

Human Research Protections Institutional Review Board

1 Park Avenue | 6th Floor | New York, NY 10016

Ancillary Reviews

The purpose of this document is to describe to researchers the circumstances in which Ancillary Review is required for their study submission. Ancillary reviews are reviews conducted by committees that are not the IRB but are required for Human Subjects Research protections and are in addition to the required NYU Langone Health Institutional Review Board (IRB) review.

Note that ancillary reviews are required regardless of the IRB of record (i.e. NYU Langone Health IRB or an External IRB). Ancillary reviews are required by the institution as part of the review to ensure Human Subjects Research protections. Obtaining approval from Ancillary Review groups is the responsibility of the Principal Investigator, who must ensure all reviews and approvals are complete prior to research initiation. If an ancillary review is required prior to IRB approval being issued, it is strongly recommended that the PI work closely with the ancillary review contact personnel to ensure these reviews are completed in a timely manner and reported to the IRB of record quickly.

Review Body	Review Type	<u>Circumstances under which review is</u> required	Contact(s) and helpful links	How to Submit	Impact on IRB Review/Approval
Protocol Review and Monitoring Committee (PRMC)	Expedited or Committee	Any research related to cancer patients, cancer treatments, cancer screening/prevention.	PCC-PRMC@nyulangone.org	MyStudies – Section 01, Question 10: Cancer- Related Research.	For PI-initiated research, IRB review cannot begin until PRMC approval is in place.
			PRMC Webpage		For industry-initiated research, not required for final IRB approval, but must be in place before research begins.
Disease Monitoring Groups (DMG)	Peer Review	Any new protocols which include research related to cancer patients, treatments, and cancer screening/prevention.	<u>DMG Webpage</u>	MyStudies – Section 01, Question 10: Cancer- Related Research. Once submitted, a Senior Regulatory Specialist will contact the study team to obtain more information on the study, essential documents, and provide a link to complete the DMG form in the DMG Review portal.	PRMC review cannot take place until DMG review has been completed and research has been cleared by DMG.
Novel Technology	Department Head	Any research using novel technology (in-house built phone application, newly developed software, etc)	NovelTechnologyReviewTeam@nyu langone.org	MyStudies – Section 01, Question 13: Novel Technology.	Concurrent review allowed but required prior to IRB approval.
Radiation Safety Committee (RSC)	Expedited or Committee	Any research that involves ionizing radiation	Steven.Wagner@nyulangone.org	MyStudies – Section 01, Question 10.2. Separate submission through RadDrugs may be required.	Not required for final IRB approval, but must be in place before research begins.

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Scientific Review Committee (SRC)	Committee	Any interventional research related to COVID-19 patients, treatments, prevention, etc.	<u>Royell.Sullivan-</u> <u>Green@nyulangone.org</u>	MyStudies – Section 01, Question 4.5: COVID-Related Research	Required prior to IRB submission (system will not allow PI to submit to the IRB without SRC approval in place)
Conflicts of Interest Management Unit (CIMU)	Expedited or Committee	researcher discloses a potential	<u>CIMU Webpage</u> <u>Cimu.disclosures@nyulangone.org</u>	Conflicts of Interest module in Research Navigator – each study team member submits their own study-specific disclosure	Concurrent review allowed but required prior to IRB approval.
Employee/Student	Department Head	study Employees and/or Students and/or where the research contemplates recruitment using Direct Recruitment methods to recruit and enroll Employees and/or Students.	Students: Linda.Tweksbury@nyulangone.org Michael.Abrosino@nyulangone.org Keith.Micoli@nyulangone.org PhD Candidates: Naoko.Tanese@nyulangone.org Employees: Nancy.Sanchez@nyulangone.org	MyStudies – Section 04, Questions 5.1 and 5.2.	Concurrent; Required prior to initiation of research with this population.

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Research on Decedent Oversight Committee (RDOC)	Committee	Any research which involves recently deceased patients.	Marina.Godina@nyulangone.org	Email protocol to Marina Godina; application will need to be completed	Concurrent review allowed but required prior to IRB approval.
Center for Biomedical Research and Development (CBRD)	Department Head	All research proposing to store biospecimens at NYU Langone Health locations.	<u>CBRD Webpage</u> <u>cbrd@nyumc.org</u> <u>Policy on Human Biospecimen</u> <u>Research</u>	Completed by IRB staff during review process or contact CBRD prior to IRB submission.	If the focus of the research is to collect and store biospecimens, concurrent but required prior to IRB approval. If the focus of the research is not to collect and store biospecimens, required prior to initiation of research/storage of biospecimens.
Embryonic Stem Cell Oversight (ESCRO)	Committee	All research involving the use of human embryonic stem cells or human pluripotent stem cells.	ESCRO Webpage	Triggered in MyStudies: Section 03, Question 8. To submit, complete the ESCRO Application Form and submit to escro@nyulangone.org	Concurrent review allowed but required prior to IRB approval.
Institutional Biosafety Committee (IBC)	Committee	All research that involves recombinant or synthetic nucleic acid molecules subject to the <u>NIH Guidelines</u> is being proposed.	IBC Webpage – External IBC Webpage - Internal ibc@nyulangone.org	MyStudies – Section 03, Question 7 flags IBC review. To submit, complete a new IBC application: https://era.med.nyu.edu/IBC	Concurrent review allowed but required prior to IRB approval.
Bellevue Research Committee	Committee	Any research conducted at Bellevue	bien.lee@nyulangone.org Bellevue Research Webpage - Internal	System to Track and Approve Research (STAR).	After IRB approval; Bellevue will not review until IRB approval is in place.

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