Office of Human Research Protection
Institutional Review Board
701 Grove Rd
ESC158
Greenville, SC 29605

New Project Submission Tool

The checklist below lists items necessary for submission of a New Project for IRB review at Prisma Health. All documents can be found on IRBNet.org within the Forms and Templates Library or on our website. Documents should be uploaded to the New Project Package via the Designer page on IRBNet.

✓	Item	Description
All New Expedited & Full Board Reviewed Studies		
☐	IRB Review Fee	$2500.00 (industry-sponsored) $1000.00 (studies reviewed by (WIRB)) Fees initiated in studies with contracts submitted after 10/1/2019: $2,000 Initial IRB Full Board Review (Industry-sponsored) $1,000 Annual Full Board Review $1,000 Amendment Full Board Review $1,000 Relying IRB Review Fee (Use of external IRB)
☐	IRBNet Registrations	Each member of the study staff must complete registration within IRBNet. Within "User Profile" - Investigators need to upload a signed and dated CV, Investigator Assurance Form, and link CITI training via external accounts. Other study staff should upload a CRC Attestation form if applicable and link CITI training via external accounts.
☐	Prisma Health IRB Application (Wizard)	Must be completed in its entirety on IRBNet www.irbnet.org
☐	CITI Training / Human Subjects Protection Training	Current CITI training or equivalent human subjects protection training. CITI training must be linked to each study personnel's *User Profile* within IRBNet via "*External Accounts*"
☐	Scientific Review Signature	The Academic Vice Chair of the PI's department must be shared with READ access on the project within IRBNet so that they may sign the New Project Package. Packages missing this signature will be returned un-reviewed.
☐	Investigator Assurance Form	Investigator Assurance Forms must be completed and uploaded to each Investigator's User Profile that is listed on the project. The IA Form should then be "linked" to the New Project Submission.
☐	Clinical Research Coordinator Assurance Form	Clinical Research Coordinator Forms must be completed and uploaded to each CRC's User Profile that is listed on the project. The CRC Assurance Form should then be *linked* to the New Project Submission.
☐	Investigator's CV	A CV must be included in each Investigator's User Profile and *linked* to the New Project Package.
☐	Investigator Signatures	Each investigator listed on the project must "sign" the New Project package prior to submission.

All New Expedited & Full Board Reviewed Studies Continued…		
☐	Complete Protocol	Must be included for all projects.
☐	Advertisements/ Recruitment/ Education/ Teaching/ Patient Information – Print/Audio/Video	Any information shared with potential or enrolled patients; examples include advertisements (written or video), newspapers, periodicals, posters, flyers, TV/radio/phone scripts, etc. must be included.
☐	Data collection forms, surveys, questionnaires, etc.	Include any data collection tool, or description of what data will be collected.
☐	Conflict of Interest	The annual Prisma Health institutional conflict of interest disclosure disseminated through the Office of Corporate Integrity must be completed by all investigators.
All New Prospective Studies involving Interaction/Intervention with Living Individuals		
☐	Consent Form(s)	This should be written at a 6th grade reading level. Refer to the ICF Templates located within the IRBNet library and the Ensure Health Literacy in the Consent Process Guidance when writing your ICF.
☐	Specimen Consent Form	Required consent form for any study storing identifiable specimens (tissues, blood, bone marrow, etc.) for any future research.
All New Studies involving Vulnerable Populations		
☐	Assent Form(s)	Include for studies involving children who can give assent to participate in a study.
☐	Vulnerable Population Assessment Form	Must be completed for all studies involving vulnerable populations as participants. For more information on vulnerable populations, see our Vulnerable Populations Guidance.
All New Studies Regulated by the FDA		
☐	Form 1572	Required for studies involving an investigational drug.
☐	Investigator's Brochure(s)	Investigator's brochures are required for studies using an investigational drug.
☐	FDA IND Documentation	Required for studies involving an investigational drug. Provide documentation IND was sent to FDA.
☐	FDA IDE Documentation	Required for studies involving an investigational device.
All New Studies using FDA approved Drugs/Devices		
☐	Drug Packet Inserts	Provide drug package inserts for all FDFA approved drugs used in the study.