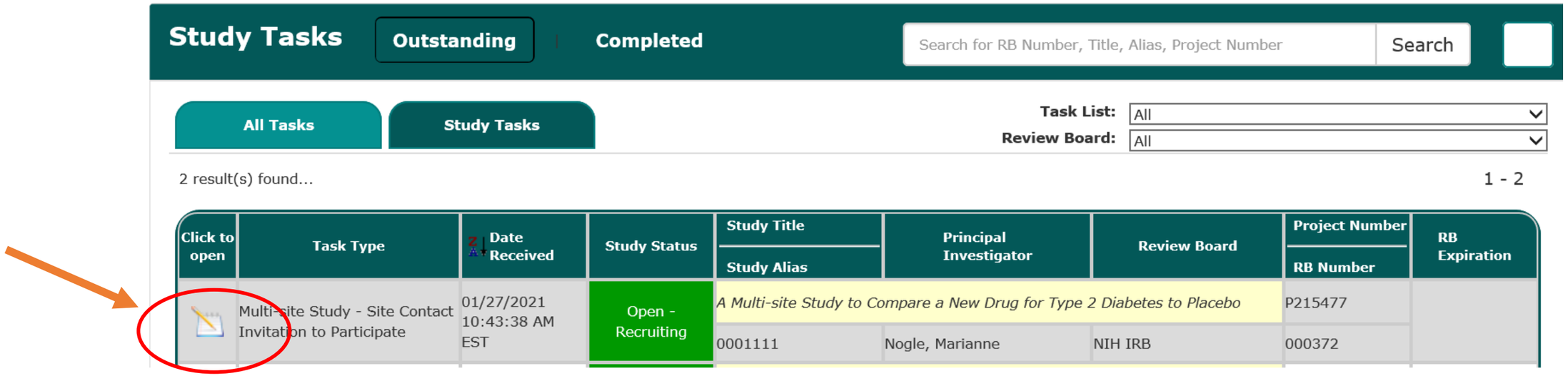


- NIH IRB reviews and approves the NIH Core Site initial review submission.
- The NIH Core Site is approved to start research activities.
- Approval of NIH Core Site triggers iRIS to send out invitations to the participating sites listed in the Initial Review form.

