

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

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

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

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