IRB submission process

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5/16/2019
DEPT OF PEDIATRICS

Role of IRB

- **Research involving systematic investigation of human subjects, and results will contribute to generalizable knowledge**
- The IRB:
  - Protects the rights and welfare of research participants.
  - Empowered to approve, require modifications, or disapprove Human Research
  - Ensures Human Research is scientifically/scholastically valid, ethical, and in compliance with all requirements
  - Ensures compliance through oversight functions
  - Serves as a Privacy Board to ensure HIPAA compliance

Timeline (start early)

- Complete CITI training
- Plan your project
- Identify Faculty member as PI
  - **Research Protocol**:
    - Hypothesis, Aims and Objectives
    - Methods, Procedures, Data Collection
    - Statistics: power analysis and statistical tests
      - Best to see statistician prior to submitting project to IRB
- Upload documents to IRBnet.org
- PI, chair (s), SRC, ancillary reviewers sign package
  - Scientific Review Committee (SRC) accesses project on IRBnet
  - PI finalizes package and SUBMITs (locked unless modifications required)
- IRB for review (see schedule)

IRB meetings/deadline

SUBMISSION DEADLINE	MEETING DATE	LEAD
April 3rd	May 1st	Nikol Celestine, BA, CIP
May 1st	June 5th	Diann Johnson, MPH
June 5th	July 10th	Nikol Celestine, BA, CIP
July 10th	August 7th	Danielle Lewis, MD, MPH
August 7th	September 11th	Diann Johnson, MPH
September 11th	October 2nd	Nikol Celestine, BA, CIP
October 2nd	November 6th	Danielle Lewis, MD, MPH
November 6th	December 4th	Diann Johnson, MPH

CITI Training

- Register for CITI training
- Affiliate with Downstate
- https://citiprogram.org
- All study staff must have current certificate (if applicable)
  - **Group 1: Biomedical Investigators and Key Personnel**
  - **Group 2: Social / Behavioral Investigators and Key Personnel**
  - Group 3: IRB

DMC and Kings County IRB

- Research at DMC **https://Irbnet.org**
  - Principal investigator, co-investigators, coordinators, residents and fellows
  - Electronic Submission of all documents (application, **registration link**, protocol, informed consent, recruitment material, training certificates, etc.)
  - Instructions and forms: **http://research.downstate.edu/irb/irb-electronic-submissions.html**
- Research at Kings County:
  - Upload DMC IRB approval letter to HHC system
  - Submit to **https://star.nychhc.org**

Is it Research?

- If conducting **systematic investigation** and it contributes to **generalizable knowledge**, then it is RESEARCH
- Requires IRB review

- If the intention is **not to create generalizable knowledge**, then it is NOT RESEARCH.
- Do **NOT** need IRB review
  - Case report or case series (up to three individuals)
  - Certain QI projects
  - Certain training or educational activity (survey, interview or observation)
  - Public health surveillance activities
  - Off-label use of FDA approved drug/biologic for clinical care

