* Follow [IRB Electronic Submissions Website (click link)](http://research.downstate.edu/irb/irb-policies.html) and [Policy IRB-01](http://research.downstate.edu/irb/irb-policies.html).
* Use this application form only for research funded by the US Department of Justice (DOJ); however, exemptions on this form CANNOT BE apply to research with prisoners.
* The DOJ is not a signatory to the July 21, 2018 Common Rule; however, they intend to become an official signatory in the future. DMC must follow both the July 19, 2018 Common Rule and the policies of the [National Institute of Justice (NIJ)](https://www.nij.gov/funding/humansubjects/pages/human-subjects.aspx) for DOJ/NIJ funded studies. When discrepancies exist between the 2018 Common Rule and the prior version of the Common Rule for DOJ requirements, follow the more restrictive requirement, such as the following requirements of the 2018 Common Rule, including Exemption category #1.
* All protocol activities must meet the specific conditions of one or more exemption categories, described below.
* For research with Protected Health Information (PHI), include the applicable HIPAA instrument(s) with this application (e.g., HIPAA research authorization, HIPAA waiver, DUA, BAA, etc.).
* Always use the latest version of IRB forms and templates; however, the IRB will generally accept previous versions of forms, provided they were available on the IRB website at least 3 months prior to the submission if they meet regulatory and compliance requirements.
* Include the protocol and all required materials with the IRB application submission.
* The IRB anticipates additional changes to the DOJ regulations in efforts to harmonize with the changes of the Common Rule outlined in Policy IRB-01. The IRB will revise this policy as soon as possible after a new regulation goes into effect. However, prior to making a policy change, the IRB may approve research under a provision of any new regulation when the Convened IRB, IRB Chair, or IRB Vice-Chair approves the change and the IRB documents the reason for such approval in an IRB approval letter.

## SECTION A: IRB REVIEW:

1. **GENERAL INFORMATION**
2. **Protocol Title:**

**OPTIONAL: Please list the IRB# of any similar or associated research projects that have been approved by the SUNY Downstate IRB. Listing such projects will inform IRB Members of past research and may help the review process.**

1. **Scientific Abstract (OPTIONAL):**

**Lay Person Abstract (REQUIRED): Please provide a summary of the study for a non-scientific reader. Use non-scientific lay language and eliminate or explain any scientific terms.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. **Principal Investigator (PI):**

Department/College:      PI Contact Information: PI Phone # (required):       PI Email (required):      Alternate PI E-mail (optional):       |  |  |  |  |  |
| Check PI Status below (check all that apply): [ ]  (1) Faculty Member at SUNY Downstate who is a sseasoned investigator with a field-specific terminal degree[ ]  (2) Clinician with privileges at NYC H+H, Kings County REMINDER: [STAR approval](http://research.downstate.edu/irb/irb-policies.html) is also required for all NYC H+H research.[ ]  (3) Faculty member under recruitment to SUNY Downstate. Written memo or e-mail from a Dean is attached.[ ]  (4) Approved to be a PI by the Downstate Institutional Official (IO). Written memo or e-mail from the IO is attached.[ ]  (5) Qualify to be a PI at an external site AND this activity makes Downstate engaged (check all that apply):[ ]  Federal funding or support is provided to Downstate[ ]  Co-investigators or key personnel are (check all that apply):[ ]  Employee(s) of SUNY Downstate[ ]  Resident(s) or Fellow(s) trained under a GME program affiliated with SUNY Downstate [ ]  Student(s) in a Downstate Academic Program1. (OPTIONAL) If someone, other than the PI, will be the main contact for this study, please provide his/her contact information below:

|  |  |
| --- | --- |
| Name:      Role on Study:       | Phone:       Email:       |

1. (OPTIONAL) If multiple Principal Investigators will be responsible for the scientific and technical direction for this study, complete the table below.

