



**IRB GUIDANCE: HOW TO SUCCESSFULLY SUBMIT AND GET APPROVAL FOR
FORM 11-A4: APPLICATION FOR DETERMINATION LETTER (IRB DECISION AID)
FOR “NOT RESEARCH,” “NOT HUMAN RESEARCH,” OR “INSTITUTION NOT
ENGAGED IN HUMAN RESEARCH.”**

TABLE OF CONTENTS:

Introduction:	1
Tip #5a: Familiarize yourself with the SUNY Downstate IRB website and read the sections that apply to Form 11-4:	2
Tip #5b: Know when you need IRB approval:.....	2
Tip #5c: Determine if Form 11-A4 is right for your project	3
Tip #5d: Submit the correct IRB application:	4
Tip 5e: Understand who can be listed on the SUNY Downstate IRB Application Forms: 4	
Tip 5f: Supply the IRB with adequate information in Form 11-A4 to make a correct determination:	6
Tip 5g: Include the proper project description and supporting documentation:	8
Tip 5h: Ensure all required parties have e-signed the IRB submission	10
Tip 5i Complete all IRB requested revisions in a timely and thorough manner and relock the submission.	11
Tip 5j Complete HIPAA compliance training, when applicable.....	11
References.....	11
Authors.....	11
Review and Approval History	12

INTRODUCTION:

This guidance document was created to support the successful submission and approval of IRB Form 11-A4. It is part of Tip 5, which is posted at: [Electronic Submissions](#) | [Institutional Review Board](#) | [Office of Research Administration](#) | [SUNY Downstate](#)

It is recommended by the IRB that this guidance be shared with students, residents, and faculty who are expected to submit Form 11-A4 to the Downstate IRB as a part of their educational experience.

Although Form 11-A4 is highly recommended by the IRB to document for non-human research activities, it is required by some Departments and Colleges for such activities and most journals will require an IRB Determination Letter prior to accepting a manuscript for publication consideration.

Downstate requires all Nursing students from the Downstate College of Nursing and other external colleges to obtain this determination. A DNP nursing student may meet with a mentor or preceptor prior to submitting the application to the IRB; however, they cannot conduct the project or activity for which the determination is sought until the IRB issues the formal determination letter.

TIP #5A: FAMILIARIZE YOURSELF WITH THE SUNY DOWNSTATE IRB WEBSITE AND READ THE SECTIONS THAT APPLY TO FORM 11-4:

- Visit: [Institutional Review Board | SUNY Downstate Health Sciences University](#)
- Visit: [Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate](#)
 - The main tips that apply to this form are Tips 2 and 5.
 - The main Steps that apply to this form would most likely includes Steps 1, 2, 4, 10, 11, 12, 15, and 17.
 - Review Step 6b-3 (optional Downstate IRB presentations) to review any relevant presentations on the topic.
 - Download the latest version for Form 11-A4 from Step 11. Save it on your computer 1st. Then open the form from within Adobe Reader software to fill out the form properly.
 - Adobe Reader software is available for free at:
<https://get.adobe.com/reader/>

TIP #5B: KNOW WHEN YOU NEED IRB APPROVAL:

Check the Downstate IRB Policy IRB-01 to see if you need to submit Form 11-A4. If you're unsure whether your activity needs IRB approval or if you should submit Form 11A-4 for an official determination please contact the IRB for guidance before you get started.

- Visit Policy IRB-01 posted at: [Institutional Review Board Policies | SUNY Downstate Health Sciences University](#)

- A summary of activities which do not require IRB approval are outlined on pages 23-27 of Policy IRB-01. Use Form 11-A4 to document an IRB Determination for these activities.
- Human (subjects') research activities that require IRB review are outlined on pages 15-23 of Policy IRB-01. Use the applicable IRB application to seek IRB approval for these activities.

Notes:

- (1) Research means: "A systematic investigation designed to develop or contribute to generalizable knowledge".
- (2) Human Research means: The research (as defined above) involves living individuals about whom an investigator (whether professional or student) conducting research either 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

CAUTION: Some evidence-based practices, quality improvement activities, or performance improvement activities may also meet the definition of human research, particularly if the intent of the project is to contribute to generalizable knowledge. If the activity meets the definition of human research, do not submit form 11-A4 to the Downstate IRB.