Participating Site Receives Invitation

Participating Site

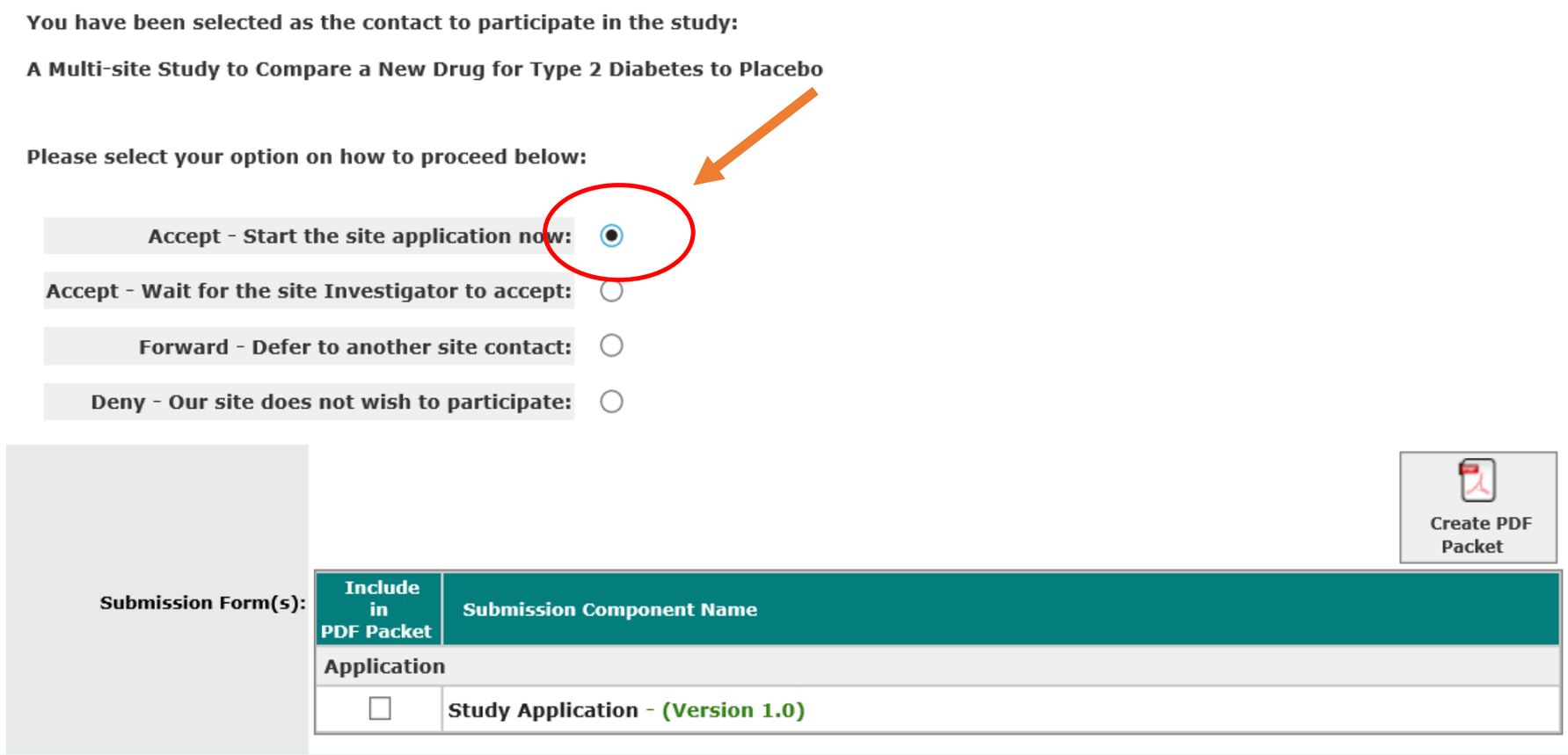
- **The Participating Site is sent a study invitation e-mail and a task will appear in iRIS.**



