



Which xForm should I use?

NEW STUDIES	
xForm NAME	WHEN TO COMPLETE
Start New Study	<p>This form helps you navigate to the correct form for submitting a new study for BRANY IRB review in IRBManager</p> <ul style="list-style-type: none"> If you're a <i>BRANY Classic</i> client, contact your relationship manager instead.
Register New Study	<p>Complete if:</p> <ul style="list-style-type: none"> you plan to submit a single-site study (yours is the only site conducting the study), or the study is industry-sponsored, or your organization uses BRANY IRB for its local IRB review
Research Application	<p>Complete when you receive your study's BRANY file # and instructions from BRANY staff.</p>
401-Single IRB: Master/Sponsor Application	<p>Complete only if the Lead Site or Overall PI and:</p> <ul style="list-style-type: none"> BRANY staff has instructed you to complete xForm #401, or you are part of the MyTRO network, or the study's funding agency, sponsor, or coordinating center has informed you BRANY IRB is the selected "central" or "single" IRB (sIRB) selected for the study
501-Single IRB: Site Application	<p>Complete only if Participating Site and:</p> <ul style="list-style-type: none"> BRANY staff has instructed you to complete xForm #501, or you are part of the MyTRO network, or the study's funding agency, sponsor, or coordinating center has informed you BRANY IRB is the selected "central" or "single" IRB (sIRB) selected for the study



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ONGOING STUDIES	
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01-Modification/Request for IRB Review	<p>To obtain IRB approval for:</p> <ul style="list-style-type: none"> • Additional or relocated research sites • Amendments to the study/protocol or consents • New or updated drug or device brochure • New or updated subject materials (e.g., ads, diaries, ID cards, surveys) • Request for translation or submission of translated material • Reports (e.g., Interim Analysis, DSMB, Annual Reports, Safety Updates)
02-Study Staff Changes (not PI)	<p>To obtain IRB approval of new key study personnel. Include:</p> <ul style="list-style-type: none"> • Evidence of training in human subject protection per your organization's requirements • FORM 01: Conflict Disclosure Statement and FORM 02: Conflict Report Form (only if answered "YES" on Form 01) • Request for User Access to obtain IRBManager account (if needed)
03-Short Form Consent Request	<p>When you encounter subject with unanticipated language and you've confirmed:</p> <ul style="list-style-type: none"> • Your organization/institution policy does not prohibit the use of short form consent, and • Your study sponsor contact concurs (if applicable), and, • You can ensure subject materials can be made available in the unanticipated language (if applicable).
04-Study Status Change (Closed / Enrollment Closed)	<p>To notify BRANY IRB of enrollment closure or study closure <u>at your site</u>. Include Minor Deviation Log if reporting study closure.</p>
05-Request for Waiver of Authorization to Release PHI for Research	<p>To request an alteration to, or partial or full waiver of HIPAA authorization.</p>



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11-Continuing Approval Application	Complete to request ongoing approval from BRANY IRB. Include the Supplement for Multi-Center Research Projects when applicable.
14-Change of Principal Investigator (PI)	Complete to request approval for a change of Principal Investigator. Include (when applicable): <ul style="list-style-type: none">• New PI CV, license, and Evidence of training in human subject protection per the research organization's requirements
16-Reportable Event	To request approval of Protocol Exceptions, or to report: <ul style="list-style-type: none">• Serious Adverse Events (SAEs)• Major Deviations• Unanticipated problems involving risks to subjects or others• Unanticipated adverse device effects• Compassionate use requests• Emergency Use requests