Levels of review

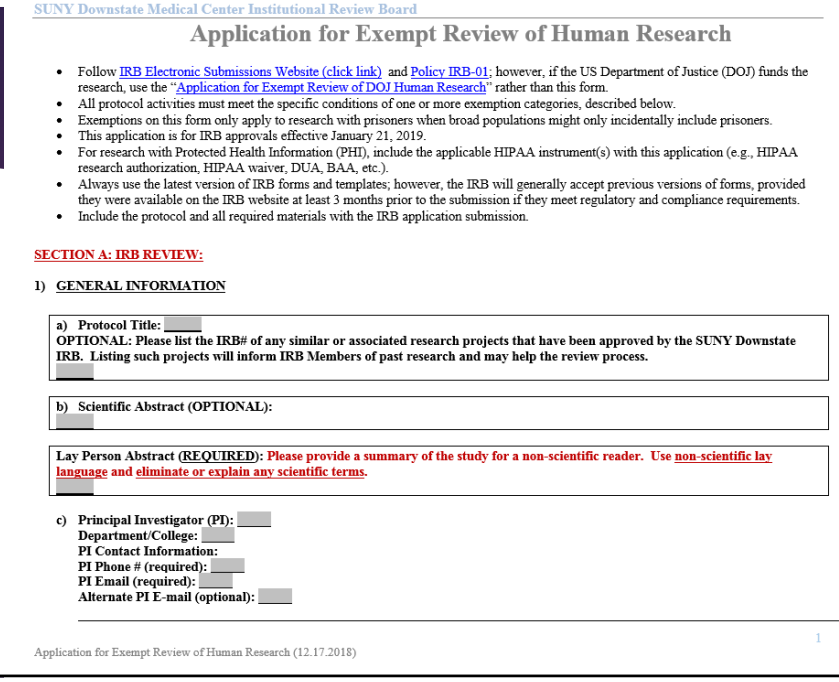
- Non-research studies do not need to be reviewed
- Exemption
- **Expedited (reviewed by 1 or 2 members)**
- **Full Board (convenes once a month)**
- External IRB review accepted for multisite study with IRB approval from another site
  - Must complete IRB application at DMC
- Clinical Use of an Humanitarian Use Device (HUD)
- Expanded Access to Investigational Drug/Biologic for Treatment Use

Exemption Status (IRB review)

Intention is to create generalizable knowledge:

1) Normal educational practices in established educational settings (surveys, interviews etc)
2) Educational tests, surveys, interviews, or observation of public behavior
3) Benign behavioral interventions with adults with prospective agreement
4) Secondary research for which consent is not required
5) Federal research and demonstration projects
6) Taste and food quality evaluation and consumer acceptance studies

- Complete Application for Exempt Review for Human Research
  - HIPAA/HITECH regulations still apply
  - Exemption determined prospectively by IRB



SUNY Downstate Medical Center Institutional Review Board

Application for Exempt Review of Human Research

- Follow IRB Electronic Submissions Website (click link) and Policy IRB-01; however, if the US Department of Justice (DOJ) funds the research, use the "Application for Exempt Review of DOJ Human Research" rather than this form.
- All protocol activities must meet the specific conditions of one or more exemption categories, described below.
- Exemptions on this form only apply to research with prisoners when broad populations might only incidentally include prisoners.
- This application is for IRB approvals effective January 21, 2019.
- 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.

SECTION A: IRB REVIEW:

1) GENERAL INFORMATION

a) 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.

b) 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.

c) Principal Investigator (PI):
Department/College:
PI Contact Information:
PI Phone # (required):
PI Email (required):
Alternate PI E-mail (optional):

1

Application for Exempt Review of Human Research (12.17.2018)

Examples of Expedited Review

- Clinical studies of drugs and medical devices only under specific conditions
- Chart reviews
- Survey research which is sensitive **and** includes identifiable information
- Collection of blood samples
- Biological specimens obtained by non-invasive means
- Collection of data through non-invasive means
- Materials collected solely for non-research purposes
- Collection of data from voice, video, etc.
- Research employing surveys, focus groups, etc.
- Continuing review under specific conditions
- See: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

Expedited Review

- Complete Application for Expedited or Full Board Review of Human Research to see if expedited review criteria is met
- Expedited Review is not allowed for:
  - **Initial review of intervention studies (medication or devices) involving children/neonates, pregnant women, prisoners, or cognitively impaired adults**
  - Or if reviewer determines that there are questions about study design or sensitive issues, goes to full board
- Can be allowed for research with minimal risk for children (no drugs or devices)

Vulnerable populations

- **Children/neonates***
- **Minority**
- Pregnant women
- Prisoners
- **Limited English Proficiency**
- **Economically or educationally disadvantaged**
- Students or subordinates
- Cognitively impaired adult
- **Patients being recruited by their Doctor for study**

Research involving Minors

- **No more than minimal risk (404)**
  - Minimal risk is the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
- **Greater than minimal risk but presenting the prospect of direct benefit to the individual child (405)**
- **Greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition (406)***
- 407* After initial IRB review, refer to FDA or OHRP
- ***Two parents/legal guardian consent required (unless otherwise not available):**
  - Research involving enrollment of a child as a normal control
  - When required by a sponsor

SUNY Downstate Medical Center Institutional Review Board

Application for Expedited or Full Board Review of Human Research

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- 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.