Participating Site Accepts Invitation

Participating Site

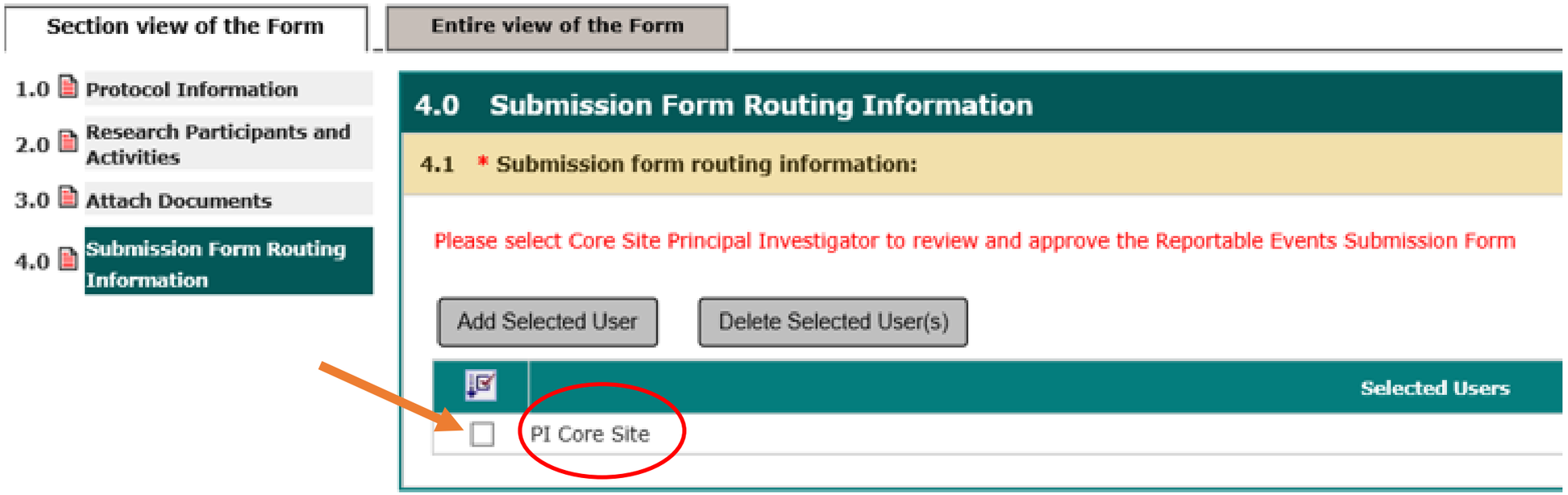
- **Participating Site accepts the invitation to begin working on its Site Study Application.**



