

IRB APPROVALS

- ◆ Submission of external Safety Reports within 90 days (10% verified)
- ◆ Alternate procedures are allowed (encouraged by SWOG)
- ◆ Submission of internal Serious Adverse Events

SAEs REPORTABLE TO IRB
01/25/2007 to 01/27/2010

Protocol Number	Investigator	IRB	Day
17401	IRB1	01-11-2008	01-14-2008
17402	IRB1	01-11-2008	01-14-2008
17403	IRB1	01-11-2008	01-14-2008
17404	IRB1	01-11-2008	01-14-2008
17405	IRB1	01-11-2008	01-14-2008
17406	IRB1	01-11-2008	01-14-2008
17407	IRB1	01-11-2008	01-14-2008
17408	IRB1	01-11-2008	01-14-2008
17409	IRB1	01-11-2008	01-14-2008
17410	IRB1	01-11-2008	01-14-2008
17411	IRB1	01-11-2008	01-14-2008
17412	IRB1	01-11-2008	01-14-2008
17413	IRB1	01-11-2008	01-14-2008
17414	IRB1	01-11-2008	01-14-2008
17415	IRB1	01-11-2008	01-14-2008
17416	IRB1	01-11-2008	01-14-2008
17417	IRB1	01-11-2008	01-14-2008
17418	IRB1	01-11-2008	01-14-2008
17419	IRB1	01-11-2008	01-14-2008
17420	IRB1	01-11-2008	01-14-2008
17421	IRB1	01-11-2008	01-14-2008
17422	IRB1	01-11-2008	01-14-2008
17423	IRB1	01-11-2008	01-14-2008
17424	IRB1	01-11-2008	01-14-2008
17425	IRB1	01-11-2008	01-14-2008
17426	IRB1	01-11-2008	01-14-2008
17427	IRB1	01-11-2008	01-14-2008
17428	IRB1	01-11-2008	01-14-2008
17429	IRB1	01-11-2008	01-14-2008
17430	IRB1	01-11-2008	01-14-2008
17431	IRB1	01-11-2008	01-14-2008
17432	IRB1	01-11-2008	01-14-2008
17433	IRB1	01-11-2008	01-14-2008
17434	IRB1	01-11-2008	01-14-2008
17435	IRB1	01-11-2008	01-14-2008
17436	IRB1	01-11-2008	01-14-2008
17437	IRB1	01-11-2008	01-14-2008
17438	IRB1	01-11-2008	01-14-2008
17439	IRB1	01-11-2008	01-14-2008
17440	IRB1	01-11-2008	01-14-2008
17441	IRB1	01-11-2008	01-14-2008
17442	IRB1	01-11-2008	01-14-2008
17443	IRB1	01-11-2008	01-14-2008
17444	IRB1	01-11-2008	01-14-2008
17445	IRB1	01-11-2008	01-14-2008
17446	IRB1	01-11-2008	01-14-2008
17447	IRB1	01-11-2008	01-14-2008
17448	IRB1	01-11-2008	01-14-2008
17449	IRB1	01-11-2008	01-14-2008
17450	IRB1	01-11-2008	01-14-2008
17451	IRB1	01-11-2008	01-14-2008
17452	IRB1	01-11-2008	01-14-2008
17453	IRB1	01-11-2008	01-14-2008
17454	IRB1	01-11-2008	01-14-2008
17455	IRB1	01-11-2008	01-14-2008
17456	IRB1	01-11-2008	01-14-2008
17457	IRB1	01-11-2008	01-14-2008
17458	IRB1	01-11-2008	01-14-2008
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17460	IRB1	01-11-2008	01-14-2008
17461	IRB1	01-11-2008	01-14-2008
17462	IRB1	01-11-2008	01-14-2008
17463	IRB1	01-11-2008	01-14-2008
17464	IRB1	01-11-2008	01-14-2008
17465	IRB1	01-11-2008	01-14-2008
17466	IRB1	01-11-2008	01-14-2008
17467	IRB1	01-11-2008	01-14-2008
17468	IRB1	01-11-2008	01-14-2008
17469	IRB1	01-11-2008	01-14-2008
17470	IRB1	01-11-2008	01-14-2008
17471	IRB1	01-11-2008	01-14-2008
17472	IRB1	01-11-2008	01-14-2008
17473	IRB1	01-11-2008	01-14-2008
17474	IRB1	01-11-2008	01-14-2008
17475	IRB1	01-11-2008	01-14-2008
17476	IRB1	01-11-2008	01-14-2008
17477	IRB1	01-11-2008	01-14-2008
17478	IRB1	01-11-2008	01-14-2008
17479	IRB1	01-11-2008	01-14-2008
17480	IRB1	01-11-2008	01-14-2008
17481	IRB1	01-11-2008	01-14-2008
17482	IRB1	01-11-2008	01-14-2008
17483	IRB1	01-11-2008	01-14-2008
17484	IRB1	01-11-2008	01-14-2008
17485	IRB1	01-11-2008	01-14-2008
17486	IRB1	01-11-2008	01-14-2008
17487	IRB1	01-11-2008	01-14-2008
17488	IRB1	01-11-2008	01-14-2008
17489	IRB1	01-11-2008	01-14-2008
17490	IRB1	01-11-2008	01-14-2008
17491	IRB1	01-11-2008	01-14-2008
17492	IRB1	01-11-2008	01-14-2008
17493	IRB1	01-11-2008	01-14-2008
17494	IRB1	01-11-2008	01-14-2008
17495	IRB1	01-11-2008	01-14-2008
17496	IRB1	01-11-2008	01-14-2008
17497	IRB1	01-11-2008	01-14-2008
17498	IRB1	01-11-2008	01-14-2008
17499	IRB1	01-11-2008	01-14-2008
17500	IRB1	01-11-2008	01-14-2008

