Changes to the NIH IRBs and Common Rule

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DIRECTOR: OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

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DIRECTOR: IRB OPERATIONS

Key Team members

Tiffany Gommel: Director IRB Operations

Nicole Grant: Associate Director OHSRP and Executive Chair, IRB

OHSRP staff

Current staff of all IRBs

Current and future IRB members

Who I am

Clinician

Researcher

IRB professional

Why I am here

Centralize the NIH IRBs

Implement the revised Common Rule

- Effective date: January 21, 2019

Create an efficient, effective and compliant IRB system

Provide optimal protections for participants

Facilitate research

Partner with investigators

Improve IRB member experience

Keep everyone on the right side of the regulations

- Including revised CR compliance

Current State

Strengths

- Dedicated engaged membership
- Broad and deep expertise
- Committed IRB staff

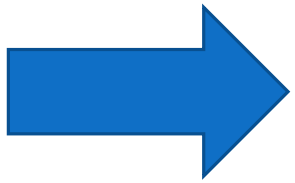
Current state

27 ICs

12 IRBs

12 IRB administrative offices

12 different ways of doing things

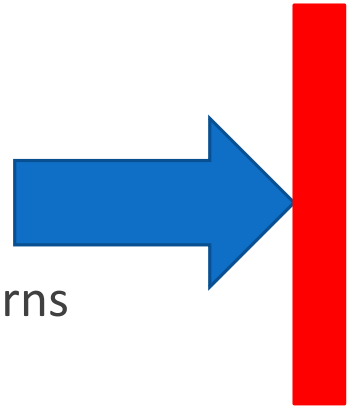


Inefficiency

Inconsistency

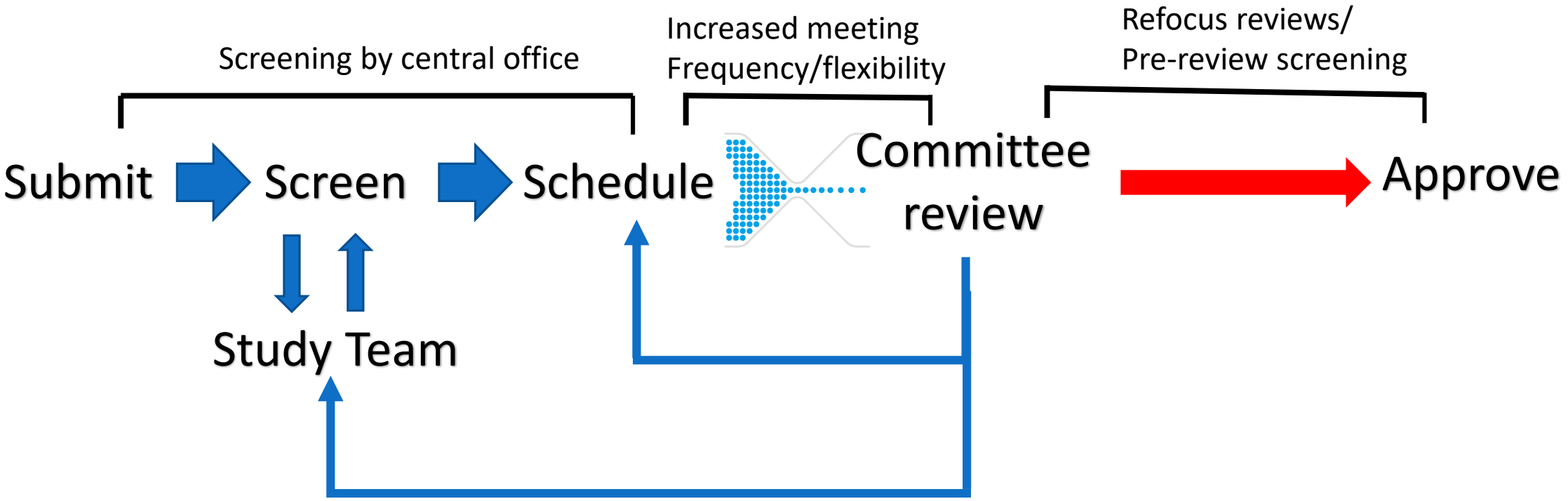
Variable quality

Best practice concerns



Revised Common Rule Compliance

System inefficiencies and bottlenecks



What we have to do

Steps to success

- Revise policies for CR compliance
- Stand up centralized administrative office
- Reorganize IRBs