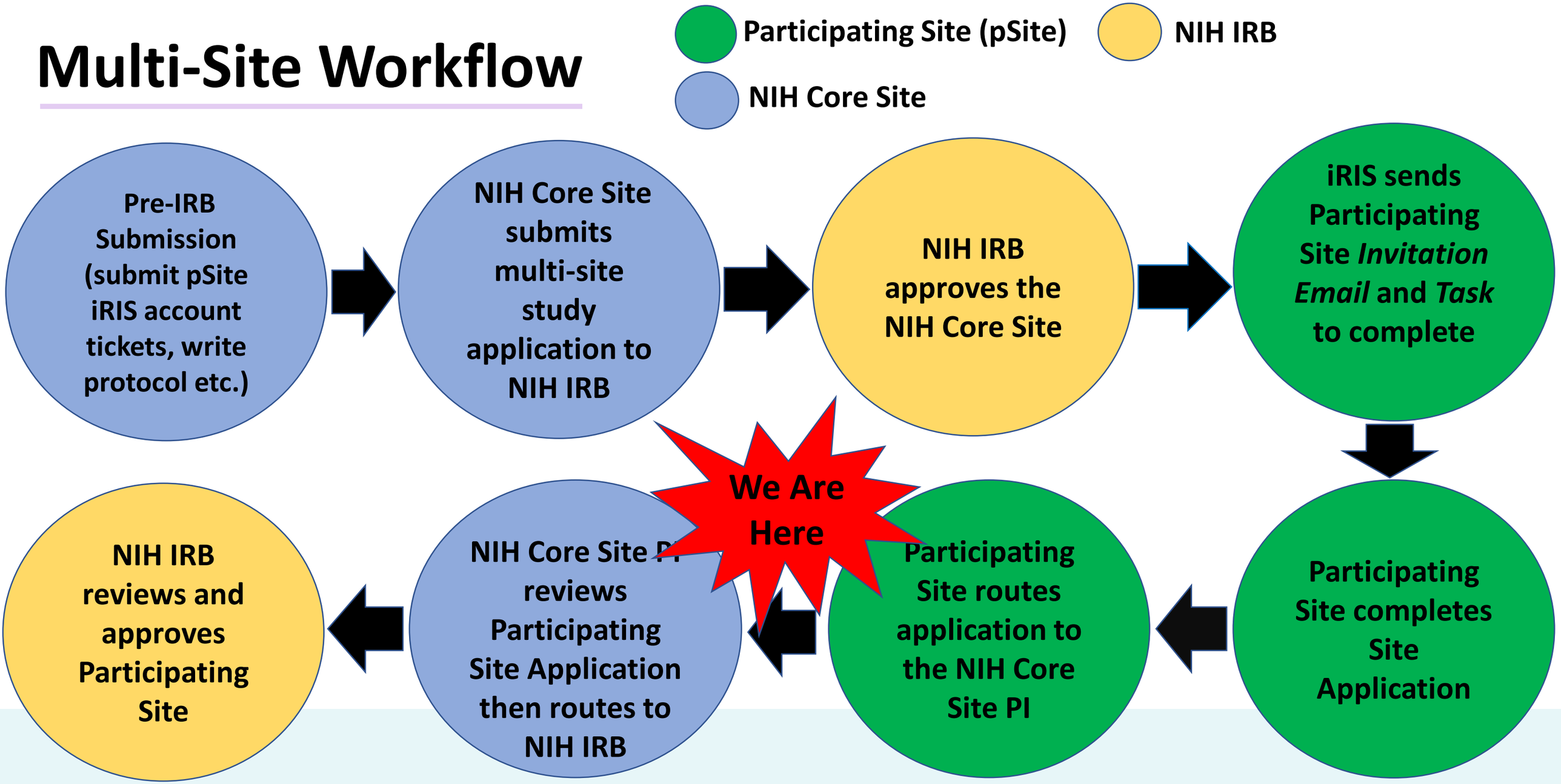
Participating Site Completes Site Application

