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| --- |
| **Whenever you are not sure how to answer a question, contact the IRB for help. Questions may be directed initially to the IRB Office Staff at (718) 613-8480 or** [**IRB@Downstate.edu**](mailto:IRB@Downstate.edu)   * For Downstate’s policy on human research, including important regulatory definitions used to make these determinations, see [Policy IRB-01](http://research.downstate.edu/irb/irb-policies.html). * For federal guidance, see [HHS/OHRP Decision Charts](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html). * Privacy and HIPAA related questions may be directed to the Downstate Privacy Officer, Shoshana Milstein, at (718) 270-7470 or [shoshana.milstein@downstate.edu](mailto:shoshana.milstein@downstate.edu) * Information Security related questions may be directed to the Downstate Information Security Officer, David Loewy at (718) 270-2431 or [david.loewy@downstate.edu](mailto:david.loewy@downstate.edu) * For animal research, refer to the Institutional [Animal Care and Use Committee (IACUC)](http://research.downstate.edu/iacuc/iacuc.html). |

**Instructions for requesting an IRB Determination Letter:**

Complete the questions on this form and submit the completed form in IRBNet:

* + - Set up an IRBNet User Account, if you do not have one already, and submit the request in IRBNet.
    - Instructions for obtaining an account are on the [IRB's Electronic Submissions website](http://research.downstate.edu/irb/irb-electronic-submissions.html).
    - Submit your request in IRBNet as a new submission. Follow instructions for submitting a new project, as outlined in the IRB Guidance [“IRBNet™: IRB Application and Reporting System”](http://research.downstate.edu/irb/irb-policies.html)

*Note: An IRBNet Registration Form is not required.*

* + - E-sign the submission in IRBNet to attest the information submitted to the IRB is accurate to the best of your knowledge with the understanding that if anything changes, the request will be amended.

**Defining Human Research:**

For a non-FDA regulated activity to be considered research under the Common Rule, it must be both 1) a systematic investigation (including research development, testing, and evaluation) and 2) be designed to develop or contribute to generalizable knowledge. Some demonstration and service programs may include research activities.

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 1) obtains information or biospecimens through *intervention* or *interaction* with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) obtains, uses, studies, analyzes, or generates *identifiable private information* or *identifiable biospecimens.*

**SECTION A: IRB REVIEW**

1. **Is the primary intent of this project to develop or contribute to generalizable knowledge?**

Yes  No **Note: If yes, do not use this form.**

1. **Project Title:**
2. **Downstate Department or College:**
3. **Check if project will also take place outside of Downstate locations:**
   1. NYC H+H, Kings County (Specify Department):
   2. UPB
   3. Downstate Incubator (Specify company):
   4. Other (specify):
4. **Project Lead:**       Phone:       E-mail
5. **Alternate Contact:**       Phone:       E-mail
6. **List all individuals participating in this project:**
7. **Describe activities carried out by a faculty members, employees, students, residents, fellows, or agents of the institution(s) conducting this project:**

1. Who is providing funding for this activity? (Check all that apply):
2. Downstate Department or College. Specify Department/College:

*Note: Check if using departmental funds, equipment, resources, or labor.*

1. NYC +HH, Kings County. Specify Department/College:

*Note: Check if using departmental funds, equipment, resources, or labor.*

1. Industry Sponsor: Specify funding entity:       Sponsor Award #:
2. Federal Sponsor. Specify agency:       Specify Federal Award #

*Note: Check even if funds are passed through another institution*

1. Inbound Subcontract (Specify funding entity):       Date of anticipated funding:
2. Other: Specify:
3. What is the status of funding?

This project is fully funded.

Project is partially funded at this time. List approved sources of funding:

Pending: Potential sources:       Date of anticipated funding:

1. **Provide a lay summary of the activity:**

1. **Is there any intent to publish findings or present at a meeting outside of the institution?**

Yes  No

1. **Documents included, as applicable:** 
   * 1. Project description
     2. Protocol
     3. External IRB approval letter
     4. Data collection tools
     5. List of data elements
     6. Agreement (e.g., DUA, BAA, etc.)
     7. Other(describe):
2. **Description of proposed type of activity(ies):**
3. **Healthcare Operations Activity (HOA)** (e.g., Performance Improvement, Resident Training) that is NOT designed to develop or contribute to generalizable knowledge.
4. **Case Report(s) or Case Series** involving up to three (3) individuals.
   1. If the box above was checked, indicate the total number of all individuals (including relatives) discusses in the case report or case series:
5. **Authorized operational activities** (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions
   1. Provide the name of the agency for this activity:

* 1. Describe the source(s) of the materials:

1. **Not engaged in human research.** Involvement of employees or agents in an activity is limited to one or more of the activities listed in [Section III (B) of the October 16, 2008 OHRP Guidance on Engagement of Institutions in Research](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html).
   1. Check to confirm Department Chair, Dean, or Senior Hospital Administrator approves activity
   2. Check to confirm activity does not represent a violation of an informed consent, HIPAA Authorization, or hospital policy
2. **Pilot activity, feasibility activity, or evidence-based practice activity** that does not involve human research as defined by Policy IRB-01.
3. **Training or educational activity** that does not involve human research as defined by Policy IRB-01.