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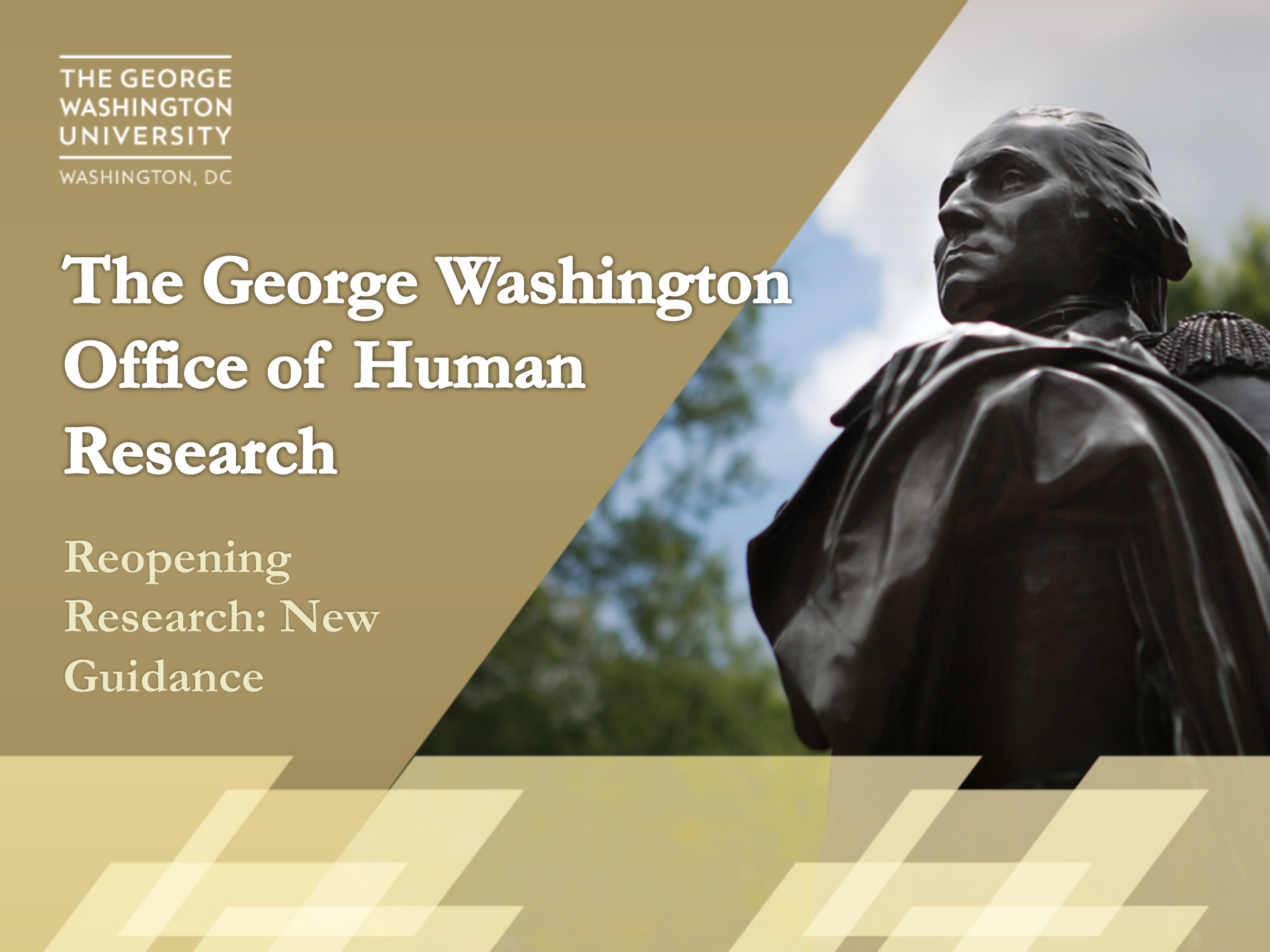
WASHINGTON, DC

The George Washington Office of Human Research

Reopening Research: New Guidance



Overview

- Update on OHR operations
- IRB review process
- COVID-19 guidance

OHR Operations

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Increase in IRB submissions due to COVID-19 research and modifications

- New study submission increase:
  - 202 studies May 2019 vs 250 studies May 2020
- Modification submission increase:
  - 100 modifications May 2019 vs 164 modifications May 2020
- OHR is also experiencing an increase in rush review requests and communication from researchers as COVID-19 related research is prioritized and time sensitive.

What is OHR doing well?

- IRB meeting attendance has increased and IRB meetings are more efficient
- New rush review processes have allowed for COVID-19 related research to have faster review times
- New COVID-19 questions in IRB Application help facilitate review

Human Subjects Research Review Process

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Different Types of IRB Review

There are strict rules about what kinds of research may receive which review

- Determination involves the population being studied and the study procedures
- Level of risk will dictate the review category (risk is contextual!)

