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)

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)

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

Full Board review:  
Form 11-A2 for Full Board Review  
OR, when applicable:  
Rely on External (Reviewing) IRB

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:  
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:  
Strongly recommend IRB Determination (Form 11-A4).