Centralized administrative office

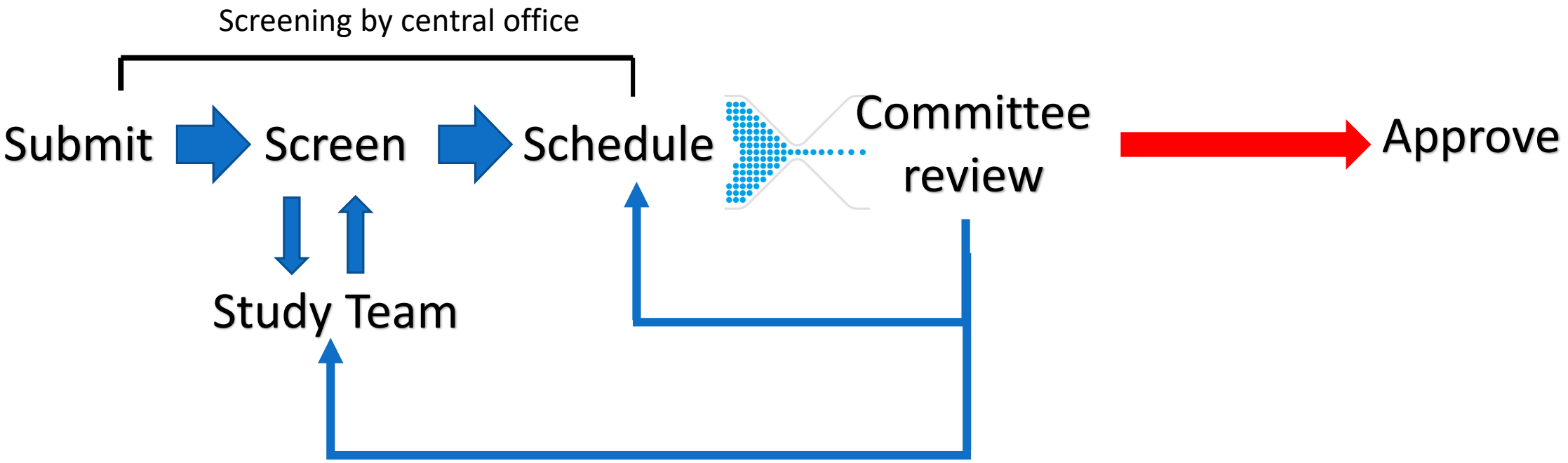
Office of IRB Operations (IRBO)

- Director: Tiffany Gommel

Functions

- Exempt/NHSR determinations
- Expedited Review
- Administrative screening for Full Board Review
- NIH iRIS system
- Coordinate sIRB activity