SECTION A: IRB REVIEW:

1) GENERAL INFORMATION

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.

a) 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.

b) 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 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 Program

c) (OPTIONAL) If someone, other than the PI, will be the main contact for this study, please provide his/her contact information below:
Name: **Phone:** **Email:**
Role on Study:

d) (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.

e) 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 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

☐ **Inbound Subcontract (Specify funding entity):** ____ **Date of anticipated funding:** ____

☐ **Other: Specify:** ____

f) 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:** ____

g) Is this a clinical investigation designed to evaluate the safety and effectiveness of a medical device? ☐ **Yes** ☐ **No**
If yes, is this study exempt from IND requirements? ☐ **Yes** ☐ **No**
If no, what type of study is this? ☐ **Significant Risk (SR)** ☐ **Non-Significant Risk (NSR)**
If SR, provide IDE # ____

If implanting an investigational medical device, answer the following questions:

i. **Where are devices stored?**
____

ii. **How does the study team track the use of the devices?**
____

iii. **How does the study team return or destroy any devices that are not used?**
____

h) Does this study involve <u>any</u> drugs or biologics? ☐ **Yes** ☐ **No**
If yes, complete the chart below for each agent in the study.

Trade Name	**Generic Name**	**Investigational?** **Yes** (Not FDA approved as indicated for the research) **No** (Used according to FDA label)	**If Investigational, list IND/BB-IND #** ***Note: submit FDA Form 1572 and IND letter from the sponsor or FDA***	**If Investigational, list Holder of IND**
____	____	☐ **Yes** ☐ **No**	____	____
____	____	☐ **Yes** ☐ **No**	____	____
____	____	☐ **Yes** ☐ **No**	____	____
____	____	☐ **Yes** ☐ **No**	____	____

i) For clinical investigations involving an IND, the FDA recommends including the following to support IRB review. Check if any of the materials are provided:
Note: The IRB reserves the right to request this material when needed to fully evaluate the research.

☐ Published literature about the chemistry, manufacturing, and control of the drug substance and product;
☐ A summary of previous human experience with the drug product;
☐ Sufficient information regarding the source, purity, quality, and method of preparation and delivery of the drug used in the research;
☐ Information regarding the pharmacology and toxicity of the drug product in animals.

Comments regarding above materials: ____

j) Does the Sponsor require compliance with the International Conference on Harmonization ICH Good Clinical Practice (GCP) E6 Guidelines?
☐ **Yes** ☐ **No** **IF YES, be sure to include a copy of the PI's CV to meet GCP requirements.**
Note: To fully comply with ICH requirements, please refer to the E6 GCP Guidance located at http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf.

k) Is this a "Qualifying/Deemed Clinical Trial" under the CMS regulations? ☐ Yes ☐ No
For more information, see: https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/downloads/finalnationalcoverage.pdf

l) Is this study an "Applicable Clinical Trial"?
☐ Yes ☐ No
If yes was checked above:
i. **ClinicalTrials.gov NCT# or anticipated date for registration** ____
ii. **Confirm the exact following language is included in the informed consent document by placing an "X" in the following box:**
☐ A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
iii. **Who is the responsible party for registering the trial and submitting results:** ____

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 employment *REMINDER: STAR approval 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 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

Conflict of interest (yearly and each project)

4) **RESEARCH PARTICIPANTS:**

a) **What is the age range of the study population?** ____

b) **Please indicate whether you are including any of the following individuals:**
- ☐ Males
- ☐ Females
- ☐ Patients

c) **Location of the research participants?**
- ☐ SUNY Downstate
- ☐ NYC H+H, Kings County *REMINDER: STAR approval 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.

d) **Indicate the following as it pertains to the above sites:**
- i) ____ Number of patient charts to be reviewed.
- ii) ____ Number of research participants who will be *screened.*
- iii) ____ Number of research participants who will be *enrolled.*

e) **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)*

f) **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, when applicable to the study.