Rationale for using a multiple PI approach:      *NOTE: Each PI must e-sign the initial IRB submission in IRBNet. The first PI listed in the IRB application will serve as the contact PI.*

|  |  |  |  |
| --- | --- | --- | --- |
| Additional PI Name | PI Status (for coding, see #s above) | Contact Information | Description of the roles, responsibilities and the working relationship to the primary PI. |
|       | [ ]  (1), [ ]  (2), [ ]  (3), [ ]  (4), [ ]  (5) | Phone #       Email :       |       |
|       | [ ]  (1), [ ]  (2), [ ]  (3), [ ]  (4), [ ]  (5) | Phone #       Email :       |       |
|       | [ ]  (1), [ ]  (2), [ ]  (3), [ ]  (4), [ ]  (5) | Phone #       Email :       |       |

***Attach additional sheets if needed.***1. Who is providing funding for this study? (Check all that apply):

[ ]  Downstate Department or College: Specify:      *Note: Check if using departmental funds, equipment, resources, or labor.*[ ]  NYC H + H, Kings County REMINDER: [STAR approval](http://research.downstate.edu/irb/irb-policies.html) is also required for all NYC H+H research.*Note: Check if using departmental funds, equipment, resources, or labor.*[ ]  Industry Sponsor: Specify funding entity:       Sponsor Award #:       [ ]  Federal Sponsor. Provide additional information below: Specify department or agency:       Investigator initiated? [ ]  Yes [ ]  No Federal Award #       GCP training complete for NIH funded research? [ ]  Yes [ ]  No **If the research is not funded from NIH, will a Certificate of Confidentiality be obtained from the NIH?** [ ]  Yes [ ]  No *For more information, please see:* [*https://grants.nih.gov/grants/policy/coc/index.htm*](https://grants.nih.gov/grants/policy/coc/index.htm)[ ]  Inbound Subcontract (Specify funding entity):       Date of anticipated funding:       [ ]  Other: Specify:      1. 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:        |

2) TABLE OF STUDY STAFF:

For training and conflict of interest disclosure requirements see: <http://research.downstate.edu/irb/irb-training.html>

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| a. Name & degree | b. Role(s) on Project. Examples: Principal Investigator, Co-Investigator, Coordinator, Consultant, Fellow, Resident, Student, Research Staff, Healthcare Operations only, Access to de-identified data only, Specimen shipment, etc.  | c. Place of employmentREMINDER: [STAR approval](http://research.downstate.edu/irb/irb-policies.html) is also required for all NYC H+H research. | d. Will this person be obtaining verbal or written Informed Consent/Authorization | e.Is this person an “Investigator for the purposes of COI reporting”?*REQUIRED FOR DOJ FUNDED STUDIES.* *THE PI IS ALWAYS CONSIDERED AN INVESTIGATOR FOR COI PURPOSES.* | f.Will this person aid the shipment of hazardous materials (e.g., dangerous goods, specimens) to be transported by a public carrier? |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |
|       |       | [ ]  SUNY Downstate[ ]  NYC H + H, KC[ ]  Other:       | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No | [ ]  Yes [ ]  No |

*Attach additional pages if needed.*

**3) PROPOSED EXEMPTION(S):**

**Indicate the Exemption Category(ies) proposed for this project and answer any related questions for the proposed category(ies).**

|  |
| --- |
| **1) Does the research meet the criteria indicated below for 2018 Common Rule Exemption Category 1 [45 CFR 46.104 (d)(1)]:**  **[ ]  Yes [ ] No****2018 Common Rule Exemption Category 1 [45 CFR 46.104 (d)(1)]: Research, conducted in established or commonly accepted educational settings that specifically involve normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.** **Complete the following if the above box was checked:****Describe the established or commonly accepted educational setting:**      **Describe the normal educational practice:**      **Describe the reasons why this activity is is not likely to adversely impact the students’ opportunity to learn required educational content:****Describe the reasons why this this activity is not likely to adversely impact the assessment of educators who provide instruction:****Please provide any additional information for the IRB to consider:**       |
| **2) Does the research meet the criteria indicated below for the 2009 Common Rule EXEMPTION CATEGORY #2? [ ]  Yes [ ] No*****NOTE: Exemption category 2 cannot be applied to research involving children, except for research involving observation of public behavior when the investigators do not participate in the activities being observed.*****2009 COMMON RULE EXEMPTION CATEGORY #2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:*** + 1. **information obtained is recorded in such a manner that research participants can be identified, directly or through identifiers linked to the them; and**
		2. **any disclosure of the research participants’ responses outside the research could reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.**

