**Application for Amendment**

**(EXCEPT FOR STUDY STAFF)**

**NOTES:**

* **Attach revised documents and indicate proposed changes in tracked changes when possible.**
* **Update IRBNet Registration Form if indicated.**
* **To change study staff, submit “Application for Amendment-STAFF CHANGES ONLY.”**
* **To request an acknowledgement by the IRB (e.g., notices from an external IRB, external reportable events, new training documents, etc.), submit an “Application for Acknowledgement.”**
* **To report reportable events, use the “Application Form for Reportable Event.”**
* **All amendments must be approved by the IRB before they can be implemented.**

## SECTION A: IRB REVIEW:

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

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

Phone # (required):       Email (required):       Alternate E-mail (optional):       |  |

1. **If someone, other than the PI, is the main contact for this study, please provide his/her contact information below:**

|  |  |
| --- | --- |
| Name (if not PI):      Role on Study:       | Phone:       Email:       |

1. **SUMMARY OF CHANGES**
2. **Does this amendment come at the request of the sponsor?**

[ ]  Yes [ ]  No ***If Yes to A*, please upload documentation from the sponsor regarding the amendment.**

1. **Check box(es) below to indicate type of change(s):**
	1. **[ ]  Funding or study status.**
	2. **[ ]  Number of research participants (e.g., screening, enrollment, charts, specimens) or recruitment methods.**
	3. **[ ]  Recruitment methods, advertisements, reimbursement, or compensation.**
	4. **[ ]  Study sites.**
	5. **[ ]  Protocol or abstract.**
	6. **[ ]  Consent, Assent, Parental Permission, Information Sheet, HIPAA Authorization, Consent Addendum, Waiver of Informed Consent requirements, HIPPA Waiver, or other similar forms.**
	7. **[ ]  Investigator Brochure**
	8. **[ ]  Funding status or funding changes.**
	9. **[ ]  Changes due to changes required by ancillary review (IBC, Pathology, Pharmacy, STAR, Department Chair, SRC, etc.)**
	10. **[ ]  Amendment to transition existing IRB approved research to the 2018 Common Rule**
	11. **[ ]  Other. Describe:**
2. **Describe all changes:**

1. **Reason for proposed change:**

1. **Describe any impact these changes may have on study participants, if any (or indicate N/A):**

## SECTION B: EXPEDITED REVIEW:

[ ]  **(OPTIONAL) Check here to request expedited review and indicate reason:**

*Note: If not sure, leave unchecked. The IRB will make the final determination.*

 [ ]  The study received approval via expedited review when the study was initially approved.

[ ]  The proposed change represents a minor change in the research.

[ ]  The study is 1) not an FDA regulated clinical investigation 2) not DOJ/DIJ funded, 3) initially approved by the full board after January 20, 2019, and 4) AND has progressed to the point where it involves one or both of the following:

[ ]  data analysis only

 [ ]  accessing follow-up clinical data from clinical care

[ ]  The research is NOT conducted under an investigational new drug application (IND) or investigational device exemption (IDE) ***and*** the IRB has determined and documented at a full board meeting that the research involves no greater than minimal risk ***and*** no additional risks have been identified. If known, please indicate meeting date or IRB submission package # for when this determination was made:

## SECTION C: ANCILLARY REVIEWS:

## Please check the types of ancillary reviews required for this amendment. Consult with the ancillary reviewer or IRB for guidance if not sure.

[ ]  other departments or colleges

[ ]  [UHB Pathology Laboratories](http://www.downstate.edu/lab/index.html)

[ ]  [Institutional Biosafety Committee (IBC)](http://research.downstate.edu/administration/biosafety.html)

[ ]  [NIH NOVEL AND EXCEPTIONAL AND RESEARCH ADVISORY COMMITTEE](https://osp.od.nih.gov/biotechnology/novel-exceptional-technology-research-advisory-committee/) (NExTRAC-FORMALLY KNOWN AS Rac)

[ ]  UHB PHARMACY