New Staff: Institutional Review Board Orientation

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SUNY RF
The Research Foundation for
The State University of New York

Institutional Review Board (IRB) & Privacy Board

- Protects the rights and welfare of Research Participants (Human Subjects).
- Empowered to approve, require modifications, or disapprove Human Research.
- Ensures Human (Subjects) Research is scientifically/scholastically valid, ethical, and in compliance with all requirements.
- Ensures compliance through oversight functions.
- Serves as a Privacy Board to ensure HIPAA compliance.

Q1: Is it Research? (Under the Common Rule)

- A Research Activity is BOTH:
  - A **systematic investigation** (including research development, testing, and evaluation) (i.e., activity that is planned, orderly, methodical, and uses data collection to answer a question)

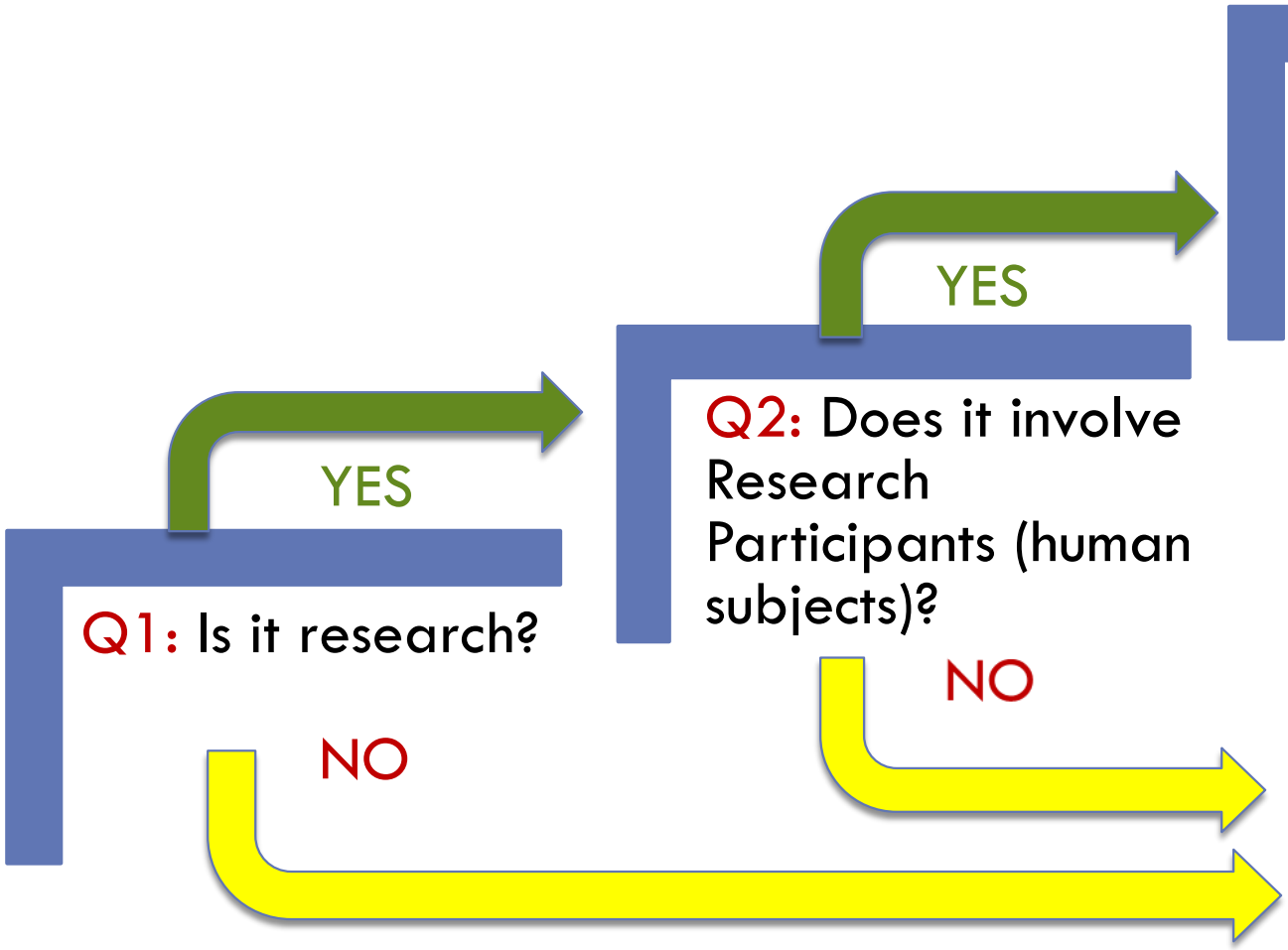
-AND-

  - Designed to develop or contribute to **generalizable knowledge** (i.e., knowledge gained from a study may be applied to populations outside of the specific study population).