- Review additional Web Resources, if needed:
 - [Human Subject Regulations Decision Charts: 2018 Requirements | HHS.gov](#)
 - [Engagement of Institutions in Human Subjects Research \(2008\) | HHS.gov](#)
 - [Definition of Human Subjects Research | grants.nih.gov](#)

TIP #5C: DETERMINE IF FORM 11-A4 IS RIGHT FOR YOUR PROJECT

Use the latest version of Form 11-A4 to request a determination letter from the IRB if your project falls under the following categories:

- **Not Research:** An Activity that doesn't meet the definition of "Research," as defined above.
- **Not Human Research:** An activity that meets the definition of "Research" BUT doesn't meet the definition of involve "Human Research," as defined above.

- **Not engaged in human (subjects') research:** This refers to activities where individuals or organizations are not actively involved in conducting activities involving Human Research at Downstate, Kings County, UPB; however, members of the workforce are conducting an activity in order to support Human Research at an engaged institution (which receives IRB approval at the engaged institution). Furthermore, the local activity does not meet the definition of "exempt human research." For more information, see: [Engagement of Institutions in Human Subjects Research \(2008\) | HHS.gov](#)

NOTES:

- (1) *In general, a determination of "not-engaged in human research" of Downstate, Kings County, or UPB would not apply to a research project that is determined to be "Exempt" human (subjects') research" by the main study site's IRB. However, a determination of "not research" or "not human research" might apply to the activities overseen by the Downstate IRB. For more details, see Tip #5e.*
- (2) *If the activity is human research and qualifies for exempt, expedited, or full board review it does not qualify for form 11-A4, see Tip #5d.*

TIP #5D: SUBMIT THE CORRECT IRB APPLICATION:

If your activity is Human Research, submit another appropriate IRB application, rather than Form 11-A4. All IRB applications are available at Step 11 at: [Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate](#)

If you are unsure which form to use, contact the IRB office at irb@downstate.edu

TIP 5E: UNDERSTAND WHO CAN BE LISTED ON THE SUNY DOWNSTATE IRB APPLICATION FORMS:

The Downstate IRB may make IRB determinations and issue IRB approvals for members of the Downstate Workforce, Kings County Hospital, and University Physicians Brooklyn (UPB). If you are unsure whether someone is a member of the Downstate workforce, please see Step 4a at: [Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate](#)

A “Project Lead” for Form 11-A4 is not required to have “PI Status” and may e-sign the IRBNet submission as “Other Signatory” or “Principal Investigator”. A Fellow, Resident, or Student may serve as a “Project Lead.”

Notes:

- 1) *Certain students are not permitted to conduct human research projects based on their program requirements. For example, a DNP Student in the College of Nursing may not conduct human research as part of their program. If it is determined their project meets the definition of human research, including exempt research, the project must be redesigned to meet program requirements.*
- 2) *If a project that was submitted for a non-human research determination is determined by the IRB to represent a human research activity, Form 11-A4 cannot be used. All human research activities must be reviewed and approved by the IRB using the applicable form. The Principal Investigator (PI) on a human research study must meet the qualifications for “PI Status” as outlined in Step 3 at: [Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate](#). A PI with PI Status is required for Forms 11-A1, 11-A2, 11-A3, 11-A5, 11-8, 11-9, and A1B.*

Other external collaborators (i.e., those who are not part of the Downstate, Kings County, or UPB workforce) should consult with their own IRB or Human Research Protections Office or other applicable leadership at their site to ensure compliance with state and federal regulations. When needed, an IRB Reliance Agreement or Individual Investigator Agreement may be executed between the Institution or Investigator, when all applicable requirements are met, or an external IRB may be used when appropriate. External collaborators cannot be listed in Section 1 of the IRB application Form 11-4, unless Downstate has established an IRB Reliance Agreement (IRA) with the external collaborator’s institution or an Individual Investigator Agreement (IIA) with the external collaborator. External collaborators may be listed on the IRBNet Registration form, if their specific role is defined and/or they may be listed in Section 8 of the form; however, the Downstate IRB does not have jurisdiction to provide a determination for these individuals without execution of an IRA or IIA.

