

The Heart of a Healthy Community

IRB Submission Guidelines

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Submitting to the IRB

- The IRB requirements vary depending on the type of study you wish to conduct
- The next slide summarizes the necessary documents required for submission according to your study



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IRB APPLICATION PROCESS AT A GLANCE

Choose the appropriate application process for your study

	1. Sponsored Study		2. Prospective Study		3. Retrospective Study		4. Case Study
0	Research Financial Form	0	IRB Application	0	IRB Application	0	Statement of Intent
0	IRB Application	0	CITI/NIH Certificates	0	CITI/NIH Certificates	0	Patient consent
0	CITI/NIH Certificates	0	Protocol Summary	0	Protocol Summary	0	CITI/NIH certificates
0	Protocol Summary	0	Informed Consent (English	0	HIPAA authorization		
0	Informed Consent (English		& Spanish)		waiver		
	& Spanish)	0	Questionnaire, survey,				
0	PHI form		educational materials, etc.				
0	Questionnaire, survey,	0	PHI form				
	educational materials, etc.						
0	Clinical Trial Agreement/						
	Contract						



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After Submission:

- Once you have submitted all of the necessary forms to the IRB, they will be reviewed by the IRB Coordinator and IRB board members
- Prospective studies require a full board review and will be reviewed and voted on at the bi-monthly IRB meetings
- All other studies are reviewed and approved on a rolling basis by the board members
- If changes to your study need to be made or adjusted you will be notified
- If no changes are requested an IRB approval letter will be provided to all study members so you may begin your study



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After Submission continued:

- All studies will be assigned a Protocol number and will be always be referenced by that protocol number
- If you have further questions on what needs to be submitted you may contact Julie the IRB Coordinator:
 - Via email: <u>ARMC-</u> <u>IRB@armc.sbcounty.gov/Christiaj@armc.sbcounty.gov</u>
 - Via Phone: 909-580-6298
 - In person: located on the lower level of the hospital (across the hall from Pharmacy) door number #GC150A



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