**Application for Continuing Review / Progress Report Submission**

**WITH EXTERNAL IRB OVERSIGHT**

**The progress report and all required materials must be provided and all required training and conflict of interest disclosures must be complete at least three (3) weeks in advance of the expiration date.**

**WARNING: If the required training or conflict of interest disclosures are pending at the time of Downstate IRB review and acknowledgement, the investigators listed on the study may not conduct any research, until local Downstate requirements are met.**

|  |
| --- |
| **Please attach the following materials:**  **1) External IRB approval letter**  **2) Any informed consent or recruitment materials that requires stamping by the SUNY DMC IRB.**  **3) Any External IRB letters or notices which have not yet been acknowledge by the SUNY DMC IRB.** |

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

1. **Research Foundation (RF) Award Number, if applicable:**

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

1. **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 employment  *REMINDER:* [*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”?  *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 +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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 employment  *REMINDER:* [*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”?  *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 +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |
|  |  | SUNY Downstate  NYC +HH, KC  Other: | Yes  No | Yes  No | Yes  No |

*Attach additional pages if needed, or send a copy of the IRB application to the* [*IRB@downstate.edu*](mailto:IRB@downstate.edu) *and request additional rows be added.*

1. **EXTERNAL IRB NOTICES:**

Have all IRB notices or letters from the external IRB must be submitted to the DMC IRB for local acknowledgement, within 30 days of approval notice?

**Yes  No**

**If no, explain:**

**Please attach any notices or letters that are pending acknowledgment by the DMC IRB.**

1. **ANCILLARY REVIEWS:**

## Please review the following sections to confirm or determine if any ancillary reviews are required.

## For any ancillary reviewer other than IBC, please share the IRBNet submission with the ancillary reviewer. Although the IRB may grant a “conditional approval” of the research when ancillary review is required, the research CANNOT begin until the IRB has granted final IRB approval after all required ancillary reviews are complete.

1. **UHB Pathology Laboratories:**

***NOTE: The criteria for the requirement of pathology ancillary review and approval were clarified on February 16, 2018.***

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

**At least one box MUST be checked.**

(4a1) 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).”

 (4a2)  Services or assistance of the UHB Pathology Laboratories (Clinical Laboratory, Histology Lab and/or Surgical Pathology).

(4a3) 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 box “4a1” or “4a2” is checked above, please indicate which past IRBNet package contains UHB Pathology Approval:***

***If box “4a1” or “4a2” is checked above and this project has not yet received UHB Pathology Approval, or if you are uncertain if Pathology Approval is needed, please do the following:***

**Step 1:**

1. Refer to the UHB Pathology Instructions, Forms, and Fees posted in UHB Pathology website: <http://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.
2. 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.  E-signature is required before the IRB can grant final approval.

**Step 3:** After IRB and Biosafety (if needed) approvals are granted, complete and submit the “Step 3 Form: Protocol of UHB Laboratory Use/Patient specimens for Research Projects: Clinical, Histology, and Surgical Pathology Labs. Your pathology approval number will then be assigned.

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

1. **Biosafety Approval:**

***NOTE: The criteria for the requirement of IBC ancillary review and approval were clarified on December 12, 2016.***

* 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:  Please contact Ms. Lydia Bailey at the IBC Office at (718) 270-3912 or [IBC@downstate.edu](mailto:IBC@downstate.edu).
* 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.

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

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

No to (B.i.), 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.

Yes to (B.i.), this study involves the use of recombinant or synthetic nucleic acid molecules, infectious agents, human cells or body fluids, or hazardous substances and the materials are not collected nor handled by a (CLIA) certified laboratory.

* 1. **If YES was selected to (B.i), please indicate the status of your IBC approval the study or is the review pending?**

**I have already received approval from the IBC and previously submitted said approval to the IRB for their records. *Submitted in Package #*:**

**I have already received approval from the IBC BUT I *have not* previously submitted said approval to the IRB for their records. *Therefore, I am attaching said approval to this package.***

**I have not yet obtained approval from IBC approval. HOWEVER, I have an application pending with the IBC.**

**I have not yet obtained approval or applied for approval from the IBC.**

***The IRB recognizes that the requirements for when IBC approval has changed on December 12, 2016.  Check the following as it pertains to your study:***

**All of the research interventions with participants and specimens are complete and there are no interactions with research participants, no use of specimens, no storage or shipment of specimens, and no plans to publish in a journal that requires documentation of IBC approval. If this box is checked, please notify the IBC of this determination. Submit a copy of the IBC approval letter to the IRB for acknowledgment within 30 days of receipt of IBC approval.**

**Ongoing research still involves interactions with research participants, use of specimens, storage or shipment of specimens, or plans to publish in a journal that requires documentation of IBC approval. If this box is checked, please submit an application to the IBC for this research activity within 30 days and submit a copy of the IBC approval letter to the IRB for acknowledgment within 30 days of receipt of IBC approval.**

