

WHEN DOES A STUDENT INVESTIGATOR NEED TO BE ADDED TO A FACULTY PROTOCOL AND THE IRB HS eFORM? *

	SOCIAL BEHAVIORAL	BIOMEDICAL, NOT FDA-REGULATED	BIOMEDICAL, FDA-REGULATED
Greater than Minimal Risk (GMR) Research	ALL STUDENTS/LEARNERS who will assist with the research	ALL STUDENTS/LEARNERS who will assist with the research	ALL STUDENTS/LEARNERS who will assist with the research
Expedited Studies (Minimal Risk)	ONLY STUDENTS/LEARNERS who <ul style="list-style-type: none"> Interact/intervene with human subjects, AND/OR Recruit, obtain informed consent (documented or verbal), AND/OR Access, use, generate, or analyze PHI or identifiable information 	ONLY STUDENTS/LEARNERS who <ul style="list-style-type: none"> Interact/intervene with human subjects, AND/OR Recruit, obtain informed consent (documented or verbal), AND/OR Access, use, generate, or analyze PHI or identifiable information 	ALL STUDENTS/LEARNERS who will assist with the research
Exempt Studies			
Quality Improvement (QI)	NO REQUIREMENT for students/learners to be added	NO REQUIREMENT for students/learners to be added	N/A
Not Human Subjects Research (NHSR)	NO REQUIREMENT for students/learners to be added	NO REQUIREMENT for students/learners to be added	N/A

***NOTE:** The table above pertains to **student investigators only**. **Consultants, statisticians, study coordinators for FDA-regulated studies, and regulatory specialists** need to be included in the HS eForm if they will interact or intervene with human subjects, have access to subject's personally identifiable information, obtain informed consent (verbal or documented), access/use/generate/analyze PHI, participate in the investigation of a FDA-regulated product, or handle IRB submissions.

WHO NEEDS TO BE INCLUDED ON A STUDENT PROTOCOL AND THE IRB HS eFORM?

Per the CU HRPP policy manual, undergraduate students **may not** serve as principal investigator (PI) for a research study.

	SOCIAL BEHAVIORAL	BIOMEDICAL
Greater than Minimal Risk (GMR) Research	Students may not serve as PI on GMR research	Students may not serve as PI on GMR research
Expedited Studies (Minimal Risk)	<ul style="list-style-type: none"> • STUDENT PI (medical students may not serve as PI for Expedited studies) • FACULTY MENTOR • ALL CO-INVESTIGATORS INCLUDING STUDENTS/LEARNERS who <ul style="list-style-type: none"> (1) Interact/intervene with human subjects, AND/OR (2) Recruit, obtain informed consent (documented or verbal), AND/OR (3) Access, use, generate, or analyze PHI or identifiable information 	<ul style="list-style-type: none"> • STUDENT PI (medical students may not serve as PI for Expedited studies) • FACULTY MENTOR • ALL CO-INVESTIGATORS INCLUDING STUDENTS/LEARNERS who <ul style="list-style-type: none"> (1) Interact/intervene with human subjects, AND/OR (2) Recruit, obtain informed consent (documented or verbal), AND/OR (3) Access, use, generate, or analyze PHI or identifiable information
Exempt Studies		
Quality Improvement (QI)	<ul style="list-style-type: none"> • STUDENT PI • FACULTY MENTOR 	<ul style="list-style-type: none"> • STUDENT PI • FACULTY MENTOR
Not Human Subjects Research (NHSR)	<ul style="list-style-type: none"> • STUDENT PI • FACULTY MENTOR 	<ul style="list-style-type: none"> • STUDENT PI • FACULTY MENTOR