**If category #2 is checked, please answer the following:**1. **Check if any of the following are involved in the research:**

**[ ]  Observation of public behavior of adults****[ ]  Observation of public behavior of children when the investigators do not participate in the activities being observed****[ ]  Educational tests (cognitive, diagnostic, aptitude, achievement) with adults****[ ]  Survey procedures with adults****[ ]  Interview procedures with adults**1. **Will information obtained is recorded in such a manner that research participants can be identified, directly or through identifiers linked to the research participants? [ ]  Yes [ ] No**
2. **Will any disclosure of the research participants’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation? [ ]  Yes [ ] No**
3. **Please provide any additional information for the IRB to consider:**
 |
| **3) Does the research meet the criteria indicated below for the 2009 Common Rule EXEMPTION CATEGORY #3? [ ]  Yes [ ] No****2009 COMMON RULE EXEMPTION CATEGORY #3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) above, if:*** 1. **the research participants are elected or appointed public officials or candidates for public office; or**
	2. **federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.**

**If category #3 is checked, please answer the following:**1. **Will the research participants be elected or appointed public officials or candidates for public office? [ ]  Yes [ ] No**
2. **Are there Federal statute(s) that require without exception that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter? [ ]  Yes [ ]  No**
3. **Please provide any additional information for the IRB to consider:**
 |
| **4) Does the research meet the criteria indicated below for the 2009 Common Rule EXEMPTION CATEGORY #4? [ ]  Yes [ ] No****2009 COMMON RULE EXEMPTION CATEGORY #4: Research involving the collection or study of \*existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available OR if the information is recorded by the investigator in such a manner that research participants cannot be identified, directly or through identifiers linked to the research participants.*****NOTE: \*existing means before the research is approved by the IRB (e.g., already on the shelf). This does not apply to prospective research activities after IRB approval.*****If category #4 is checked, please indicate which materials will be used in the research:****[ ]  *EXISTING* data****[ ]  *EXISTING* documents****[ ]  *EXISTING* records,****[ ]  *EXISTING* pathological specimens****[ ]  *EXISTING* diagnostic specimens****If category #4 is checked, please answer the following:**1. **Are these sources publicly available? [ ]  Yes [ ]  No;**
2. **If *Yes, p*rovide website or location of information:**
3. **Is the information recorded by the investigator in such a manner that research participants cannot be identified, directly or the exemption through identifiers linked to any individuals? [ ]  Yes [ ]  No**
4. **Please provide any additional information for the IRB to consider:**
 |
| **5) Does the research meet the criteria indicated below for the 2009 Common Rule EXEMPTION CATEGORY #5? [ ]  Yes [ ] No****2009 COMMON RULE EXEMPTION CATEGORY #5: Research and demonstration projects which are conducted by or subject to the approval of federal department or** **federal agency heads, and which are designed to study, evaluate, or otherwise examine:*** 1. **Public benefit or service programs;**
	2. **Procedures for obtaining benefits or services under those programs;**
	3. **Possible changes in or alternatives to those programs or procedures; or**
	4. **Possible changes in methods or levels of payment for benefits or services under those programs.**

