

Investigator Checklist for New Biomedical UMCIRB Submissions

Type of Research	Number of Copies	UMCIRB Forms
Exempt/Expedited Research Proposal	1	<ul style="list-style-type: none"> • Research Form (required) <i>*Ensure all applicable signatures have been attained prior to submission</i> • Protocol/Proposal/Grant/Thesis (as appropriate) • Letter of Support (required for research conducted outside of ECU/PCMH) • Consent/Assent/Permission Form (as appropriate) • Instruments/Tools/Questionnaires (as appropriate) • Ads/Flyers/Brochures (as appropriate) • Conflict of Interest Disclosure Form (required) • Institutional Approval for Research Form (as appropriate) <i>*Ensure all applicable signatures have been attained prior to submission</i> • HIPAA Authorization or Waiver of Authorization <i>*Required only if protected health information is being used or disclosed for research purposes.</i>
Convened Committee Research Proposal	1 Copies should be collated and all signatures should be original. This packet will be for the UMCIRB file.	Same documents as required for Exempt/Expedited research submissions, plus: <ul style="list-style-type: none"> • Sponsor template: Consent/Assent (as appropriate) • Investigators Brochure/Package Insert/Instructions for Use (as appropriate) • FDA 1572 (as appropriate)
	3 Copies should be double-sided and collated into individual packets.	Same documents as required for Exempt/Expedited research submissions, plus: <ul style="list-style-type: none"> • Sponsor template: Consent/Assent (as appropriate) • Investigators Brochure/Package Insert/Instructions for Use (as appropriate)
	16 Copies should be double-sided and collated into individual packets.	<ul style="list-style-type: none"> • Research Form (required) <i>*Ensure all applicable signatures have been attained prior to submission</i> • Consent/Assent/Permission Form (as appropriate) • Instruments/Tools/Questionnaires (as appropriate) • Ads/Flyers/Brochures (as appropriate)
Institutional Approval <i>*This meeting will occur the day after the IRB meeting for new studies reviewed by the convened IRB committee. This meeting is separate and distinct from the IRB meeting.</i>	25 Copies should be double sided and collated into individual packets containing each of the 4 documents	<ol style="list-style-type: none"> 1. Institutional Approval for Research Form 2. Financial Services Review Form 3. Research Form 4. Consent/Assent/Permission Form <p style="color: red; margin-top: 20px;"> <i>*These forms are necessary for research taking place at Pitt County Memorial Hospital and Brody School of Medicine at ECU</i> <i>*If a research study is Tabled at the convened IRB meeting, these forms must be resubmitted with any other necessary material as documented on the UMCIRB letter.</i> </p>

- ❖ Required submission documents and number of copies for continuing review are located on the [Continuing Review/Closure Form](#)
- ❖ Required submission documents and number of copies for revisions are located on the [Revision Form Instructions](#)