For more information in enrolling participants with LEP, see IRB-01 policy and IRB Guidance on Obtaining Legally Effective Informed Consent and HIPAA Authorization.

Expedited/Full Board IRB Application 12.17.2018 6

☐ **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.

g) **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: ____

h) **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: ____

i) **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: ____

j) **Check if either are planned for screening, recruiting, or determining eligibility of a research participant**
Note: This process is not permitted for an FDA regulated clinical investigation.
A HIPAA waiver or authorization is required, if the process involves PHI.

☐ The investigator will obtain information through oral or written communication with the prospective research participant or the LAR/surrogate.
If checked, describe: ____
☐ Check if written communication will be used, and include the document with IRB submission

☐ The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
If checked, describe: ____

☐ None of the above.

k) **(Optional): Please describe any plans for consent monitoring:** ____

l) **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/

☐ 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:

a) **Describe any costs that participants incur during their participation:** ____

b) **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 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:

a) **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**: ____

7) INFORMED CONSENT
Note: Consent Form Template(s) and Assent Templates are available in the "Forms and Templates" page in IRB Net at https://www.irbnet.org

a) **How does the study team ensure informed consent is obtained in a private setting?** ____

b) **Indicate whether you will obtain a HIPAA Authorization, a HIPAA waiver, or whether the study does not involve access, review, or disclose Protected Health Information (PHI) also known as Individually Identifiable Health Information (IIHI).**
☐ Will obtain a HIPAA Authorization (IIHI Authorization) combined with a consent document or information sheet (e.g., "What information will be kept private" section of templates)
☐ Request a HIPAA Waiver (e.g., for retrospective review of PHI/IIHI, and/or waive or alter signature or other required elements, and/or to review of PHI/IIHI for recruitment purposes and obtain a HIPAA Authorization during enrollment, if applicable)
☐ N/A - the study does not involve access, review, or disclosure of PHI/IIHI.
☐ N/A – this study involves release of a limited dataset and a Data Use Agreement (DUA) or a Business Associates Agreement (BAA)

c) **Did any researcher seek access to PHI/IIHI in preparation for this IRB Application for the research project?**
☐ Yes ☐ No
If **YES**, complete and upload a "Research Certification for Reviews Preparatory to Research" to the new submission package. This form is available in the IRBNet on the Forms & Templates page.

d) **Check if requesting a waiver of informed consent requirements:**
☐ Request to waive the process of the entire informed consent process (e.g., for retrospective review of data or for recruitment purposes)
☐ Request to waive required elements of informed consent
☐ Request to waive documentation (signatures) of informed consent

e) **Does the study design (e.g., such as deception research or clinical trial with a placebo) require withholding information (e.g., purpose of the research, name of investigational agent or nature of treatment arm) from research participants?**
☐ Yes ☐ No
If YES, please explain: ____
If YES, describe whether and how the research participant will be debriefed about the withheld information, after their participation in the study is complete? ____

f) **Does the research involve the collection of identifiable private information or identifiable biospecimens?**
If Yes, which of the following required statements is provided within the informed consent document?
☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the research participant or LAR/surrogate, if this might be a possibility; or

☐ A statement that the research participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

g) Does the European Union General Data Protection Regulation (EU GDPR) apply to this research?
Effective May 25, 2018, is a data privacy regulation that may apply to some DMC research including research conducted in the European Union (EU), research sponsored by an EU entity, or research involving transmission of protected data within the EU.
☐ Yes ☐ No

h) Check if any of the following apply to the research?
☐ Use of the research participant's biospecimens (even if identifiers are removed) for commercial profit.
☐ Plans to disclose clinically relevant research results to research participants.
☐ Whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
☐ None of the above

i) Is this a clinical trial, as defined by the Common Rule & conducted or supported by a Federal department or agency?
☐ Yes ☐ No
If yes, which web site will be used to post one IRB-approved informed consent form after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any research participant, as required by the protocol?
☐ www.ClinicalTrials.gov, or
☐ Docket folder on www.Regulations.gov (Docket ID: HHS-OPHS-2018-0021)
☐ N/A – This is not a clinical trial, as defined by the Common Rule