**If category #5 is checked, will the activity involve research and demonstration projects which is approved by a Federal Department or Agency Head (e.g., Secretary or Health and Human Services)? [ ]  Yes [ ] No****If yes, which of the following is the research activity designed to study, evaluate, or otherwise examine?** **[ ]  Public benefit or service programs?** **[ ]  Procedures for obtaining benefits or services under those programs****[ ]  Possible changes in or alternatives to those programs or procedures****[ ]  Possible changes in methods or levels of payment for benefits or services under those programs** |
| **6) Does the research meet the criteria indicated below for the 2009 Common Rule EXEMPTION CATEGORY #6? [ ]  Yes [ ] No****2009 COMMON RULE EXEMPTION CATEGORY #6: Taste and food quality evaluation and consumer acceptance studies,** 1. **if wholesome foods without additives are consumed or**
2. **if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental**

**contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or** **the Food Safety and Inspection Service of the U.S. Department of Agriculture.****If category #6 is checked, will the activity involve taste and food quality evaluation or consumer acceptance studies? [ ]  Yes [ ] No****If *Yes, which of the* following apply to the research?****[ ]  Wholesome foods without additives are consumed** **[ ]  Food is consumed that contains a food ingredient, agricultural chemical, or environmental contaminant at or below the level found to be** **safe by the Food and Drug Administration (FDA), or approved by the Environmental Protection Agency (EPA) or the Food Safety** **and Inspection Service of the U.S. Department of Agriculture (USDA)** |

## RESEARCH PARTICIPANTS:

* 1. What is the age range of the study population?
	2. Please indicate whether you are including any of the following individuals:

[ ]  Males

[ ]  Females

[ ]  Patients

## Location of the research participants?

## [ ]  SUNY Downstate

## [ ]  NYC H+H, Kings County REMINDER: [STAR approval](http://research.downstate.edu/irb/irb-policies.html) is also required for all NYC H+H research.

[ ]  **Other site that is not a legal entity of Downstate:**

*Note: If other is checked, it is recommended (not required) that the PI obtain a letter of support from the relevant faculty member or director of the external site and include it with the IRB application.*

## Indicate the following as it pertains to the above sites:

##      Number of patient charts to be reviewed.

##      Number of research participants who will be screened.

##      Number of research participants who will be enrolled.

## If this is a multisite study, what is the total number of research participants needed for all sites (e.g., including those not included above and approved by a different IRB)?

##       (if not multi-site, type N/A)

* 1. **Does the research involve any of the following “Possibly Vulnerable” populations?**

[ ]  Patients recruited by their providers.

[ ]  **Pregnant women.**

[ ]  **Emancipated minors.**

[ ]  **Children (including any neonates)**

[ ]  **Children who are Wards.**

[ ]  **Prisoners.**

[ ]  **Research participants with Limited English Proficiency (LEP) or Non-English Speakers:**

**If checked, indicate anticipated language(s) and the number of participants expected with LEP (e.g., Spanish (3), Russian (3), etc.):**

***Note: Please submit copies of the*** [***Short Forms***](http://research.downstate.edu/irb/irb-electronic-submissions.html)***, when applicable to the study.***

***For more information in enrolling participants with LEP, see*** [***IRB-01 policy***](http://research.downstate.edu/irb/irb-policies.html) ***and IRB Guidance on*** [***Obtaining Legally Effective Informed Consent and HIPAA Authorization***](http://research.downstate.edu/irb/irb-policies.html)***.***

[ ]  **Minorities** [including American Indians, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, Black/African American (not of Hispanic Origin) and Hispanic]

[ ]  **American Indians or Alaskan Natives.** Specify tribe(s), if known:

[ ]  **Economically or educationally disadvantaged**

[ ]  **Study staff or investigators named on this application**

[ ]  **Employees, Students, Residents, or Fellows who are subordinate to the investigative staff**

[ ]  **Cognitively-impaired adults**

**If cognitively-impaired adults will be enrolled through a surrogate consent process, please provide a compelling justification for recruitment of these individuals:**

[ ]  None of the above.