Q2: Does it Involve Research Participants (Human Subjects)? (Under the Common Rule)

- In order for research to be considered human research (and thus requiring IRB approval before the study begins), the research must involve **living individuals** about whom an investigator (whether professional or student) conducting research either
  - obtains **information or biospecimens** through **intervention or interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - obtains, uses, studies, analyzes, or generates **identifiable private information or identifiable biospecimens**.

Is IRB Approval Required?



If "YES" to Q1 and Q2:
Submit an IRB application

If "NO" to Q1 or Q2:
Consult with "IRB Decision Aid", IRB@downstate.edu or call X8480.

Is IRB Approval Required for Performance Improvement Activities?

- It depends! Does the activity to improve internal operations meet the definition of human research?
- Is there an intent to develop or contribute to *generalizable knowledge?
  - YES: IRB approval is required
  - NO: IRB approval is NOT required

Example:

- A clinic surveys patients to improve the quality of service
- Without changing intent, clinic staff could
  - Share the results at a conference
  - Publish the results

* Publication in

Is IRB Approval Required for Case Reports or Case Series?

- Case Reports/Series of up to three (3) individuals do not need IRB approval
  - Such limited activities are generally not considered to be both systematic and generalizable
- Examples:
  - Review records of 3 patients
  - Review records of one patient and ask questions of 2 family members
- May request an IRB Determination letter (may be required by journal or conference)
- Some journals require informed consent/HIPAA Authorization

SUNY Downstate Health Sciences University

Office of Research Administration

IRB Electronic Submission Process:

Below is a step by step process for preparing and submitting an IRB application along with all related materials to the IRB for approval of human research activities.

The order of these steps is designed for a new investigator and are not meant to be prescriptive and many of the steps can take place in parallel to save time. A more experienced investigator or coordinator who has a good grasp on the IRB process may wish to carry out the steps in a different order.

Note: For more information on whether an activity requires IRB approval, please refer to the Downstate IRB FAQs.To request an IRB determination letter for activities which do not require IRB approval, skip to step 11 (below) and review the information on the IRB Decision Aid form.

- Click here if you looking for a for a specific form, template, policy or guidance document within the steps below...

- STEP 1: Review the Downstate IRB website, policies, and guidance.
- STEP 2: Plan the project.
- STEP 3: Identify a Principal Investigator.
- STEP 4: Determine whether investigators are members of the Downstate workforce.
- STEP 5: Determine which IRB to use and establish any required agreements.
- STEP 6: Complete training and submit conflict of interest disclosures.
- STEP 7: Develop the research protocol.
- STEP 8: Develop consent materials or applicable waivers.
- STEP 9: Develop Short Forms, if applicable.
- STEP 10: Determine if any additional materials are required.
- STEP 11: Determine which IRB Application Form to use for initial review.
- STEP 12: Upload all application materials.
- STEP 13: Obtain Scientific/Scholarly Review, when required.
- STEP 14: Obtain ancillary reviews, when required.
- STEP 15: Obtain Downstate Department Chair or Dean Approval.
- STEP 16: Submit final application in IRBNet.
- STEP 17: Respond to IRB within deadlines.
- STEP 18: Complete requirements for external sites.
- STEP 19: Submit required updates after IRB approval.

Summary

- Submit online applications to obtain initial IRB approvals and submitting required updates
- Follow instructions and guidance
- Call or visit the IRB Office for help

IRB Contacts

Clinton Brown, MD, IRB Chair	(718) 270-1729
Stanley Friedman, MD, Vice Chair	(718) 270-1335
Jeannette Jakus, MD, Vice Chair	(718) 270-1229
Kevin L. Nellis, MS, CIP, Executive Director, Human Research Protection & Quality Assurance	(718) 613-8461
Diann Johnson, MPH, Associate IRB Administrator	(718) 270-4341
Nikol Celestine, BA, CIP, IRB Management Analyst	(718) 270-4411
Nakih Gonzales, IRB Assistant	(718) 270-4372
IRB Office (BSB 3-26) IRB@downstate.edu Appointments recommended; walk-ins welcome	(718) 613-8480

Additional Contacts

Office of Compliance and Audit Services (Privacy Officer, HIPAA, Compliance Training, Audits, Internal Controls, Clinical Reimbursements, Financial Conflict of Interest Committee)	(718) 270-4033
Igor Gorelik, Information Security Officer	(718) 613-8593 (929) 359-0401
Sponsored Programs Administration (Contracts, Grant Review, Submission, and Management)	(718) 270-2680
Finance and Administration (Financial Analysis, HR, Payroll, Purchasing)	(718) 270-3027
Technology Commercialization (Commercialization and IP)	(718) 613-8514
Michele Follen, MD, PhD, MBA, Director of Research and Chair, Facility Research Review Committee (KC)	(718) 613-8401
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