11 rows retained.

IRB APPROVALS

CIRB

- ◆ All documentation of CIRB approvals must be provided by the local site
- ◆ Documentation of CIRB notification that they are IRB of record
- ◆ Documentation of approval or implementation of consent versions

MAJOR IRB DEFICIENCIES

- ◆ Protocol modifications (major changes) not reviewed within 90 days
- ◆ Failure to update the consent with critical updates within 90 days
- ◆ Delays in annual review > 30 days
- ◆ Delay in annual review of a long term follow-up protocol > 1 year

MAJOR IRB DEFICIENCIES

- ◆ Failure to submit external Safety Reports
- ◆ Failure to report internal Serious Adverse Events

LESSER IRB DEFICIENCIES

- ◆ Protocol modifications (minor changes) not reviewed within 90 days
- ◆ Delay in annual review < 30 days
- ◆ Delay in annual review of a long term follow-up protocol < 1 year
- ◆ Failure to provide adequate documentation of IRB actions

MOST COMMON IRB DEFICIENCIES

- ◆ Protocol modifications not reviewed within 90 days
- ◆ Delays in annual review < 30 days
- ◆ Failure to submit external Safety Reports

CONSENT FORM CONTENT

- ◆ Compared to model consent
- ◆ Contains all elements required by federal regulations
- ◆ Updated by protocol modifications
- ◆ Specimen banking questions as in model, if applicable

COMMON CONSENT FORM DEFICIENCIES

- ◆ Missing required elements (e.g. risks, confidentiality)
- ◆ Not updated with new findings from protocol updates
- ◆ Specimen banking questions missing or different from model

PATIENT INFORMED CONSENT

Review of consent to verify:

- ◆ Signed prior to enrollment
- ◆ Contains all required signatures
- ◆ Specimen banking intent reported correctly / amended if applicable
- ◆ Patient informed of new findings

COMMON PATIENT CONSENT DEFICIENCIES

- ◆ Most current version of the consent not used (updated consents should be implemented within 10 days of approval)
- ◆ Specimen banking intent reported incorrectly at time of registration
- ◆ If patient changes responses to specimen questions at any time after initial consent, updated responses must be reported to the sponsor

COMMON PATIENT CONSENT DEFICIENCIES

- ◆ Patient not informed of new findings (i.e. new risks, early study closure)
- ◆ Follow instructions in the protocol update that specify whether re-consent is required and timeframe for informing patients
- ◆ If informed verbally, action **MUST** be documented in the research record

COMMON PATIENT CONSENT DEFICIENCIES

- ◆ Improper editing techniques
- ◆ Missing required signatures
- ◆ Missing and/or incorrect dates
- ◆ Patient's signature dated by research personnel

SOME HELPFUL HINTS

- ◆ Routinely monitor bi-monthly SWOG/CTSU distributions in order to submit protocol modifications as soon as possible
- ◆ Create a system for tracking submission of external Safety Reports, if applicable
- ◆ Alternatively, encourage your IRB to implement an alternate procedure for handling external Safety Reports

SOME HELPFUL HINTS

- ◆ Verify approvals for long term follow-up protocols against your list of patients on long term follow-up
- ◆ Implement a system to ensure you use the most current version of the consent when consenting new patients
- ◆ Document the consent process in the research record including any unusual circumstances

SOME HELPFUL HINTS

- ◆ Implement procedures for informing research staff about changes that require patients to be re-consented or informed of new findings
- ◆ Implement a secondary review process to ensure consent forms are complete after modifications are made (e.g. no missing risks)