|  |
| --- |
| **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. **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. **Will the activity include to posting or providing advertising or recruitment materials within the institution to inform others about research taking place at another external institution?**
5. Yes  No
   1. If yes, list external institution:
6. **Project Lead:**       Phone:       E-mail
7. **Alternate Contact:**       Phone:       E-mail
8. **List all individuals participating in this project:**
9. **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. **Provide reasoning or rationale why this study does not need approval by the Downstate IRB & Privacy Board:**

1. **Is the activity an investigation of a drug, biologic, or medical device?**

Yes  No

1. **Is the activity a systematic investigation?**

Yes  No

1. **Is the project designed to develop or contribute to generalizable knowledge?**

Yes  No

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

Yes  No

1. **Will anyone on this project obtain information or biospecimens through an intervention or interaction with an individual?**

Yes  No

1. **Will anyone on this project obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens?**

Yes  No

1. **Check if the activity involves obtaining, accessing, using, disclosing, or sharing any of the following:**

At least one box must be checked. Check all applicable boxes.

* 1. Individually identifiable private information from a living individual
  2. Education records that can be linked to any living individual
  3. Protected Health Information (PHI) about any individual (living or deceased)
  4. PHI from individuals who have been deceased for more than 50 years
  5. Data from deceased individuals without PHI
  6. PHI from individuals who have been deceased for less than 50 years with a Researcher Certification for PHI of Decedents
  7. Substance abuse information that can be linked to any individual (living or deceased)
  8. Genetic information that can be linked to any individual (living or deceased)
  9. HIV related information that can be linked to any individual (living or deceased)
  10. Identifiable specimens (from any living individuals or any deceased individuals)

* 1. Use of ANY human specimen(s) to validate a medical device, diagnostic instrument, or laboratory test
  2. Specimens obtained from a producer or supplier (e.g., commercial cell line) that cannot be linked to an individual, by the Investigators.
  3. Use of a limited data set under a Data Use Agreement (DUA) and investigators cannot readily identify the individuals about whom the data pertains and does not have access to the key to any codes to identify the individuals.
  4. De-identified. If checked, indicate the name of the person or entity providing the de-identified materials to the project team:
  5. Coded materials. If checked, check the process in place to prohibit release of code to investigators and provide a copy to IRB:
     1. Written agreement prohibits the release of the code to the investigators.
     2. Written document or policy prohibits the release of the code to the investigators.
     3. Independent Honest Brokers Assurance Agreement in place to prohibit the release of the code to the investigators.
  6. Secondary data (e.g., data originally collected for another purpose). If checked, list source:
  7. None of the above

1. **Describe how the safety, rights, welfare, privacy and confidentiality are ensured for affected individuals protected?**

1. **Describe any risk mitigation strategies:**

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. Research Certification for Reviews Preparatory to Research
     8. Researcher Certification for PHI of Decedents
     9. Agreement or document that limits the individuals from obtaining a key to coded materials
     10. 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. **Scholarly and journalistic activities** including the collection and use of information that focuses directly on the specific individuals about whom the information is collected.
   1. If the box above was checked, indicate type:
      1. Oral history,
      2. Journalism
      3. Biography
      4. Literary criticism
      5. Legal research
      6. Historical scholarship
      7. Other, describe:
   2. If any of the boxes above are checked, please check at least one box below to confirm IRB approval is not required:
      1. Intent is NOT to form a hypothesis, draw conclusions, or generalize the findings
      2. This is not a systematic activity that is planned, orderly, and methodical
6. **Public Health Surveillance Activities**.
   * 1. Provide the name of the health authority for this activity:

1. **Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.**
   1. Provide the name of the criminal justice agency for this activity:

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

1. **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. **Clinical Care**
   1. If the box above was checked, describe the clinical care activity:
   2. Check if this is an Off-Label Use of an FDA Approved Drug or Biologic
      1. Provide the name of the drug or biologic:
      2. Describe the off- label purpose:
      3. Has the Pharmacy approved this use?

Yes  No

If Yes, please request pharmacy e-signature on IRBNet submission.

1. **Preparatory to research activity** (e.g., review of protected health information in preparation for research.
2. **Referring others** (e.g., patients, employees, prior research participants) **from SUNY DMC to a new study.**

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.

**SECTION B: ANCILLARY REVIEWS**

other departments or colleges:

1. **Does this research impact or involve other Departments or Colleges, outside of the PI’s location?**  Yes  No
2. **If yes, describe impact or involvement and obtain Department Chair/Dean approval**:

**UHB Pathology Laboratories:**

**Check the box below to indicate whether the research involves any of the following:**

**At least one box (A, B, or C) MUST be checked.**

**(A)** Patient Material: Use of any past, present, or future UHB patient material (tissue, blood and fluids) requires UHB Pathology Review, except for the following:

1) Extra blood sample or extra urine sample which will not be tested in UHB pathology laboratory.