8) ANTICIPATED RISKS OR DISCOMFORTS

b) Describe any anticipated risks or discomforts for this study, based on each of the following categories:

TYPE	EXAMPLE	DESCRIBE ANY ANTICIPATED RISK OR DISCOMFORT FOR THIS STUDY. BE SURE TO INCLUDE THESE IN THE INFORMED CONSENT OR INFORMATION SHEET, AS APPLICABLE
Physical Risks	e.g pain, bruising and infection associated with venipuncture, adverse reactions to drugs, muscle soreness and pain as a consequence of exercise testing, heart attack induced by maximal exercise test, radiation risk (e.g. x-ray, CT-scan, radiation therapy, radioisotopes, fluoroscopy)	
Psychological Risks	e.g depression and confusion as a result of administration of drugs, feelings of guilt precipitated by a sensitive survey	
Social Risks	e.g. invasion of privacy, breach of confidentiality, loss of community standing	
Legal Risks	e.g. criminal prosecution or revocation of parole	
Economic Risks	e.g. loss of employment, loss of potential monetary gain	

c) What is done to minimize risks (e.g. inclusion/exclusion criteria, monitoring procedures, etc)?

d) What is the proposed level of risk for this study (IRB will make final determination)?
☐ **No greater than minimal risk**
☐ **Minor increase over minimal risk**
☐ **Greater than minimal risk**

9) BENEFITS

a) Is there a prospect of direct therapeutic benefit to individual research participants that will be enrolled in the study?
☐ Yes ☐ No ☐ N/A

b) If "Yes" to (8a), describe the benefit that is listed in the informed consent document:

c) If "Yes" to (8a), please describe the plans to recruit and enroll those with Limited English Proficiency (LEP) (e.g., plans to submit amendment for translated materials, submission of short forms now, etc.) *OR* describe the risks or barriers that prohibit the enrollment of those with LEP (e.g., scientific instruments not valid, lack of financial support, study is too complex, limited access to certified interpreters during the study, interpreters lack important medical knowledge, etc.):

Note: The ethical principles of the Belmont report must be balanced. It is important to maximize the benefits for the research, while minimizing risks to research participants. When recruiting those with LEP the PI and IRB must ensure this is done in a reasonable, non-exploitive manner using well considered procedures that are administered fairly and equally. Please include the Short Forms in

the submission package, if you are requesting the use of the Short Forms for enrolling participants with LEP. See IRB Guidance: "Obtaining Legally Effective Informed Consent and HIPAA Authorization" for various options for recruiting those with LEP.

d) What are the other potential benefits of the research (e.g., benefits to society, advanced monitoring of the participant, etc.)?

Note: Do not list financial compensation as a benefit.

e) Does this study involve comparative effectiveness research (*Comparative effectiveness research is the conduct and synthesis of systematic research comparing different interventions and strategies to prevent, diagnose, treat and monitor health conditions*)?

☐ Yes ☐ No

If Yes, please answer the following questions:

(1) Describe any standard interventions incorporated into the study?
or check N/A: ☐ N/A

(2) What would be the standard treatments/procedures, if the participants were not enrolled in this research?
or check N/A: ☐ N/A

(3) How do the risks and potential benefits of the research interventions differ from standard care?
or check N/A: ☐ N/A

10) SAFETY MONITORING:

Important: If your study includes a large study population, multiple study sites, highly toxic therapies, high expected rates of mortality, or high probability of early termination, a Data Safety Monitoring Board (DSMB) will likely be required. Monitoring activities should be appropriate to your study, study phase, population, research environment, and degree of risk involved.

Check the type of safety monitoring for this research:

☐ **Data Safety Monitoring Board (DSMB). Describe:**
☐ **Data Safety Monitoring Plan (DSMP). Describe:**
☐ **None. If none, explain why:**

11) BIOLOGICAL SPECIMENS

a) Does the study make use of biological specimens (e.g. blood or tissue or body fluids samples)?

