



OSPIP Contracts Officer Guidance FAQs Human and Animal Subjects Process For Sponsor Request for Certification

Office of Sponsored Projects & Industry Partnerships
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Topic	Question / Answer
Certification Required	Question: When is a Certification Form Required?
	Answer:
	<ul style="list-style-type: none"> ▪ Anytime the funding sponsor requests verification of human / animal approval
	<ul style="list-style-type: none"> ▪ Whenever the OSPIP CO “signs and certifies” something to the sponsor agency relating to human or animal subjects
	<ul style="list-style-type: none"> ▪ NIH JIT
	<ul style="list-style-type: none"> ▪ Submission of a NIH non-competing continuation
	<ul style="list-style-type: none"> ▪ NON-NIH awards during the pre-award phase
	<ul style="list-style-type: none"> ▪ Acceptance of a new award ▪ Acceptance of an amendment or increment on an existing award.
Updated Certification	Question: Why does OSPIP require updated certification if the sponsor doesn't require it?
	<p>Answer: Lab policy requires up to date HARC approval prior to expenditure of funds in the relevant budget period. In addition, when the OSPIP CO accepts an award, s/he certifies to a list of criteria specified in the sponsor's master certifications, one of which is confirmation that human and/or animal research has been</p>

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	<p>reviewed and approved by the appropriate IRB or IACUC. Although the sponsor is not requiring the specific HARC certification document for its files, they are requiring OSPIP confirm and document in the official award file that the requirement has been met.</p>
<p>Update CRF / Exempt</p>	<p>Question: When do I need to update Certification if my research was determined to be exempt?</p>
	<p>Answer: When the exemption file closes – the date will appear on the HSC Exemption Letter; or when the science changes requiring a new review by HARC.</p>
<p>Certification Status</p>	<p>Question: How can I tell if the last Certification I received is still current?</p>
	<p>Answer: Two criteria must be met for a previously issued Certification to be current:</p> <ol style="list-style-type: none"> 1) It must be signed within the last 12 months; and 2) All of the protocols listed on the Certification have not expired and are currently approved
<p>Re-Certification</p>	<p>Question: I just received a Certification when I submitted my non-competing continuation to NIH, why do I need another one 2 months later when the Notice of Award arrives?</p>
	<p>Answer: One of the protocols listed on the Certification has ended and a new Certification showing the protocol was renewed is required.</p>
<p>Subcontractor Certification</p>	<p>Question: Do I need a Certification if all the human and/or animal work is being performed at a subcontractor's site?</p>
	<p>Answer: Yes. If LBNL is the prime recipient, the LBNL HARC office must certify so that the OSPIP signature can</p>

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	certify compliance.
Not Human Use / Exempt	Question: What should I do if I'm not sure whether my science is Not Human use (NHU) OR "Exempt?"
	Answer: Contact HARC and ask them to review the specifics of your research and provide their guidance. There are very specific definitions for each of these two categories.
Proposal	Question: Why is HARC not getting the proposals from OSPIP?
	Answer: The proposal should be submitted with the CRF and the PI is the one required to submit the CRF.