When an individual has a dual role at one or more institutions, the Downstate IRB will make its determination based on the jurisdiction of IRB Oversight. Please refer to the examples below for additional clarification for students who are required to conduct the activity in order to fulfill their educational requirements.

Note: Depending on the institution, some IRBs may use the term “exempt” rather than issuing a not-research, not human research, or not engaged determination.

- Example 1: A Downstate student is employed at another institution and is conducting research on behalf of their employer and is approved by their employer’s IRB. The student only has access to the identifiable data when they are acting as an

investigator on behalf of their employer as approved by their employer's IRB. No identifiable data nor identifiable specimens are shared with other members of the Downstate workforce. The student is not using any Downstate resources (funding, space, equipment, etc.) and there are no research interactions or interventions on the Downstate campus.

- In general, when “exempt” research is conducted at the main site, the Downstate IRB may make a determination of “not human research” for the above activities.
 - In general, when “non-exempt” human research is conducted at the main site, the Downstate IRB may make a determination of “not engaged” for the above activities.
- **Example 2:** A Downstate student is employed at another institution and is conducting human research on behalf of their employer and is approved by their employer's institution's IRB. Identifiable data or identifiable specimens are shared with Downstate, which may include protected health information (PHI).
 - In general, when “exempt” research conducted at the main site, the best approach is to have both IRBs approve the research. *Please note however, that the Downstate IRB cannot approve a HIPAA waiver for an outside entity without an IRB Reliance Agreement in place and therefore would require documentation that their employer's IRB has approved the HIPAA waiver.*
 - In general, when “non-exempt” human research is conducted at the main site, both IRBs may review the research or ONE IRB may review research provided all applicable agreements are executed in advance of IRB review. *Please note that Single IRB (sIRB) may be required for certain research based on federal regulations. For more information on when sIRB is required, see Step 5 at: [Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate](#).*
 - The Downstate IRB does not have the jurisdiction to require the IRB approval letters or determinations of the student's IRB from where they are employed, the Downstate IRB reserves the right to request any clarification of supporting documentation that is provided to the Downstate IRB.

Note: For more information on determining which IRB to use, which agreements are required, and which IRB fees to budget, please see Step 5 at: [Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate](#)

TIP 5F: SUPPLY THE IRB WITH ADEQUATE INFORMATION IN FORM 11-A4 TO MAKE A CORRECT DETERMINATION:

- In order for the IRB to make an efficient determination, when submitting Form 11-A4, please do the following:

Guidance Form 11-A4

- Follow the instructions and answer all questions carefully.
- Fill out Form 11-A4 completely.
- Use Adobe software to complete the fillable PDF Form 11-A4. Follow Tip #2 posted on the IRB Submission Tips to understand how to fill out a fillable PDF. Forms that are not completed properly will get rejected by the IRB and will slow down the process.
- Provide responses where required and appropriate.
- Not every question within the Application Form 11-A4 requires a response, and based on previously selected (or unselected) options, it may be inappropriate to provide any response in a given section. Only provide responses where appropriate, based on previous selections.
 - For example, Section 4 of the form is divided into 3 subsections [A (not research), B (not human research), or C(not engaged)]. Respond only to the subsection applicable to the request. For example, answering questions in subsections that do not apply (i.e., answer questions in subsection B and C may create confusion when Section A is completed to request a “not research” determination. Providing inappropriate responses may slow down the review process, may cause the IRB to request revisions or may cause a rejection of the application.
 - “Not Applicable” is often an appropriate response and is preferred over leaving a question unanswered.
 - Provide consistent and non-contradictory responses. Application Form 11-4A has several queries regarding the type of data and information that project staff intend to collect and/ or will have access to. When completing Form 11-4A, be sure that the responses provided are consistent in regard to data and the identifiability of that data. For example, question “J” on page 6 request specific responses about obtaining, accessing, using, disclosing, or sharing certain types of data, materials, or specimens. The responses to this section, cannot be inconsistent with the rest of the application and submitted materials.
 - If project staff are concerned that some of their responses may seem contradictory, please explain why seemingly contradictory responses have been provided.
 - Be careful with your terminology.
 - Do not use the terms “research, human research, investigator, study, etc.” when it is not appropriate to use these terms. For example, when proposing a quality improvement project that is also described as research with identifiable information, your application will get rejected and you may be advised to submit an IRB application for human research. Use the terms “project” or “activity” rather than “research” or “study” when appropriate.
 - Use the terms “project lead” or “project staff” rather than “Principal Investigator” (PI) or “Co-Investigator” (Co-I) or