- **Review Categories**
  - **Exempt**: Less than minimal risk to subjects
  - **Expedited**: Minimal risk to subjects
  - **Full Board**: Greater than minimal risk

Minimal Risk means the probability and magnitude of discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102 (i)]

GW IRB Review Process

EXEMPT

(Minimal Risk) Studies

Triage

Process the intake of submission and prepares submission for IRB review

Collaborative process which may involve back and forth communications between the research team and IRB triage

IRB Analyst Review

IRB Analyst conducts review of submission

Collaborative process which may involve back and forth communications between the research team and IRB analyst

IRB Exempt Registration

Research team will receive an IRB exempt registration memo indicating the research can proceed

Local Context Review

For some research, a local context review may be conducted with a subject matter expert during the review of the submission.

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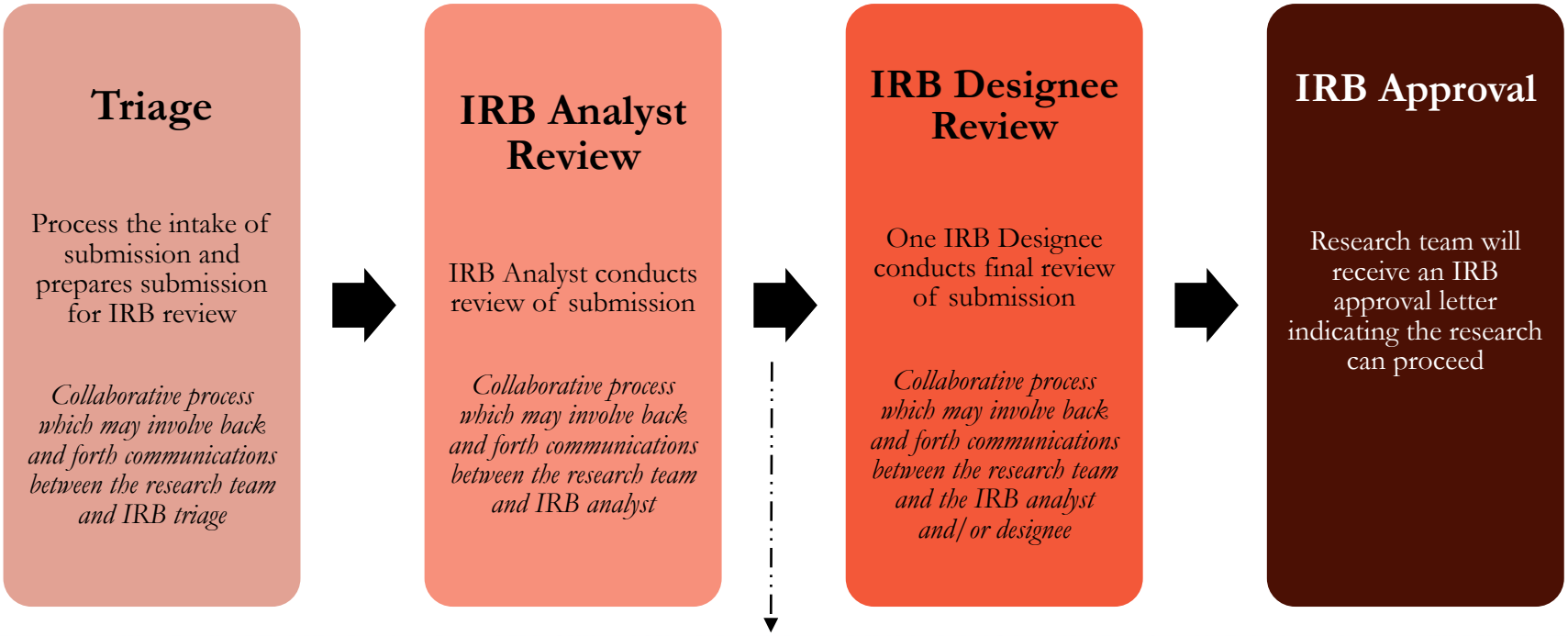
GW IRB Review Process

EXPEDITED

(Minimal Risk) Studies

Note: For studies involving reliance agreements, email ohr_irbreliance@email.gwu.edu. These agreements will be processed separately from the IRB review.