***NOTE: If IBC approval cannot be granted within 60 days of the IBC submission, the IRB recommends the PI voluntarily suspend the research until IBC approval is granted and notify the IRB and IBC of the suspension.   Voluntary suspensions by the PI are not reportable to the US Office of Human Research Protections (OHRP); however, if the IRB determines lack of IBC approval is serious or continuing non-compliance or if the IRB must suspend or terminate IRB approval, the Downstate Institutional Official must report the event to OHRP, and when applicable report to the FDA and Sponsor.***

**If the above box was checked, indicate whether IBC approval will be requested?**

**YES  NO Comments:**

* 1. **If Yes to (B.i), 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

**If yes**, approval by both the IBC and the NIH Recombinant DNA Advisory Committee (RAC) is required, prior to Final IRB approval.

* 1. **If yes to (b.iii), has the NIH RAC approved the study or is the review pending?**

**Yes.** **If YES, please upload the approval letter within the new IRBNet Submission package or indicate which package this was previously submitted:**

**PENDING NIH RAC approval; however, conditional IRB approval is requested.**

1. **Ancillary review by Research Pharmacy:**

***Note: For more information see SUNY Policy Number PHA-11: Investigational Drug/Dispensing and Utilization, which was revised Jan 2016.***

*See:* [*http://www.downstate.edu/regulatory/pdf/policies/PHA-11.pdf*](http://www.downstate.edu/regulatory/pdf/policies/PHA-11.pdf)

1. **Does this study involve drugs or biologics at Downstate?**  Yes No **IF NO, proceed to question (D).**

*Note: For research at NYC H+H, Kings County, a Kings County Pharmacist may review the research, once it is entered in STAR.*

1. **If yes, to (C.i), please indicate the status of your Research Pharmacist approval:**

**I have already received approval (e-signature) from the Research Pharmacist or designee. The e-signature can be found in the IRB records. *E-signature in Package #*:**

**I have already received approval (e-signature) from the Research Pharmacist or designee BUT I *have not* previously shared and / or obtained e-signature from the Research Pharmacist or designee for the IRB for records. *Therefore, I have shared this study with the research pharmacist and (s)he has e-signed this package.***

**I have not yet obtained approval from the Research Pharmacist or designee. *If you selected this response, please share this IRB Submission with the Research Pharmacist or designee, so that (s)he may electronically sign the submission and answer the following:***

**Check the types of patients that will be involved in the study:** Inpatients Outpatients Other, specify:

**What days of the week will participants be enrolled or recruited?** Weekdays Seven days per week Other, specify:

**What hours of the day will participants be enrolled or recruited?** 9am – 5pm Any time of the day Other, specify:

**How much time does the Pharmacy have from randomization/enrollment to drug administration?**       (Hours)

**Drug formulation:** Injectable  Oral  Topical Other, specify:

**If intravenous, for how many hours is the product stable for once prepared?**

**Who can randomize a patient into the study?**

PI Sub investigator/Co-Investigator Study coordinator Pharmacist Other, specify:

**Who can receive drug treatment assignment via IVRS/IWRS?**

PI Sub investigator/Co-Investigator Study coordinator Pharmacist Other, specify:

**What is the enrollment goal?**       (Number of research participants)

**Anticipated quantity of drug shipped to site (if known):       (Number of kits)**

**Size of kits (if known):**       (**Dimensions)**

1. **Ancillary review by other multiple Departments:**
2. **Does this research impact or involve other Departments, other than those listed above?  Yes  No *If NO, skip to section 13.***
3. **If yes to (d.i), describe how each specific Department is involved or impacted:**

1. **If yes to (d.i), please indicate the status of your approval from the impacted or involved Department(s):**

**I have already received approval (e-signature) from the impacted or involved Department chair(s). The e-signature(s) can be found in the IRB records. *E-signature(s) in Package #*:**

1. **I have already received approval from the impacted or involved Department chair(s), BUT I *have not* previously shared and / or obtained e-signature from the impacted or involved Department chair(s) for the IRB for records. *Therefore, I have shared this study with the impacted or involved Department chair(s) and (s)he has e-signed this package.***
2. **I have not yet obtained approval from the impacted or involved Department chair(s). *If you selected this response, please share this IRB Submission with the impacted or involved Department chair(s), so that (s)he may electronically sign the submission***
3. **ADDITIONAL INFORMATION:**
4. **If you wish to add additional information for the IRB to consider, please add it here:**

1. **SIGNATURES**

**The IRBNet package must be electronically signed by the PI before submitting the package to the IRB.**

**If Pharmacy, Pathology, or an additional Department Chair is conducting an ancillary review, please have the designated individual e-sign the submission.**

**If the IBC is reviewing the research, please provide a copy a copy of the IBC approval letter.**