Participating Site

- Participating Site completes the Site Application and attaches supporting documents e.g., protocol site addendum, site consents etc.
- Submission is then routed to the NIH Core Site PI to review.



Multi-Site Workflow

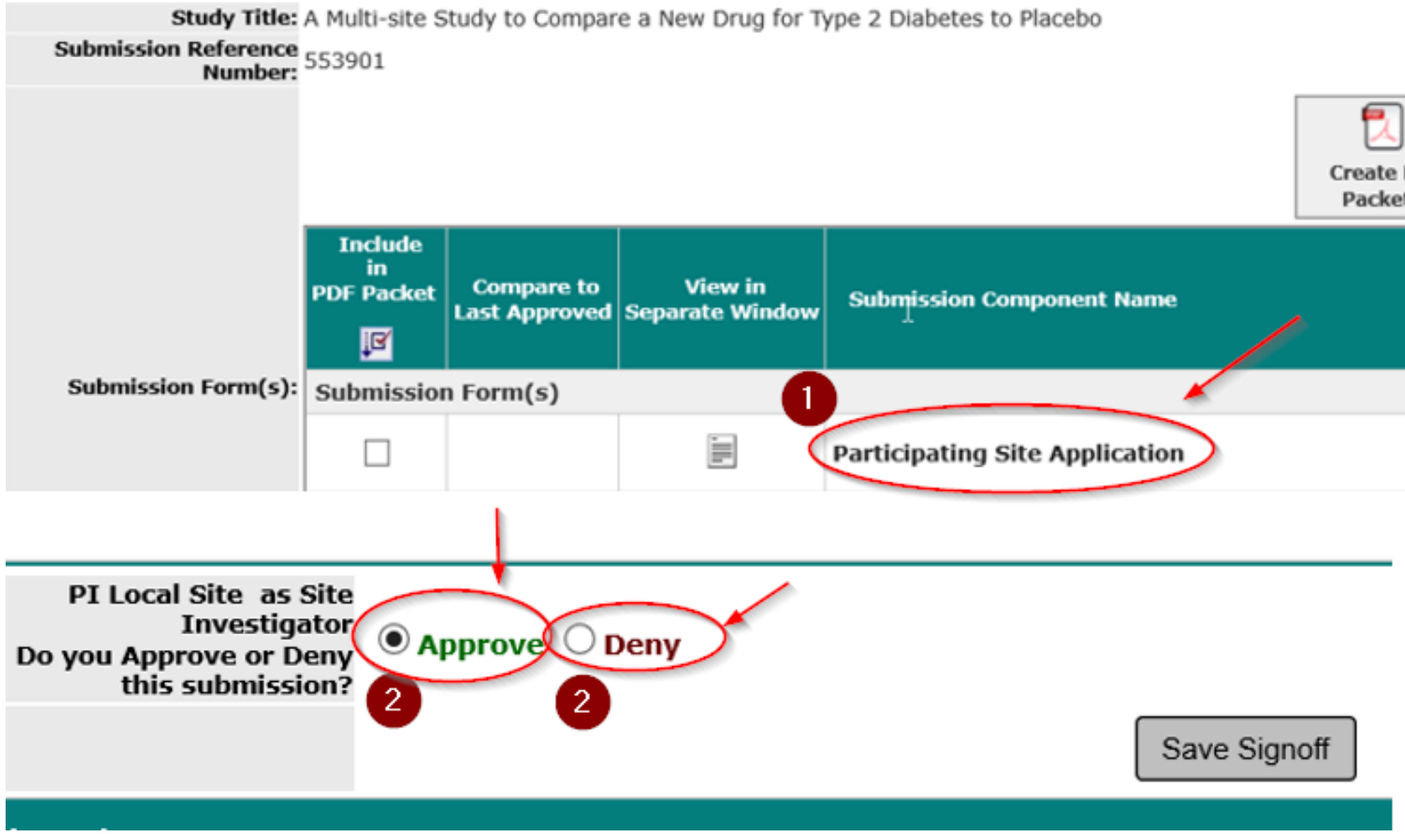


NIH Core Site PI Receives Sign-off Task

NIH Core Site

NIH Core Site PI:

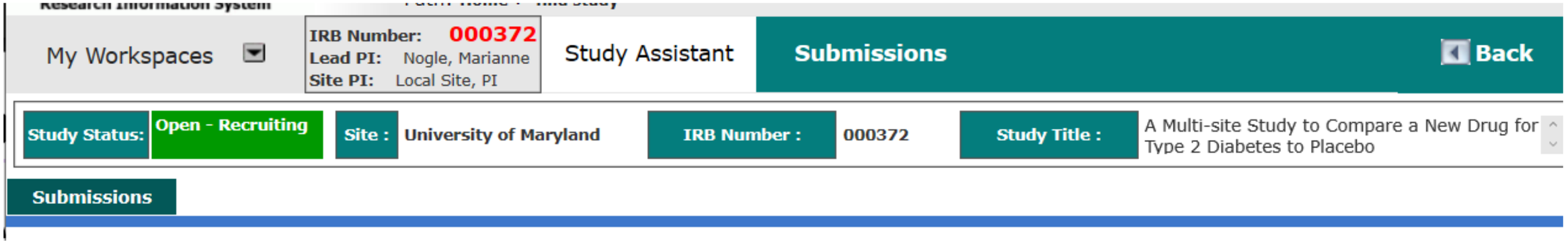
- Receives a sign-off task in iRIS
- Reviews the Participating Site Study Application
- Determines if it is ready to submit to the NIH IRB.
  - <u>Deny</u>
    - Further information is needed, or required documentation is missing.
    - iRIS provides PIs with a text box to explain the reason for denying the submission to the pSite.
    - The pSite carries out changes and can then re-submit to Core Site PI.
  - <u>Approve</u>
    - The submission is complete and consistent with Core Site expectations of the pSite.



Participating Site Receives Approval

Participating Site

- **The NIH IRB will review and approve the Participating Study Application and supporting documents.**
- **Once approved, the Participating Site will be issued a Site Approval Letter.**