[ ]  **Other** (describe):

**If any box is checked above, please describe** strategies to reduce the possibility of undue influence or coercion, when recruiting these individuals:

*Enter N/A if there are no interactions with the above populations.*

*Note: Patients usually have a great deal of respect for their physicians and may wish to please them or comply with their physician’s wishes to recruit them or misconceive research for therapy; therefore, it may be important to develop a strategy that mitigates the possibility of undue influence or coercion. Whenever there is a power imbalance, such as faculty recruiting their students, or supervisors recruiting their employees, additional strategies should be included to reduce the possibility of undue influence or coercion.*

* 1. **Does the study specifically target any specific population?** [ ]  Yes [ ]  No

**If YES, please answer the following:**

**Identify the specific population(s):**

**Explain why they are targeted:**

**Provide the scientific rationale:**

**What protections are in place to ensure their safety:**

* 1. **Does the study specifically exclude any specific population?** [ ]  Yes [ ]  No

**If YES, please answer the following:**

**Identify the specific population(s):**

**Provide the scientific rationale:**

* 1. **How will the study team identify potential research participants?**

[ ]  From the patient population of the study team

[ ]  Colleagues

[ ]  Subject Recruitment Authorization Form (Signed by patient). *Template available in IRBNet or OCAS website.*

[ ]  Physician’s Documentation of Patient’s Verbal Authorization.*Template available in IRBNet or OCAS website.*

[ ]  Chart Reviews *(If chart review will be utilized to identify potential participants, and the person doing the chart review is not responsible for the care of the patient, please request a partial waiver of HIPAA Authorization for the purpose of identifying individuals for recruitment.*

[ ]  Other/Describe:

* 1. **What recruitment materials will be used to recruit research participants?**

***Upload all proposed recruitment materials*** *to the IRB application submission package in IRBNet. If these are not ready, please do not check the box below, but submit later as an Amendment once the study has been approved.*

***NOTE: Any Downstate representation on social media must be authorized by SUNY Downstate’s Office of Institutional Advancement after IRB approval is granted. See:*** [***http://www.downstate.edu/policy/***](http://www.downstate.edu/policy/)

|  |  |  |
| --- | --- | --- |
| [ ]  Flyer – Distributed where      | [ ]  Printed Ad  | [ ]  Internet Posting; Website:       |
| [ ]  Radio/TV | [ ]  Information Brochure | [ ]  Emails |
| [ ] Letter to Doctors | [ ]  Direct Subject Contact  | [ ]  Social Media; Describe:       |
| [ ] Letter to potential research participants | [ ]  Referral  | [ ]  Other/Describe:       |

## 5) COSTS AND PAYMENTS:

### Describe any costs that participants incur during their participation:

### Will participants receive any reimbursement or remuneration for their participation? (Payments should not be an amount that could be considered coercive or create undue influence)

|  |  |
| --- | --- |
| [ ]  No [ ]  Yes |  |

**If YES, give details including, total amount and amount per visit**

*Note: Include the* [*Consent Addendum for SUNY RF Payment*](http://research.downstate.edu/irb/irb-electronic-submissions.html) *with an IRB submission when providing compensation (not including travel reimbursements) to research participants of $600 or more per calendar year, when the SUNY RF processes payments to the participants. The IRB stamps the form specific to a study, once approved. This form is not required when using a commercial vendor (e.g., credit card payment vendor) for processing payments and reporting income to the Internal Revenue Service.*

## 6) ADDITIONAL INFORMATION:

1. **Does the research team plan to use the Downstate Clinical & Translation Science Center (CTSC) for any part of the research?**

For more information about CTSC resources, see: <http://www.downstate.edu/ctsc/resources.html>

|  |  |  |
| --- | --- | --- |
| [ ]  No | [ ]  Yes  | **If YES, please describe**.       |

**b) Please provide any additional information for the IRB to consider:**

## 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 Form 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, MDorCaitlin Otto, PhD.  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 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: