



CHECKLIST-Protecting Employees Who Participate as Research Subjects			
NUMBER	VERSION	APPROVED BY	PAGE
HRP-423	5/7/19	E. White/C. Hautala-Bateman	1 of 2
See HRP-001 for definitions of applicable key terms and acronyms.			

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314-WORKSHEET-Criteria for Approval. For the IRB, this checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure) that involve worker populations.

- For initial review using the expedited procedure and modifications and CRs where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the operating procedures along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to “Submit Designated Review” activity.
- For initial review using the convened IRB and for modifications and CRs where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
 1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the operating procedures along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
 2. The convened IRB completes this checklist to document determinations required by the operating procedures along with protocol specific findings justifying those determinations and the IRB uploads this checklist in the “Submit Committee Review” activity.

Protocol Name:	
Investigator:	

DOCUMENTATION OF PROTECTING EMPLOYEES WHO PARTICIPATE AS SUBJECTS (Check if “Yes”. All must be checked.)	
<input type="checkbox"/>	Subject selection is not based solely on the subject’s ready availability or malleability.
<input type="checkbox"/>	The protocol explains that this is not a sample of convenience.
<input type="checkbox"/>	The description of the use of the employees as subjects for which use or access is included in the protocol summary and is necessary for the research.
<input type="checkbox"/>	Advertisements will be posted throughout the site to recruit subjects from a broad base of employees, contractors, and students. If, not justification was provided.



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<input type="checkbox"/>	The use or disclosure of the workers population or data involves no more than a minimal risk to the worker.
<input type="checkbox"/>	Recruitment materials includes how objectivity and validity of the data will be ensured.
<input type="checkbox"/>	Specific steps should be included about how potential coercion will be minimized.
<input type="checkbox"/>	If the Investigator is including direct reports justification has been provided for why this is needed. (Participation of direct reports to the research team should be avoided whenever possible.)
<input type="checkbox"/>	The research could NOT practicably be conducted without using this population.
If reviewing using the expedited review procedure, the designated reviewer signing below has determined that the above requirements are met, and are described in the protocol is necessary.	
Reviewer Signature:	
Date:	