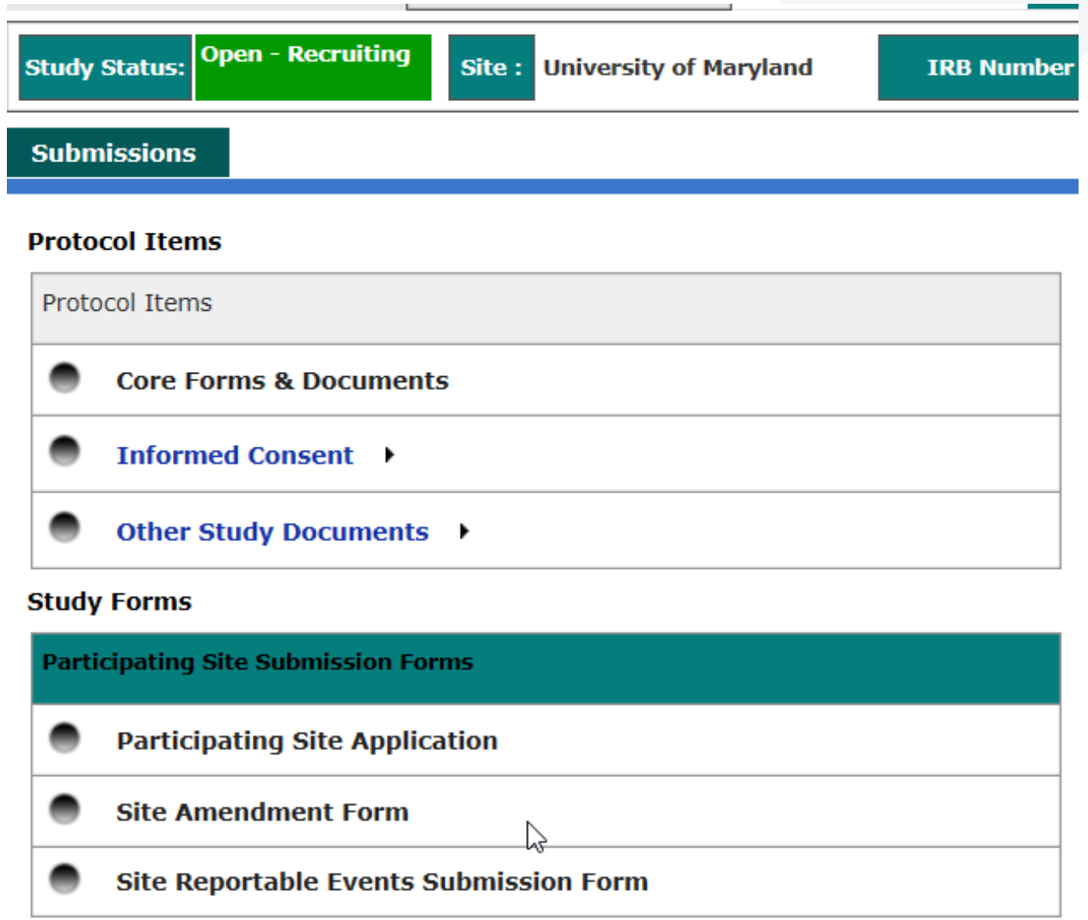
After Participating Site Approval

Participating Site

After approval, participating sites can submit the following site-specific actions to the NIH IRB:

- **Amendments**
- **Reportable Events**

Before reaching the NIH IRB, each pSite submission gets routed to the NIH Core Site for sign-off. If accepted, the action is submitted to the NIH IRB.



Implementation

- **Target Date**
  - End of First Quarter 2021 (March)

- **Rollout Plan**
  - NEW Multi-Site Studies

  - Existing Multi-Site studies where NIH is the Reviewing IRB will continue in iRIS as usual.

Training

- **Conducted by the iRIS Training Team**
- **Recurring training sessions before go-live.**
- **User Guides**
- **1 on 1 training is available.**

Summary

- Participating Sites function under the umbrella of the Core Site in a tangible way

- Main changes from current practice:
  - Introduces specific forms for the pSites
  - pSite iRIS account tickets are submitted by the Core Site Study Team
  - After Core Site receives Initial IRB approval, each pSite receives an invitation via iRIS to complete a pSite Study Application
  - The NIH IRB approves a Participating Site following review of a pSite Study Application and supporting documents; this will no longer be done via an amendment

- Multi-Site Module should hopefully provide efficiencies and simplify the review process

Summary of iRIS Multi-Site Forms

Core Site	Participating Site*
Core Site Study Application	**Participating Site (pSite) Application (*new)*** *Submitted after Reliance Agreement in place*
Amendment Form *Overall and/or NIH-specific*	**Site-Specific Amendment (*new)***
Reportable Event Form (Overall and/or NIH-specific)	**Site-Specific Reportable Event Form (*new)***

*** Proposed pSite forms; subject to change**

Contact Us

NIH IRB Reliance & sIRB Team

For further guidance or questions:

Web: Reliance and sIRB IRBO webpage

Email: NIH-Reliance-sIRB@nih.gov

NIH iRIS Support

Customer Service Support Team:
iRIS Training Team: iris_training@od.nih.gov
(for training needs and/or general 'how to' assistance when using the iRIS system)

iRIS IT Technical Support Team: https://iris.helpdesk.nih.gov
(for technical issues, e.g., account setups/issues, error messages, glitches, etc.)