

Levels of IRB review*

*This graphic covers the most commonly used forms. If you have any questions, please consult the [Electronic Submissions IRB website \(Step 11\)](#), Downstate [Policy IRB-01](#), or contact the IRB at IRB@downstate.edu.

Is this **research**?

Is this a “**Systematic Investigation**” **WITH** the intent is to **contribute to “Generalizable Knowledge”**?

IF NO:
Not Research

Strongly recommend IRB Determination (Form 11-A4) or IRB Determination for QI/QA/PI/EBP (Form 11-A4Q)

OR, when applicable:

Rely on External (Reviewing) IRB

Form 11-10 for External IRB Oversight with Downstate activation.

If **YES**: Is this **research** with **human subjects**?

Does the activity obtain **Information or Specimens** via an **Intervention or Interaction**?

OR

Does the activity involve **identifiable private information or identifiable specimens**?

IF NO: Not Human Subjects Research

Strongly recommend IRB Determination (Form 11-A4) or IRB Determination for QI/QA/PI/EBP (Form 11-A4Q)

OR, when applicable:

Rely on External (Reviewing) IRB

Form 11-10 for External IRB Oversight with Downstate activation.

If **YES**: Does this **human research** qualify as **Exempt**?

Are all procedures covered in the HHS-defined Exempt categories?

IF YES:

Form 11-A1 for **Exempt Review**

OR, when applicable:

Rely on External (Reviewing) IRB

Form 11-10 for External IRB Oversight with Downstate activation.

If **NO**: Can it be **Expedited** ?

Is the study “no greater than minimal risk” with all research procedures fitting into one or more of the “**Expedited review categories**”?

IF YES:

Form 11-A2* for **Expedited Review**
OR, when applicable:

Rely on External (Reviewing) IRB

Form 11-A3 for External IRB Oversight with Downstate activation.

If **NO**:

Full Board review:

Form 11-A2* for **Full Board Review**

OR, when applicable:

Rely on External (Reviewing) IRB

Form 11-A3 for External IRB Oversight with Downstate activation.

NOTE:

If Downstate is not Engaged in a multi-site human research activity, use Form 11-A4.

*Include Form 11-8 or 11-9 when enrolling or excluding pregnant people, or for studies which require contraception, pregnancy testing, or for studies that may involve or impact partners of participants who become pregnant.

SUNY DHSU IRB Review