2) Tissue listed in UHB Exempt Tissue Policy:  “[LAB 03 Human Tissue Fluid and Foreign Matter Exempt From Submission for Pathology Examination](http://www.downstate.edu/pnp/lab/policies.html).”

 **(B)** Services or assistance of the UHB Pathology Laboratories (Clinical Laboratory, Histology Lab and/or Surgical Pathology).

**(C)** None of the above.  UHB Pathology Laboratories ancillary review is not required.

If uncertain about the need for ancillary review by UHB Pathology, please consult [Susan Gottesman, PhD, MD](mailto:Susan.Gottesman@downstate.edu)or[Caitlin Otto, PhD](mailto:Caitlin.Otto@downstate.edu).  It is best to set up an appointment.  A list of all specimens that you propose using for your research will be needed.  If they state that Pathology Ancillary review is not required, they will document this in an email. A copy of the e-mail must be attached to the IRB submission.

If **(A)** or **(B)** is checked, answer the following:

**(i)**: Will there be any division (e.g., splitting, aliquoting, etc.) of any clinical patient materials for research purposes?

Yes  No

**(ii)**: If yes to **(i)**, please describe:

**(iii)**: Will the research use of any clinical patient materials interfere or limit diagnostic ability or increase risks to patients?

Yes  No

**(iv)**: Explain reasoning for response to **(iii)**:

**If box “A” or “B” is checked above, or if you are uncertain, please do the following:**

**Step 1:**

1. Refer to the UHB Pathology Instructions, Forms, and Fees posted in UHB Pathology website: <https://www.downstate.edu/pathology/research-services.html>
2. Complete and submit “Step 1 Form: Preparation for Use of UHB Laboratory/Patient specimens for Research Projects: Clinical, Histology, and Surgical Pathology Labs Feasibility Determination” to Pathology.
3. Schedule a meeting with Dr. Gottesman or Dr. Otto to discuss the feasibility of the request, scheduling, ordering, availability of samples, fee schedule, etc. The Step 1 form and meeting must be done prior to IRB or IACUC approval. Any request for samples from fresh tissue submitted to the surgical pathology laboratory will require a review by a surgical pathology attending to ascertain that patient care will not be compromised.

**Step 2:**

1. Complete and submit the IRB application after the UHB Pathology Laboratories approves the feasibility of using their services to obtain IRB approval.

When submitting the IRB application in IRBNet, please share the IRBNet submission with the pathology representative so that (s)he may e-sign the submission

***Caution: If any changes are required after final IRB approval, an amendment must be submitted to the IRB.***

**Institutional Biosafety Committee (IBC)**

* All research involving the use of Recombinant or Synthetic Nucleic Acid Molecules, infectious agents, human cells or body fluids, or hazardous substances must be reviewed and approved by the Institutional Biosafety Committee (IBC) to ensure that all applicable biosafety standards are met.  Early submission of the protocol to the committee is advisable to allow time for any necessary clarification, revision and reconsideration, and approval.  The IBC will determine if the study requires approval from the NIH Recombinant DNA Advisory Committee. For more Information, contact Ms. Lydia Bailey at the IBC Office at (718) 270-3912 or [IBC@downstate.edu](mailto:IBC@downstate.edu) or see: <http://research.downstate.edu/administration/biosafety.html>
* Protocols involving work with human-derived biological materials that are collected by and handled, processed, analyzed in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory are exempt from IBC review. However, any work on human-derived biological materials (including packaging and shipping) in Research laboratories at DMC is subject to IBC review.
* If your study requires Institutional Biosafety Committee approval or NIH Recombinant DNA Advisory Committee approval, your study cannot be approved by the IRB until you have received the applicable approvals.

**Does your study require approval from the Institutional Biosafety Committee (IBC)?**

**(A)** No, this study does NOT involve recombinant or synthetic nucleic acid molecules, infectious agents, human cells, human tissues, or human body fluids, or hazardous substances.

**(B)** No, this study involves infectious agents, human cells or body fluids, or hazardous substances; however, all materials are human-derived and are collected by and handled, processed, analyzed in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory.

**(C)**Yes, the project involves the use of one or more of the following checked items:

Work on human-derived biological materials at Downstate which does not take place in a CLIA certified lab,

Packaging and shipping of human-derived biological materials at Downstate,

Hazardous substances,

Infectious agents, or

Recombinant or synthetic nucleic acid molecules

**(D)** If yes to (C), does this study involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules into one or more human research participants?

Yes  No

**(E)** If yes to (D), has the NIH RAC approved the study or is the review pending?

Yes. NIH RAC approval letter is provided with IRB submission.

NIH RAC approval is pending. Estimated approval date: