

Single IRB: Institutional Engagement Scenarios

These scenarios help illustrate examples of institutional involvement in research that would be considered engaged and NOT engaged. They do not represent all potential scenarios and may also apply to research not using sIRB. In all scenarios the activity has been determined to be non-exempt human subjects research. See the [Institutional Engagement Definitions](#) document for further clarity.

SCENARIO 1: PRINCIPAL INVESTIGATOR WITH DUAL APPOINTMENTS

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SCENARIO 5: INVESTIGATOR PART OF SMALL BUSINESS AND UNIVERSITY

SCENARIO 1: PRINCIPAL INVESTIGATOR WITH DUAL APPOINTMENTS*

A physician has an individual practice as well as an appointment at an academic institution (affiliate institution). The physician is participating as the principal investigator in a non-exempt human subjects research study at his/her/their practice. Is the affiliate institution engaged in the research?

Variation 1A: All research activities are performed at the physician's practice

	Physician's practice	Affiliate institution
Analysis	<ul style="list-style-type: none"> Research activities performed entirely at practice Practice is recipient of grant Research performed solely by physician and other employees of practice 	<ul style="list-style-type: none"> No employees or agents are involved in the research Not receiving funding for research No research activities performed at affiliate institution Other than physician relationship with the affiliate institution, there is no interaction by affiliate institution's employees or agents with human subjects or their identifiable information or biological specimens Physician will not name institution in publications
Determination	<p>Engaged:</p> <ul style="list-style-type: none"> Practice directly receiving grant The investigator and staff are interacting and intervening with human subjects for research purposes 	<p>Not Engaged:</p> <ul style="list-style-type: none"> Neither the affiliate institution facilities nor staff are involved in the research Physician is conducting research as part of employment at practice Affiliate institution will not receive recognition or be named in publications

* Consider this scenario alongside CTTI's [Engagement Flowchart](#).

To learn more about CTTI's sIRB work, please visit <https://www.ctti-clinicaltrials.org/projects/single-irb>

Recommended Follow-up:

1. Affiliate institution has determined it is NOT engaged and should:
 - Reach out to the physician to clarify that the affiliate institution would not be engaged in human subjects research. Therefore contracting and IRB oversight should be addressed via the physician’s practice.
 - Remind physician not to use affiliate institution appointment in any publications.
2. Physician’s practice is engaged; see [responsibilities in the Engagement Overview document](#).

Variation 1B: Same as 1A, with some clinical procedures performed at affiliate institution

	Physician’s practice	Affiliate institution
Analysis	<ul style="list-style-type: none"> • Research activities performed at practice • Practice is recipient of grant • Informed consent and study intervention performed by physician and other employees of practice 	<ul style="list-style-type: none"> • Employees or agents are involved • Affiliate institution is not receiving direct funding for research • Protocol dictated magnetic resonance imaging (MRI) scan being performed at affiliate institution • Affiliate institution’s employees will perform scan that is routinely performed as part of clinical services • Institution’s employees will not obtain consent or administer study intervention • Institution’s employees’ access to identifiable information is limited to performing the MRI and sending the results to the physician’s practice • Physician will not name institution in publications
Determination	<p>Engaged:</p> <ul style="list-style-type: none"> • Directly receiving grant • The investigator and staff are interacting and intervening with human subjects for research purposes 	<p>Not Engaged:</p> <ul style="list-style-type: none"> • The institution’s involvement is limited to providing a procedure dictated by the protocol that is routinely performed as part of routine care

Recommended Follow-up:

1. Affiliate institution has determined it is not engaged and should:
 - Review with the physician exactly what portions of the research activity will occur at the affiliate institution and confirm those procedures are standard clinical procedures normally provided by the affiliate institution employees for non-research purposes.
2. Physician’s practice is engaged. See [responsibilities in the Engagement Overview document](#), and:
 - Set up agreement and/or billing procedure for use of affiliate institution’s equipment and staff to perform MRI scan.
 - Contact affiliate institution’s HRPP/IRB to determine if institutional review is required.

* Consider this scenario alongside CTTI’s [Engagement Flowchart](#).
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SCENARIO 2: MULTICENTER STUDY SITE PERFORMS ACTIVITIES ACROSS TWO PRACTICES*

Site principal investigator is an employee of both a physician owned and operated multispecialty group and a radiology practice. Sub-investigators are employees of multispecialty group. Employees/agents of both the multispecialty group and the practice are potentially involved in the research.

	Radiology practice	Multispecialty group
Analysis	<ul style="list-style-type: none"> • Radiology Associates is the recipient of grant • Radiology Associates employees will interact with human subjects by obtaining informed consent, administering study intervention, and performing follow-up activities 	<ul style="list-style-type: none"> • Sub-investigators are employees/agents of multispecialty group • Not receiving direct funding • Research activities performed at multispecialty group practice by radiology practice employees • Sub-investigators will participate in obtaining informed consent
Determination	<p>Engaged:</p> <ul style="list-style-type: none"> • Directly receiving grant • Investigator and staff are interacting and intervening with human subjects for research purposes 	<p>Engaged:</p> <ul style="list-style-type: none"> • Sub-investigators are employees of multispecialty group, and they are interacting and intervening with human subjects for research purposes

Recommended Follow-up:

Tri-State and Radiology Associates are engaged; see [responsibilities in the Engagement Overview document](#), including confirming existing, or obtaining new, FWA coverage.

* Consider this scenario alongside CTTI's [Engagement Flowchart](#).
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SCENARIO 3: RESEARCH CONDUCTED AT DIFFERENT SITES AT ONE HEALTH SYSTEM*

Research is conducted at different sites throughout one health system (e.g. hospitals and universities and other components that seem like one organization but have several FWAs) – which institutions are engaged?

Variation 3A: University employees conducting research at hospital

	Hospital	University
Analysis	<ul style="list-style-type: none"> • Not receiving direct funding • Research activities occur at hospital • Hospital employees are not involved in research, have no interaction with human subjects 	<ul style="list-style-type: none"> ○ Prime awardee ○ Employees of university are performing all research activities
Determination	<p>Not Engaged:</p> <ul style="list-style-type: none"> • Role limited to use of facilities by university employees 	<p>Engaged:</p> <ul style="list-style-type: none"> • Receiving direct funding • Employees are interacting and intervening with human subjects for research purposes

Recommended Follow-up:

1. For the hospital to not be engaged, it should confirm no hospital employees are interacting or intervening for research purposes with human subjects.
2. University is engaged; see [responsibilities in the Engagement Overview document](#). Determine if any institutional reviews, service arrangements, or other agreements are required by hospital.

Variation 3B: University receives funding, research conducted by hospital employees at hospital

	Hospital	University
Analysis	<ul style="list-style-type: none"> • Not receiving direct funding • Research activities occur at hospital • Hospital employees are performing research activities including obtaining informed consent and administering intervention 	<ul style="list-style-type: none"> • Prime awardee • University employees are not performing research activities
Determination	<p>Engaged:</p> <ul style="list-style-type: none"> • Hospital employees are interacting and intervening with human subjects for research purposes 	<p>Engaged:</p> <ul style="list-style-type: none"> • University is receiving direct funding

Recommended Follow-up:

Hospital and university are engaged; see [responsibilities in the Engagement Overview document](#).

* Consider this scenario alongside CTTI's [Engagement Flowchart](#).
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SCENARIO 4: COORDINATING CENTERS (CC), DATA COORDINATING CENTERS (DCC), AND/OR LEAD RESEARCH TEAMS PREPARING GRANTS & PROVIDING RESEARCH OVERSIGHT*

Are coordinating centers and/or hub institutions engaged in research?

Variation 4A: Coordinating Center for NIH multicenter trial

	Coordinating Center (CC)
Analysis	<ul style="list-style-type: none"> Receiving direct funding from NIH Recruits enrollment sites, trains study personnel, and employs site monitors to perform source document verification CC employees do not interact with research subjects
Determination	Engaged: Receiving direct research funding

Recommended Follow-up:

1. CC is engaged; see [responsibilities in the Engagement Overview document](#).
2. Organize and obtain single IRB approval of the study protocol and the overall study organization, and facilitate enrollment site applications to the single IRB.
3. Check with sites' local IRBs, if different than sIRB, to determine what institutional reviews are required.

Variation 4B & C: NIH multicenter clinical trial has a DCC or hub at an academic institution

	Data Coordinating Center (DCC)	Hub or Coordinating Center
Analysis	<ul style="list-style-type: none"> Receiving funding from a subaward of the prime awardee (not directly from NIH) DCC responsibilities include data management and statistical analysis DCC employees do not interact with research subjects Study database does not include Personal Identifying Information. DCC works with limited dataset, not considered de-identified. 	<ul style="list-style-type: none"> Receives funding from a subaward of the prime awardee (not directly from NIH) Hub responsibilities include guidance and advice, monitoring and motivating site performance, and helping with quality assurance and improvement Hub employees do not interact with research subjects Hub does not store any study data
Determination	Not Engaged: <ul style="list-style-type: none"> Not receiving direct funding No interaction with human subjects or personal identifying information 	Not Engaged: <ul style="list-style-type: none"> Same reasons as DCC

Recommended Follow-up:

1. IRB review by the trial's single IRB is not required as a matter of NIH policy or regulatory requirements. If institution required IRB review, this may be performed by either the institutional IRB or the single IRB at the institution's and the sponsor's discretion.
2. DCC/Hub personnel will need to follow up with their institution to determine which institutional reviews are required.

* Consider this scenario alongside CTTI's [Engagement Flowchart](#).
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SCENARIO 5: INVESTIGATOR PART OF SMALL BUSINESS & UNIVERSITY*

An investigator has university affiliation and is associated with a private company conducting research using a Small Business Innovation Research (SBIR) or Small Business Technology Transfer (STTR) grant. Is the university engaged in research?

	Small Business	University
Analysis	<ul style="list-style-type: none"> Receiving direct funding Research activities occur at small business and university 	<ul style="list-style-type: none"> NOT receiving direct funding University employees are collecting blood samples from patients, accessing medical records to collect information for the study, and storing information in study records
Determination	Engaged: <ul style="list-style-type: none"> Receiving direct funding 	Engaged: <ul style="list-style-type: none"> University employees interacting and intervening with human subjects

Recommended Follow-up:

- Both institutions are engaged; see [responsibilities in the Engagement Overview document](#).
- The small business will need to apply for FWA if it does not already hold or request university to [extend their FWA to cover](#) the investigator and small business.
- Investigator will need to include university/institution affiliation in any publications.
- Small business and university will need to establish an agreement for addressing conflict of interest, intellectual property, and use of facilities.

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