REQUIRED IRB DOCUMENTS FOR RESEARCH WITH OTHER SITES

	Arrangement	USC IRB Requirement	Notes
1)	**USC is IRB of Record and research involves a non-USC site engaged in the research**	• USC IRB Approval	
	a) Non-USC sites with an FWA	• IRB approval from that site **OR** • IRB Authorization Agreement – (version according to IRB discretion)	
	b) Non-USC sites without an FWA	• IRB Authorization Agreement – (version according to IRB discretion) **OR** • IRB approval from that site	Non-USC site Institutional Official signing the IAA is assuring that their researchers are adhering to USC policies/procedures USC PI is responsible for any follow up or monitoring adherence to USC Policies and Procedures (but not IRB)
	c) Unaffiliated Investigator engaged in research (unaffiliated with **any** institution with respect to the research being conducted)	• Unaffiliated Investigator Agreement	
2)	**USC researcher engaged in research at/with non-USC site***	• USC IRB Approval **OR/ AND** • IRB approval from non-USC site **OR/ AND** • Non-engagement determination for non-USC site **OR/ AND** • IRB Authorization Agreement Examples 1) Non-USC site is engaged. Need: (a) site IRB approval plus USC IRB approval OR (b) site IRB approval plus IRB Authorization Agreement (USC defers to site) OR (c) USC IRB approval plus IRB AA (site defers to USC). 2) Non-USC site is not engaged. Need: USC IRB approval only (no IRB AA needed); may need letter of agreement from site	***Is non-USC site "engaged"?** Engagement depends on what is occurring at that site and the involvement of that site's employees.
3)	**<u>Non</u>-USC site/researcher engaged in research at/with USC**	• IRB Approval from that site **OR** • IRB Authorization Agreement deferring to USC as IRB of record	
4)	**<u>Non</u>-USC site <u>NOT</u> engaged but serving as study site (schools, clinic, businesses, etc.) for non-exempt research**	• Written permission from that site allowing the research to be conducted Examples: permission from school for school/child research, permission from ministry of health for international research	

REQUIRED IRB DOCUMENTS FOR RESEARCH WITH OTHER SITES

	Arrangement	USC IRB Requirement	Notes
5)	**USC is the direct awardee of federal grant/contract and human subjects research (HSR) is at USC**	• USC is IRB of Record and conducts IRB review • Grant proposal, budget detail, and award letter provided to USC IRB	
6)	**USC is the direct awardee of grant/contract with subcontracted site/researcher elsewhere. Both sites engaged in HSR.**	• IRB Approval from that site **OR** • IRB Authorization Agreement (one site deferring to the other as IRB of record) **OR** • Unaffiliated Investigator Agreement • Grant proposal, budget detail, and award letter provided to USC IRB.	Continuing Review– If USC is the IRB of Record/ direct awardee, USC PI is responsible for uploading CR approval from non-USC site at the time of CR at USC.
7)	**USC has a subcontract for HSR and is IRB of record for whole award**	• IRB Authorization Agreement, direct awardee defers to USC as the IRB of record. • Grant proposal, award letter, and budget detail provided to USC IRB. When award is pending, USC will accept budget based on anticipated award.	
8)	**USC is the direct awardee of the HHS/NIH grant/contract but there is no HSR at USC**	• IRB Authorization Agreement deferring to the site where the highest risk to subjects occurs **OR** • USC non-engagement determination – must get permission from OHRP. (per OHRP Correspondence on Non-Engaged Scenarios, Sept 22, 2011) [i]	
9)	**USC has a subcontract for HSR but is not the IRB of record for the entire grant** **(USC responsible for USC HSR)**	• USC IRB Approval (for research activities at USC) • The portion of the USC grant proposal, budget detail and award letter that covers the HSR conducted under USC subcontract is required	(PI may provide the whole contract)
10)	**For situations where faculty and grant from another institution transfer to USC**		
	a) Researcher joins USC faculty and transfers grant/contract to USC (USC becomes awardee) HSR conducted at USC	• USC conducts IRB review • Grant proposal, budget detail, and award letter provided to USC IRB.	
	b) HSR does not move with the PI	• IRB Authorization Agreement deferring to the other site	
	c) HSR may be conducted at both sites	• IRB Authorization Agreement deferring to the site with the highest risk **OR** • Each site may conduct its own IRB	

REQUIRED IRB DOCUMENTS FOR RESEARCH WITH OTHER SITES

	Arrangement	USC IRB Requirement	Notes
		review If USC conducts an IRB Review: The portion of the grant proposal, budget detail and award letter that covers the HSR conducted at USC is required.	
11)	**For non-federally funded, non-FDA research that would otherwise require an IRB Authorization Agreement (see scenarios 1-3, 6-8, 10 above)**	• IRB Authorization Agreement is not required unless the outside institution requests an Agreement • If requested by the outside institution, USC will comply with the request • Additionally, USC may require an IRB Authorization Agreement at its discretion	
12)	**For non-federally funded, non-FDA research that would otherwise require an Unaffiliated Investigator Agreement (see scenarios 1, 6 above)**	• Unaffiliated Investigator Agreement does not require a USC Institutional Official (IO) signature • The IRB Director or IRB Chair signature can substitute for the IO signature	

[i] **Awardee Institution**
The institution received a grant award from the National Institutes of Health (NIH) for the conduct of non-exempt human subjects research (i.e. was an awardee institution), but no specific human subjects research studies were described in the grant application. In this case, the awardee institution planned to solicit research proposals that would be funded under the awardee institution's NIH grant. Institutions other than the awardee institution could receive these sub-awards from the awardee institution. The institution receiving the NIH award would have no involvement in the conduct of the research conducted at the other institutions.
Note that in this case, OHRP determined that the awardee institution of the NIH award was not engaged in the non-exempt human subjects research studies that were to be carried out by other institutions under the award. (OHRP Correspondence on Non-Engaged Scenarios, Sept 22, 2011 http://www.hhs.gov/ohrp/policy/engage08.pdf)