☐ Yes ☐ No **If NO, skip to the skip to the next section.**
If YES, please indicate how the biological specimens will be obtained.

b) Will specimens be transported by a public carrier?

☐ Yes ☐ No **If YES, upload a certificate of training for Hazardous Materials training to the IRB submission package in IRBNet.**

c) Will specimens be obtained in the future (e.g., prospective collection)?

☐ **Yes** ☐ **No**

If YES, select one of the following:

☐ The specimens will be obtained for research purposes only
☐ The specimens will be excess material from clinical samples

d) Are the specimens to be obtained from an existing collection? ☐ Yes ☐ No

If YES, does the original consent cover the purpose of this research? ☐ Yes ☐ No

If NO, please include a waiver of informed consent and waiver of HIPAA authorization, as applicable.
Please upload a copy of the original consent form to the IRB submission package in IRBNet.

e) Will the specimens be linked to individually identifiable information (e.g. name, ID#, code, or any of the 17 HIPAA Identifiers)?

☐ Yes
☐ No

If YES, answer the following:

(1) **Are the specimens linked during the storage process, after processing?** ☐ Yes ☐ No
(2) **Could the study yield clinically relevant information?** ☐ Yes ☐ No
(3) **Under what circumstances will participants be contacted?**

f) Will the specimens be preserved for other research?

☐ Yes ☐ No

(1) **If YES, explain for what purpose the specimen will be used:**

g) Are any of the specimens processed at UHB Pathology?

Note: If applicable, complete ancillary review by UHB Pathology.

☐ Yes ☐ No

h) If your study involves tissue banking, please fill out the following 6 questions below:

(1) What type of research is to be done with the specimens? (e.g. in the future etc…)

(2) Describe how and where specimens will be stored.

(3) If specimens will be linked to individually identifiable information (e.g. name, ID#, code) describe how the privacy of research participants and the confidentiality of their data will be protected:

(4) Describe who will have access to the specimens including the requirements for access, and who has control of this access:

(5) Describe the procedures in place for research participants to withdraw their specimens or whether de-identification makes withdrawal impossible:

(6) Is the banking of the specimens optional?
☐ Yes ☐ No.
If NO, the informed consent should adequately explain that participation in the study means the specimens will be stored indefinitely for future use or explain when the samples will be destroyed.

12) PRIVACY & CONFIDENTIALITY

a) What will be done to ensure the privacy of the research participant? (e.g., use of curtains, drapes, closed room)

b) What will be done to ensure the confidentiality of the research participants data ? (e.g. data access, data security, data disclosure, destruction of identifiers, storage, and coding)

13) COSTS AND PAYMENTS:

a) Will participants (or their insurance) be billed for any of the procedures, drugs, biologics, devices, or tests?
☐ No ☐ Yes If YES, which procedures?
Note: All costs for research participation must be disclosed in the informed consent document or information sheet, as applicable.

b) 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

c) Are there any procedures to compensate participants for study related injury?
☐ No ☐ Yes If YES, please describe.
If NO, this should be stated clearly in the informed consent.

14) 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.

2. Please provide any additional information that you would like for the IRB to consider:

SECTION B: EXPEDITED REVIEW:

☐ **(OPTIONAL) Check here to request expedited review and indicate all applicable categories below:**

Notes:

1. *The IRB will make the final determination and will consider this for all applications, regardless of whether expedited review is proposed.*
2. *DMC does not permit expedited review under category 1 or category 2 at the time of initial review, when the research includes an intervention with children, pregnant women, neonates, prisoners, or cognitively impaired adults. However, subsequent review or follow-up review to the after the initial review by the Full Board may be reviewed by expedited review for research involving these populations, unless otherwise determined and documented by the full IRB.*
3. *When a study qualifies for expedited review, the IRB may refer the initial review to the Convened (Full) Board (for sensitive issues, study design concerns, etc.) or as required above for category 1 and 2. In these situations, the study may continue to be reviewed by expedited review procedures for any follow-up required by the convened IRB, unless the IRB otherwise determines the response to the initial review must be carried out by the convened board.*

☐ **Federal expedited research review category #1A**: Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.