“Investigator” when requesting a determination for a non-research activity, such as a quality improvement activity. *Note: The IRB will accept the role of PI/investigator on the IRBNet Registration Form as it is hardwired into the software and is a limitation of the software system. In addition, the IRB will accept the electronic signature of either “Other Signatory” or “Principal Investigator” for the Project Lead in IRBNet. Please do not use the inappropriate terms in the IRB application, protocol, or other supporting documents, as this creates confusion.*

TIP 5G: INCLUDE THE PROPER PROJECT DESCRIPTION AND SUPPORTING DOCUMENTATION:

- Use an appropriate format for your project description. The IRB may develop project templates in the future; however, these are not yet available. Do not use the templates for a ‘human research protocol’ for a project is proposed to be “not research” (i.e., quality improvement) or “not human research”. Using the wrong template could unintentionally make the activity appear to be research or human research, which may require IRB approval via an exempt, expedited, or full board review process. Conversely, a human research protocol format describing all of the human research activities taking place at other sites, can be submitted to support a requesting a determination of “not engaged” when the protocol and/or Form 11-4A specify the activities proposed for Downstate, Kings County, or UPB that constitute a “not engaged” determination.
- Provide a detailed description of the project, including:
 - Short background on the importance of the project.
 - Full description of activities
 - How and where it will be conducted
 - Timeline
 - What data will be accessed and/or collected
 - Whether the project team has access to or is recording identifiable information
 - What will be done with the data
- Provide any surveys and/or data collection tools that will be used for the activity.
- Describe any data sharing between multiple sites and whether the data will be identifiable or protected health information. *Caution: It is best to shared deidentified or coded data between sites.*

- Establish any necessary agreements, such as a DUA, MTA, data agreement, contracts between institutions, etc.
 - A Data Use Agreement (DUA) is required when sharing a limited data set between institutions.
 - A Materials Transfer Agreement (MTA) may be required, as determined by either institution. At Downstate, the Department Chair, Dean, Project Lead, PI, IRB, Senior Leader, or the [Office of Innovation and Partnerships \(I&P\)](#) may determine when an MTA is required.
 - For more information and process for execution of agreements, please see Step 5F at: [Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate](#)
 - [Contact your college or departmental leadership for information on how to execute other types of agreements.](#)
- If any agreements are required, allow extra time for execution of the agreements. These agreements are not approved by the IRB; however, the IRB may help facilitate their approval or confirm congruency with the protocol or project. These agreements may take longer to negotiate or execute than it takes to obtain the IRB determination letter. Although these can be reviewed in parallel, it may be important to start the agreement review process, prior to submission of the project to the IRB.
- Provide all appropriate and required documents in the IRB submission.
 - Include a data collection sheet or describe the data elements that will be accessed and/or collected.
 - Include any surveys that are used in the project.
 - Please be sure that all documents indicated in the Application Form in “Section 3 General Information Question A” are provided in the submission, and conversely that all documents attached to the submission are represented in the response provided in the Application Form.
 - Submit any additional materials relevant to the activity as described in Step 10 at [Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate](#)
- Every IRB submission must include an IRBNet Registration Form that clearly includes all members from the SUNY Downstate, Kings County, and UPB workforce who will be involved in the activities under IRB review.
- Other staff should be described in the project description and may be included on the IRBNet registration form to note their involvement in the project, such as external mentors or consultants; however, this is optional and the Downstate IRB cannot approve these individuals without a fully executed IRB Reliance Agreement or an Individual Investigator Agreement in place. See Tip 5E for additional information.

These individuals are not required to e-sign the application, unless required by the College or Department where the research takes place.

- Make sure all application materials are congruent with one another.