System inefficiencies and bottlenecks

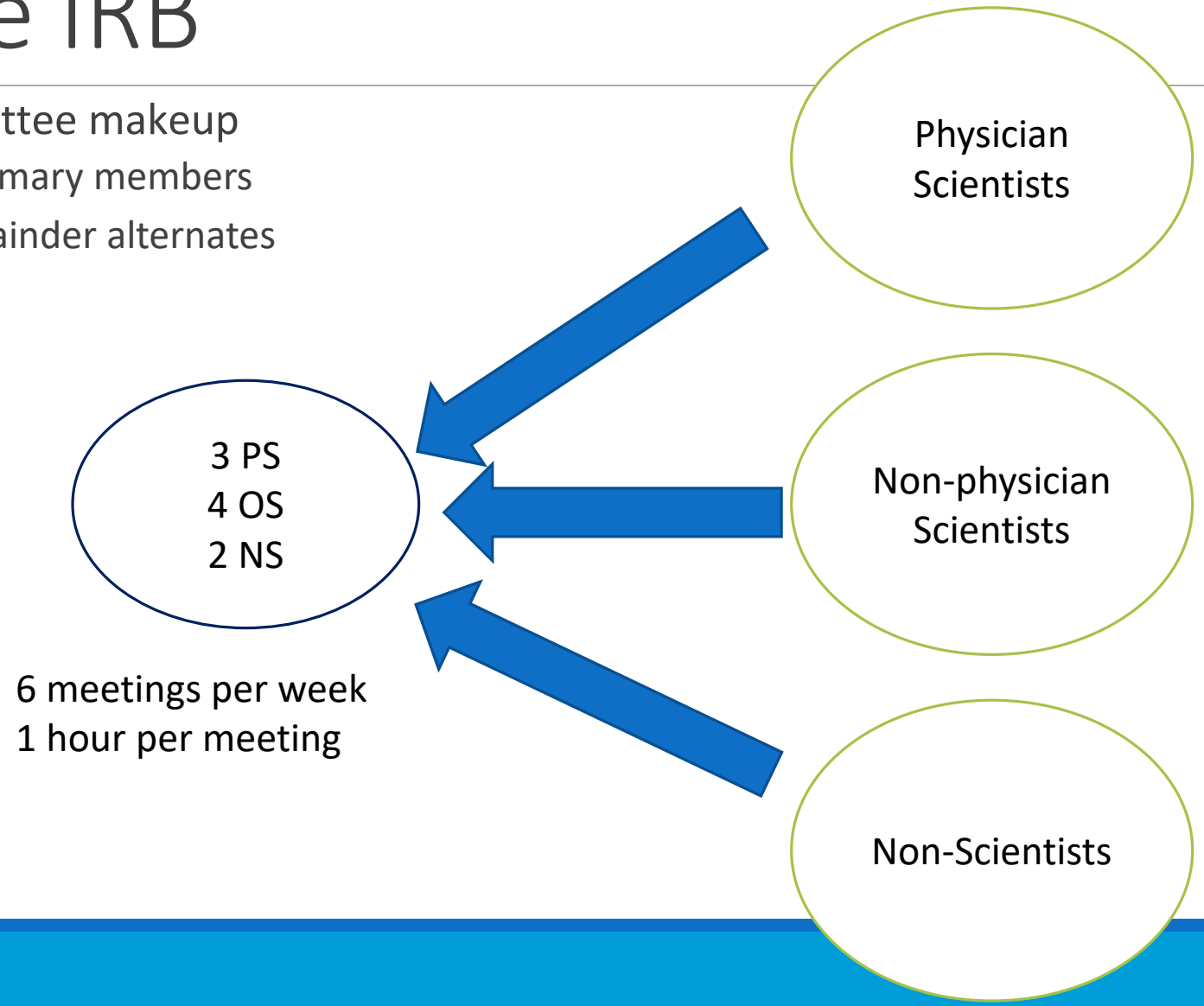


Penguins and Platypuses

Flexible IRB

Committee makeup

- 9 primary members
- remainder alternates



Screening

Scheduling

IRB member

PS OS NS

Week 1	Week 2	Week 3	Week 4
M1	M1	M1	M1
M2	M2	M2	M2
M3	M3	M3	M3
M4	M4	M4	M4

IRB meetings

IRB Chairs

Executive Chair: Nicole Grant

- Regulatory authority for approval
- Provides leadership to FB committee chairs
- Delegates authority to expedited review staff
- Provides consultation as needed to expedited review staff

Team of FB chairs

- Provide overall leadership to FB
- Lead one meeting per week (in general)
- Work together to achieve consistency across meetings

What will I be asked to do?