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GW IRB Review Process

FULL BOARD

(Greater than Minimal Risk) Studies

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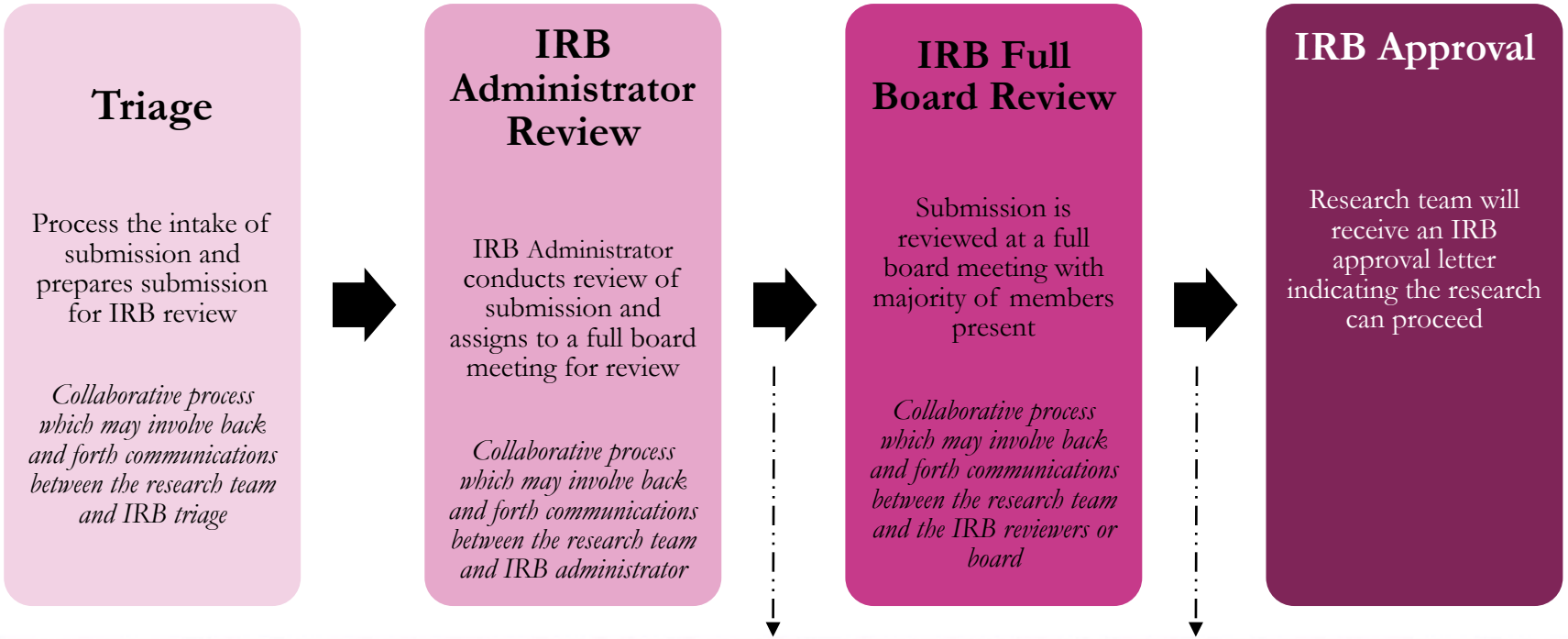

Consultant Review

For some research, a subject matter expert may also review the IRB submission.

Approved with Stipulations

Stipulations resulting from final IRB board review that must be addressed by the research team and reviewed by the IRB before final IRB approval is issued.

Deferred

When criteria of approval is not met, a deferral letter is issued to the research team. The response to the deferral will be reviewed at a future IRB meeting.

What Slows Down the IRB Review?

- No CITI training
- Unsigned forms
- Incomplete application
- Inconsistent information across documents
- Missing documents

New Guidance

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Reopening Research

- Three components:
  - Mitigate risks
  - Inform subjects of new risks
  - Departmental prioritization of research
- Department approval should be obtained for resumption of research

Appendix A: Departmental Prioritization

- Prevents overcrowding and overuse of resources
- Consider: facilities, compliance, priorities, funding, and research procedures
- Department responsibilities: educate staff on plan and guidance, determine what research will be restarted, processes to limit spread of covid-19, supply of PPE, communication plan for researchers and subjects

Appendix B: Steps to protect subjects

- Follow university, department, and local/national health authority requirements
- Document includes detailed list of safety steps that should be taken to protect subjects and minimize harms
- Example: "All research participants should be advised to arrive at the research site wearing a face mask or covering that covers the mouth and nose, which should be worn at all times in the research facility unless the participant has a medical condition that precludes wearing a face covering".

What to submit to the IRB

- **Existing studies:**
  - Receive departmental approval to resume in-person interaction
  - Submit a PRIF to the IRB that indicates the intent to resume research & certify use of the information form/addendum
- **New studies:**
  - Receive departmental approval to include in-person interactions
  - Include in the IRB application that the information sheet/addendum will be used

New information sheet/consent addendum

- Posted on website with consent templates
- Does not need IRB approval; can be used as-is
- **For currently enrolling studies:** Use with the consent process as a consent addendum and obtain signature on both the consent and the covid-19 information sheet
- **For studies re-opening where subjects have already consented:** provide subjects the form, explain information, and obtain signature

Office of Human Research

Institutional Review Board

www.humanresearch.gwu.edu

(202) 994-2715

ohrirb@gwu.edu

- The IRB review is a collaborative process, so please contact us if you need guidance or have questions!