TIP 5H: ENSURE ALL REQUIRED PARTIES HAVE E-SIGNED THE IRB SUBMISSION

- The following e-signatures are required in IRBNet
 - Project Leads/ PIs are required to e-sign the submission prior to IRB acknowledgement/ approval of any application.
 - The Dean/Department Chair (or their delegated alternate) must e-sign the IRBNet.
 - If your department requires other signatures, please include them. For example, in the DNP program, the College of Nursing requires the Faculty mentor for each student's submission to e-sign the submission.
 - In the unlikely event that this submission requires ancillary review by UHB Pathology, UHB Pathology must e-sign the submission.
 - External mentors or consultants are not required by the IRB to e-sign the application; however, this may be required by the College or Department where the research takes place.
- The submission must be "shared" with those individuals who need to e-sign.
- To share access to the study package within IRBNet, do the following:
 - Click on **"My Projects"** and click on the project title
 - Click on **"Share this Project"** on the left menu bar, then click **"Share"**
 - Select SUNY Downstate Medical Center
 - Search for user, select type of access, then enter a comment to the user, for example, to request e-signature.
 - *NOTE: If a particular user's name does not come up, contact that user. It is possible they have not yet registered with IRBNet or they did not complete the registration process for IRBNet.*
- Based on the nature of the project it is possible the IRB will request additional e-signatures prior to acknowledgment but the IRB will guide project staff in such cases. For example, if the project impacts another Department or College or the patient care of another area, the Department Chair or Dean of the affected area e-signs the submission or provides a letter of support.

- If the project or research impacts another area of Downstate, the IRB may request an e-signature from the Dean or Department Chair for that area.

TIP 5I COMPLETE ALL IRB REQUESTED REVISIONS IN A TIMELY AND THOROUGH MANNER AND RELOCK THE SUBMISSION.

- Please address any request of the IRB and “lock” the revised submission within 2 weeks of the IRB request or request additional time; otherwise the submission is automatically considered withdrawn. When the submission is re-locked, the IRB receives an electronic notice that the submission was re-locked. You **must** lock the revision of the submission in order for the process to continue; otherwise, the IRB will not know that a response has been submitted.
- Please do not hesitate to contact IRB staff for guidance, clarification, and/ or to request additional time to address the revisions as needed.
- If you disagree with the IRB’s request, please provide a written justification for why you disagree. Investigators may appeal the IRBs determinations by following the process for appeals outlined in Policy IRB-01.

TIP 5J COMPLETE HIPAA COMPLIANCE TRAINING, WHEN APPLICABLE.

When submitting a request for an IRB determination using Form 11-4A for a project that involves protected health information (PHI), all staff listed on the application must complete HIPAA training requirements. For more information on training requirements, please see Step 6 at: [Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate](#)

REFERENCES

- [Definition of Human Subjects Research | grants.nih.gov](#)
- [Electronic Submissions | Institutional Review Board | Office of Research Administration | SUNY Downstate](#)
- [Engagement of Institutions in Human Subjects Research \(2008\) | HHS.gov](#)
- [Human Subject Regulations Decision Charts: 2018 Requirements | HHS.gov](#)
- [Institutional Review Board | SUNY Downstate Health Sciences University](#)
- [Office of Innovation and Partnerships \(I&P\)](#)

AUTHORS

Nikol Celestine
Heather Jewett
Diann Johnson
Nakih Gonzales
Kevin Nellis

With input from:

Margaret Hammerschlag
Jeannette Jakus
Ronnie Lichtman
Sarah Marshall
Sincere McMillan
Elizabeth Ritt
Nataliya Shaforost
Jennifer Sidoti
Pamela Simmons

REVIEW AND APPROVAL HISTORY

Original Issue Date: 08.02.2023
Supersedes: 08.02.2023
Revision Date: 08.07.2023

Date Reviewed & Approved	Revision Required		Responsible Staff Name and Title or Committee	
	Yes	No		
08.02.2023		X	SUNY Downstate Health Sciences University IRB & Privacy Board	
08.07.2023		X	Kevin Nellis, Executive Director, Human Research Protections and Quality Assurance	<i>Note: Minor edits and clarifications were made to this document based on additional feedback provided by the CON.</i>