Guidance on
Submitting a New Protocol Application

Submitting a New Application to the IRB
The following procedures are required for submitting a new protocol submission packet for IRB review:

- **An IRB number must be obtained for tracking purposes**. This number will remain for identification purposes of this specific project throughout the life cycle of your project. Without this number, the IRB staff is unable to provide any information requested. This number will be requested by the staff when any inquiry is made about the project.
- You will obtain the project's identification number by contacting the Office for Clinical Trials (OCT). An e-mail or phone call is accepted. For e-mail, please e-mail: the Project Associate at 263-4170: Request for New IRB#. The following information must be supplied: Principal Investigator, Title of the Project and Funding Source. For phone calls, please call with the prior information.
- Once you receive your number you may complete the IRB paperwork. The IRB number given to you by OCT should be placed where indicated on the document. All information is required to be completed on the application, if applicable. Please read all instructions. If you have any questions, contact the IRB office at (212) 263-4110.
- The following are the required documents for a new protocol submission**:**

  - ✓ Receipt for New Protocol
  - ✓ Financial Disclosure Form (Note: see below)
  - ✓ Print out that all research staff have completed the required CITI tutorial
  - ✓ Consent/Authorization Form
  - ✓ Recruitment Materials
  - ✓ Questionnaires
  - ✓ Waiver of Authorization/Consent
  - ✓ Protocol summary
  - ✓ Protocol
  - ✓ NIH Grant (if applicable)
  - ✓ Investigator's Brochure or Product Information
  - ✓ Other: any other information that is pertinent to the review of your project

The application must contain all required original signatures, a complete protocol (see New York University School of Medicine Institutional Review Board Guidelines for Writing a Research Protocol) ,and the required number of copies for review. . New protocol submissions received without any of these essential elements are returned without IRB review or will be delayed.

✷NEW REQUIREMENT✷
If your research falls within one of the following categories, additional information is required: (1) Children; (2) Cognitively Impaired; (3) Data Stored for Future Use; (4) Deception; (5) Use of the GCRC (General Clinical Research Center); (6) International Research; (7) Physiological Processes; (8) Pregnant Women Fetuses and Neonates; and (9) Prisoners. Each of these categories has a corresponding supplement document that must be completed and attached to the Application for Initial Review. Each supplement requests information specific to the type of

research being done that must be reviewed and analyzed to ensure specific federal regulations regarding the review of such research is practiced.

Documents you may not need to submit:.

- No Recruitment Materials –if none are being used.
- Not funded by the NIH, no need for a grant application.
- Not an Investigative New Drug Study or Device Study, no need for Inv. Brochure or Product Info
- No questionnaires to be completed or instruments to be used – no need to submit

Things that may delay your submission or require that your submission be returned

- ✓ No Protocol Submitted
  - ✓ Unless the project is an **exemption**, EVERY initial review submission should have a protocol.
- ✓ No Initial Review application
- ✓ No IRB #; we have to submit it to OCT and wait for the # to be assigned
- ✓ No Consent form or request for waiver of consent
- ✓ Other necessary forms; contact the IRB office when you are not sure what you need to submit
- ✓ Other elements missing that will not allow your project to be reviewed. Some projects may go forward with a note highlighting what is missing. Contact will made with the PI and Contact for the Study regarding what is missing from the IRB Staff requesting the information.
- ✓ **COMMUNICATE** with the IRB staff. Let them know if something for your project is coming at a different time or is delayed due to specific reasons. The IRB staff is here to help you ensure your project gets reviewed and forwarded to the correct staff.

Application for Initial Review
The Application for Intial Review (the "Application") requires the following information: Principal Investigators must fully complete the Application, designating "N/A" for any sections that do not apply. Questions on the Application should not be left blank.

The Application must state the name of the Principal Investigator and study personnel, the name of the sponsor, and the facilities in which the study will be performed. All research personnel must complete the on-line tutorials. If more research staff are to be hired after the submission of the project, upon hire have them complete the tutorial. Then please submit an amendment with the added staff members and confirmation of completion of the tutorial. Please note: **The URLs for tutorials are: Human Subjects and HIPPA tutorials created by NYU SoM IRB are only valid through September 2007). The following URL should be used in replacement of the other tutorials; https://www.citiprogram.org/default.asp (CITI; if you have not taken a tutorial, you should take this one)

Office of Clinical Trials (OCT) Billing Plan

The applications requests information to clarify if a billing plan is required for your project. If an NYU SoM Billing Plan is required, it will be generated by the Office of Clinical Trials and emailed to the P.I. for final review and approval. The approved Billing Plan will be sent to the PI, IRB, and other specified administrative offices impacted by this study. No other Billing Plan form(s) are required of the PI. For more information, see the OCT website: http://www.med.nyu.edu/oct or call 212.263.4210

Financial Disclosure *New Guidance*
All Principal, Co-Investigators and research staff members are required to complete a Financial Interest Disclosure Sheet. This is required even if no financial interest exists. Please see the policy on the Sponsored Programs Administration office at www.med.nyu.edu/spa.

The signature of the Chair of each Department(s) involved in the study must appear on the Application. The signature of Department Chairs affords them an opportunity to know of each research study conducted in the Department and provides an opportunity to offer suggestions to the Principal Investigator. The signature of the Department Chair attests that the Investigator is a member of the department in good standing. The department or NYUSOM has the resources necessary to carry out the research and the investigator is qualified to be the Principal Investigator on the project.

Investigator's Responsibilities Checklist
The final page of the new application form lists the minimum responsibilities of Principal Investigators as stated in the formal agreement between New York University School of Medicine and the Federal Office o Human Research Protection (the "Assurance"). You will be asked to check each item to indicate that you have carefully read and understand your responsibilities.

The signature of the Principal Investigator confirms the PI's responsibility of the ethical completion, management of his/her research project and following all federal and local human subject protection requirements. The Principal Investigator is sent all correspondence regarding his/her research project.

No protocol is reviewed, without the signatures of the Principal Investigator, the Chair of the Department in which the PI holds a primary appointment(or for administrative departments the appropriate administrative director in which the PI is employed) involved and any other required signatures or certifications. The IRB does not accept electronic signatures.

Is there a specific time that submissions are accepted?
Yes and No - New Protocol Applications may be submitted any time prior to the posted deadline dates on the NYU SoM website. **However, new exempt and expedited Applications are accepted one week prior to posted submission deadlines or one week after the deadline. Full board review new applications take preference on the deadline dates so if you submit and exempt and expedited projects submitted on the deadline date it may be delayed.**

Submissions are accepted during the IRB Office's hours: 8 am to 5 pm. It is preferred at this time documents be hand delivered. The office is located at the VAMC, 423 East 23rd Street, 10th Floor, West Side, NY, NY. The main number is (212) 263-4110.