Attend 1 meeting per month

- Prepare for ~6-8 agenda items (1-2 IR)
- Primary or secondary on 1-3 items

Schedule meeting attending in advance

- Does not have to be same slot each month

Be available for consultation or attendance occasionally if expertise required

Benefits

Increased efficiency

- Maximal flexibility in scheduling = minimal time in the holding pen
- Capacity can be easily matched to demand

Improved reviews

- Dynamic committee membership = diverse and fresh perspectives
- Dedicated chairs committed to the process provide consistency

Increased member engagement

- Fewer protocols per meeting = greater engagement per protocol
- Exposure to greater breadth of research

Whats the rush?

Revised Common rule e

Transition Plan

Step 1: Office of IRB Operations

- NCI and Gen Med 1 IRB staff
- Support NCI and GM1 IRBs
- Review all new protocols to be approved on or after 1/21/2019 (under revised CR)
- Exempt/NHSR determinations

Step 2: Create NIH Intramural IRB

- Review all initial reviews on or after 1/21/2019-COMPLIANT WITH NEW COMMON RULE
- **Existing committees continue to review CR and amendments (under pre-2018 CR)**

Step 3: Transition existing committees, staff and protocols to NIH IM IRB

Policy update, Guidance document preparation and PI communications

IRBO staff training
IRB member recruitment

IRBO staff screening
IRB member training

11/19/2018

- Space ready and operational
- Initial IRBO staff detailed to OD

12/15/2018

- All new protocols submissions moved over to be screened by IRBO
- NIH Intramural IRB registered with OHRP

1/21/2019

- All new protocols approved by:
  - NIH Intramural IRB
  - IRBO Expedited reviewers
- CRs/Amendments by current IRBs
- NO TRANSITIONING OF OLD STUDIES AT THIS TIME

What do I do during transition?

01

Continue to attend existing meetings

02

You will be named as an alternate to the NIH IM IRB

03

Consider attending the new NIH IM IRB meetings as a reviewer

- Look out for open scheduling announcements
- Be available to serve as a consultant

Revised Common Rule

New studies approved **on or after 1/21/2019** must be compliant with new CR

All other studies WILL remain under pre-2018 CR requirements.

- Option to transition to new CR at a later date

Revised Common Rule

First major update since 1991

ONLY APPLIES TO NEW STUDIES APPROVED AFTER 1/21/2019

Major changes

- Informed consent
  - Reasonable person standard
  - Key information
  - New elements
  - Posting requirements
- Exemptions
- Continuing review requirements
- Single IRB
- Broad Consent

Informed Consent

45.CFR 46.116 (a)(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5)(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(5)(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

Informed Consent-Reasonable person

Not defined in the regulations or preamble

“It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.”

Belmont Report

Informed Consent-Key information

Information essential for the person to make an informed decision whether or not to participate

Viewed from participants perspective

Not formulaic

May differ between studies

May differ between populations

Informed Consent-Key information

Preamble

- The fact that consent is being sought for research and that participation is voluntary
- The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research
- The reasonably foreseeable risks or discomforts to the prospective subject
- The benefits to the prospective subject or to others that may reasonably be expected from the research
- Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject.

Other “key” information

Whether there is randomization

Whether there is a placebo arm

Whether subjects will have to discontinue current treatments.

How the treatment in the protocol is similar to, or different from, the clinical care the subject would receive if not in the protocol

Any significant costs that could be incurred as a result of participation

Compensation for injury

How much time and/or how many research visits are required for participation

Payments to subjects

Impact on the subject’s future clinical care. For example, whether use of an experimental intervention is likely to make a standard clinical intervention ineffective or unavailable after the study

Potential impact on non-participants e.g., caregivers, family members, children, partners and the public at large

Post-participation access to the experimental intervention.

Informed Consent-new elements

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Informed Consent-new elements

When appropriate

- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

How will OHSRP help?

OHSRP Key information guidance sheet coming very soon

Disseminate any OHRP guidance

New consent template

- One template for all of NIH

Will help with consent document compliance during screening process

NO REVISED CONSENT FOR OLD STUDIES

Patience please!!!!!

Contact

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