EXAMPLE of Terms and Conditions in an agreement with a Central IRB *and* Natividad Medical Center (NMC)

Central IRB -Institutional Board	Relying Institution = NMC
Maintains an institutional review board (IRB) for the conduct and supervision of research and allows its IRB to serve as IRB of record for the research provided NMC maintains compliance with certain conditions.	NMC would maintain compliance with the terms and conditions stated below and create a local IRB for local oversight.
Maintain a Federalwide Assurance (FWA), which is an application for an FWA number and commitment to agree to abide by certain compliance rules (The Common Rule and Health and Human Services Regulations at 45 CFR part 46).	Maintain a Federalwide Assurance (FWA), which is an application for an FWA number and commitment to agree to abide by certain compliance rules (The Common Rule and Health and Human Services Regulations at 45 CFR part 46).
Central IRB agrees to serve as the IRB of record for the research, subject to compliance by NMC with the terms of this Agreement.	Agrees to create a local IRB to provide local context, local review and local oversight, for research projects.
Central IRB agrees to perform initial approval of all research, as well as continuing review of research, until such research or the Agreement with NMC is terminated. Review by the Central IRB will take into account any requirements of the local research context identified by the NMC.	NMC would agree to perform research at its location (unless such is agreed to in writing by the parties, in addendum or other agreement of the parties).
Central IRB shall remain the IRB of record for such research, subject to the limitations stated herein, until all research is concluded or the agreement with NMC is terminated.	NMC is required to provide the Central IRB with a copy of its FWA and any amendment and renewals of the same, upon demand, and/or within three (3) business days of receipt of any amendment or renewal by the Office of Human Subjects Protections (OHRP).
The agreement with NMC will be kept on file at NMC and will be provided to the Office of Human Subjects Protections (OHRP) or other federal agencies upon request.	Agreements with Central IRBs will be kept on file at NMC and will be provided to the Office of Human Subjects Protections (OHRP) or other federal agencies upon request.
	NMC will provide a contact person responsible for managing and coordinating the operations with the Central IRBs, including any communications with the Central IRB and between the Parties. Each Party shall promptly notify the other in writing of any change to the contact name/contact information specified. The designation of the persons named to coordinate communications between the respective Central IRBs shall not preclude investigators from communicating directly with the Central IRB, as necessary, to make reports of

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	unanticipated problems involving harm to subjects or others and/or other required reports.
Oversight includes, but is not limited to, all research materials and processes, including recruitment, consent forms, continuing reviews, waiver forms, amendments, and reports. The Central IRB has authority to conduct any audits and take any other action to ensure compliance by NMC and/or its investigators and key personnel with applicable law.	The Parties acknowledge that the Central IRB's obligation is limited by and subject to NMC's reservation of oversight of the research for purposes of ensuring compliance with any applicable state and/or local laws and regulations.
Central IRB shall review reports of events (or adverse events-see right hand slide for definition of 'events') that it receives and notify NMC in writing of any event for which it requires a further audit or investigation. As requested, the Central IRB will provide information and assistance for NMC's conduct of such investigation/audit.	NMC shall initially conduct its own investigation/audit, as necessary, of any unanticipated problems (including adverse events); injuries to subjects; protocol deviations/violations; changes to protocol initiated without prior Central IRB approval, including those to eliminate apparent harm to subjects; complaints; non-compliance; and/or cessation of research activities (hereafter collectively referred to as "events").
Central IRB will review these findings and recommendations, and determine whether it requires that further investigation/audit be conducted by NMC and/or additional remedial actions.	NMC shall make findings and recommendations as to remedial action, which it shall promptly share with the Central IRB.
Notwithstanding any investigation/audit conducted by NMC, the Central IRB reserves the right to conduct its own additional investigation/audit. Any findings from Central IRB's investigation/audit and/or recommended remedial actions. shall promptly be provided to NMC. In the event of any conflict between remedial actions sought by the Parties, the stricter will govern.	Neither Party will be required to share with the other any internal communications to the extent that such are protected by attorney-client privilege or other applicable privileges.
Both Parties agree to ensure the cooperation of their respective personnel in the conduct of any investigation/audit and in the implementation of any required remedial actions.	Both Parties agree to ensure the cooperation of their respective personnel in the conduct of any investigation/audit and in the implementation of any required remedial actions.
Central IRB will provide a sample consent form for each research protocol included under the agreement between the parties (or consent waiver, if appropriate). The form will indicate areas where NMC may add language or	NMC may add language or otherwise customize the form for their own use. Modifications to the informed consent shall be made as necessary to comply with local laws, regulations and NMC's policies.

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Central IRB -Institutional Board	Relying Institution = NMC
otherwise customize the form for its own site. Modifications to the informed consent shall be made as necessary to comply with local laws, regulations and NMC's policies. Any modifications will be subject to approval by the Central IRB, which may require additional modifications by NMC.	
	NMC shall have primary responsibility with respect to financial conflict of interest review for each research protocol and shall provide the Central IRB with a report on its review. Based on NMC's conflict of interest report, the Central IRB will have the authority to impose additional prohibitions or conflict management requirements more stringent or restrictive than what NMC has implemented that the Central IRB believes are necessary for them to approve the research
	Central IRB shall receive reports from investigators and the NMC, and the Central IRB will report promptly to the investigators and NMC, any actions taken or determinations made related to the following: a. Any serious adverse events and/or unanticipated problems involving risk to participants or others that were unanticipated, serious, and possibly related to the research; b. Any serious or continuing non-compliance issues related to the research; or c. Any hold, suspension, or termination related to the research.
Central IRB will perform the determinations required by the Health Insurance Portability and Accountability Act of 1996 and their implementing regulations (collectively, "HIPAA") with respect to the mechanisms for permitting the use and disclosure of Protected Health Information ("PHI") for any Research governed by this Agreement	NMC will conduct, and ensure all investigators and key study personnel, conduct the research in accordance with the protocol, all Central IRB directives, and all applicable federal, state and local laws and/or regulations, relating to the conduct of the research, including but not limited to: i. The Common Rule, 45 CFR 46; FDA regulations, 21 CFR Parts 50, 54, 56, 312, and 812, and; HIPAA, 45 CFR 160, et. al., as applicable;

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	ii. All applicable Central IRB policies and procedures. iii. Any directive of the Central IRB, including but not limited to termination, suspension, etc., of the research;
	NMC will perform its own local IRB reviews, as applicable and as required by its policies (such as nursing review, radiation safety, pharmacy and any others), and shall include any relevant requirements or results of such reviews that would affect its conduct of the research as part of information provided to the Central IRB. Ensure that the research is not commenced until any contract or agreement, including any subcontract, between NMC and the Central IRB, which relates to the research, is fully executed, and NMC has received written evidence that the research has been approved by the Central IRB, and that NMC's local IRB review is complete, and the Central IRB has indicated the process to enroll human subjects into the research may begin.