DOM Research Information Session: *New Scientific Review Process*

Purpose

Document the scientific rigor

Provide methodologic guidance and support

Create efficiency in the pre-review of IRB submissions

Committee

Vera Bittner, MD, MSPH will chair the committee

Committee will initially consist of 8 faculty

- Gerontology/Geriatrics/Palliative Care
- Immunology/Rheumatology
- Infectious Disease
- Nephrology
- Preventive Medicine
- Pulmonary
- Medicine & CCTS

Additional faculty can be invited

- Content experts
- Increased workload

Which protocols need to be **submitted**?

All protocols will be submitted to the DOM SRC portal

Portal will be staffed by CCTS

Protocols will be logged in and routed through the system

Which protocols will need a **review**?

Protocols that have not received a full external peer review

- Investigator initiated protocols
- Pilot projects
- Clinical trial protocols
- Protocols intended for convened (full) IRB review
- Expedited submissions

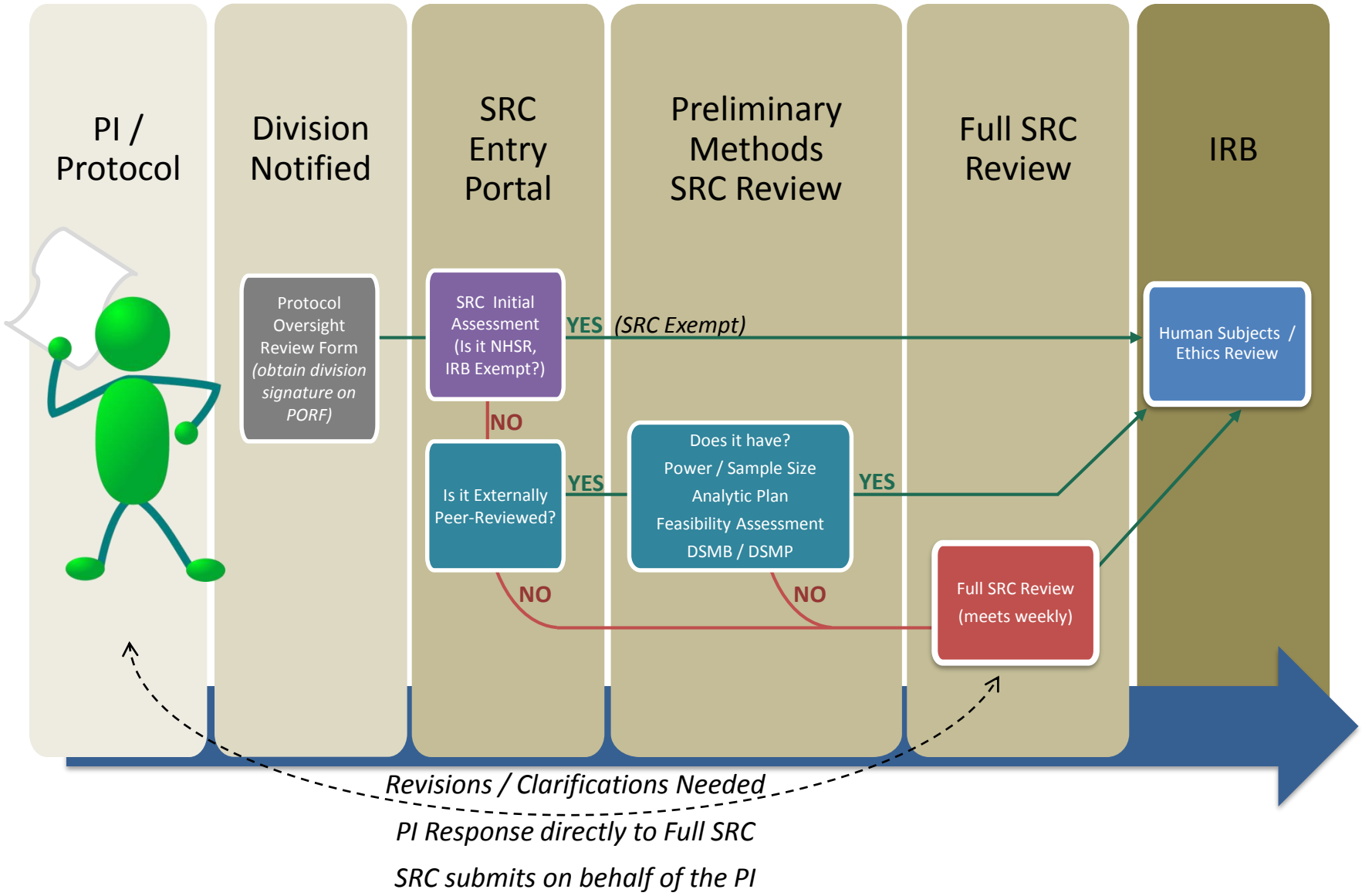
Which protocols will NOT need a **review**?

Immediate pass through to the IRB (no SRC review)

- Non-human subject studies
- Exempt submissions
- Studies with an external review with methodology sections
  - Federal or foundation funded projects that have gone through a peer-review process of its scientific validity and feasibility, including review of the protocol
  - Industry sponsored studies with an IND or IDE reviewed by the FDA

Protocols are submitted to the DOM SRC portal but will not receive a full SRC review

DOM Scientific Review Process



Process

Complete the DOM Protocol Assessment Form

Upload the entire IRB submission (HSP, ICF, etc), the protocol or grant associated, & the Assessment Form to the DOM SRC portal

Application reviewed by CCTS staff and application routed

Statistical review performed (if applicable)

Applications scheduled for full SRC committee review (if applicable)

Committee meets weekly

- Written feedback provided to investigator

Submission to the IRB

After the committee reviews the submission, the application will be submitted to the IRB on behalf of the investigator

If changes are required to the application, the investigator completes the changes and submits the revised application to the SRC

- The application is then submitted to the IRB on behalf of the investigator.

Implementation

Finalizing the committee

Finalizing forms

Installing tracking software

Update the website with the forms and guidance
- CCTS & DOM

Hold first committee meeting

Roll out across the department

Ongoing feedback with the divisions, department and CCTS

Evaluation

Approval timelines (time to committee, time at committee, time to IRB and time to IRB approval)

Quality of protocols

Satisfaction of committee members

Satisfaction of investigator

Satisfaction of submitter (if not PI)

Expedited protocols

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