☐ **Federal expedited research review category #1B**: Research on medical devices for which

- An investigational device exemption application (21 CFR Part 812) is not required; or
- The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

NOTE: For a device study to be eligible for expedited review, it must be an NSR study AND present no more than minimal risk to the research participant.

☐ **Federal expedited research review category #2A**: Collection of blood samples by finger-stick, heel-stick, ear-stick, or venipuncture from healthy, non-pregnant adults who weigh at least 110 pounds. For these research participants, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week.

☐ **Federal expedited research review category #2B**: Collection of blood samples by finger-stick, heel-stick, ear-stick, or venipuncture from adults and children, considering the age, weight, and health of the research participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these research participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week. This category may include non-healthy adults, pregnant adults, and adults who weigh less than 110 lbs., if requested in the IRB application materials.

☐ **Federal expedited research review category #3**: Prospective collection of biological specimens for research purposes by noninvasive means, not limited to the following examples, which are generally considered noninvasive:

- Hair and nail clippings in a non-disfiguring manner;
- Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- Permanent teeth if routine patient care indicates a need for extraction;
- Excreta and external secretions (including sweat);
- Un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- Placenta removed at delivery;
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- Sputum collected after saline mist nebulization;

☐ **Federal expedited research review category #4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. **Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.**

☐ **Federal expedited research review category #5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes, such as medical treatment or diagnosis.
Note: As permitted by OHRP, this category includes research involving materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research. Research may involve materials that will be collected solely for non-research purposes.

☐ **Federal expedited research review category #6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ **Federal expedited research review category #7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Ancillary Reviews

- Pathology review
  - if past, present or future specimen (tissue, blood or fluid) need to be processed through our pathology lab
  - If extra specimen and going to outside lab, no need.
- Pharmacy
  - All research with drugs/biologics that takes place at Downstate must be reviewed by Downstate Pharmacy
- Institutional Biosafety committee (IBC)
  - If human recombinant DNA, RNA, cells, infectious agents or biological specimen involved

Informed Consent with HIPAA authorization

- IC templates/forms are available on website
- Be complete and careful
- VOLUNTARY participation
- Do NOT use medical or technical jargon (6th -8th grade level)
- Explain purpose, study procedures, criteria, alternatives to research, benefits and RISKS
  - Risks can include physical, economic, social, psychological, or legal
    - discomfort from blood draw or side effects of medication, travel costs, or breach of confidentiality
    - Protection of PHI
  - Conflicts of Interest, contact information for staff, compensation, costs
- For children <18 years, **parent/legal guardian** signature (or two for 406 and 407)
- For child 13-17 years, child also signs informed consent form
- For child 7-12 years, child signs additional **ASSENT form** (4th grade level)

Other

- Short Forms (Informed consent) available if translating into other languages
  - Must use certified translators
- IND approval letter from FDA for investigational drug
- IDE approval from FDA for investigational devices
- **Data collection** tool (excel sheets or forms to collect data)
- Recruitment material (flyers, ads)

- **Application for amendment**
- **Application for Reportable Events**
- **Application for progress report (yearly)**
- **Application for Final Report**

IRB Determination

- Approve
- Approve with Conditions
- Modifications required (returns to Full Board)
- Information needed (usually IRB staff will let you know before meeting)
- Disapprove
- Exempt

- **Good idea to attend the meeting so you can answer questions**
- **IRB office is very helpful in answering your questions**

Research

- Now you are finally ready to conduct your study
- Use **IRB stamped** consent and assent forms
- Give subject copy of signed form and keep original document (could be audited)
- Store data behind DMC firewall
- Keep records for minimum of 3 years, but recommend 10 years to cover other regulations
- Keep HIPAA for minimum 6 years

IRB office
(718) 613-8480 IRB@downstate.edu

Nikol Celestine
Diann Johnson
Kevin Nellis
IRB Office

- 9 am to 5 pm
- Appointments are recommended; however, walk-ins accepted anytime
- Basic Science Building: Room 3-26
  - Take elevator bank near the cafeteria to the 3rd floor