Common information requested on site information forms for Sponsors:

1. How far in advance does the IRB require materials?	We have deadlines every Friday. Projects requiring full board review follow the posted deadline schedule available on our website.	
2. Does the study require any other reviews or approvals?	This depends on what the study involves, the following may be required:	
*If yes, specify:	IDS, RSC, IBC, Biomedical Engineering, FCOI, FACTS (Medicare coverage analysis)	
Has the IRB been audited by the FDA?	Yes	
3. *If yes, when?	January, 2014	
4. *If yes, list any findings:	No warning letter was issued and the inspection report (483) was closed.	
5. Will your IRB allow submission and review of the protocol/ICF prior to final FDA approval?	No	
6. Will your IRB allow submission and review of the protocol/ICF prior to final FDA approval if the FDA had granted *conditional* approval?	Yes	
7. *Add comments, as needed:	If conditional approval has been obtained, the IRB requires submission of the correspondence with the FDA to ensure FDA approval has been obtained prior to final IRB review and approval. Any modifications to the protocol required to satisfy the conditions of the IRB need to be included in the submission prior to final IRB review.	
Would your institution allow the use of a central IRB?	Yes - for a qualifying clinical trial	
* If yes, specify which central IRB:	Must be an AAHRPP-accredited organization	