BRI Institutional Review Board (IRB) Guidance on "Key Personnel"

WHO IS CONSIDERED "KEY PERSONNEL" AT BRI?

The Clinical Research Program (CRP) considers persons responsible for one or more of the following activities:

a. Day-to-day protocol decision-making related to the study conduct;
b. Participant recruitment, selection and eligibility;
c. Clarification of the complexities of the protocol to the participant and others;
d. Collecting participant information and entering data using procedures to maintain privacy and confidentiality;
e. Ensuring that the rights and welfare of participants are monitored throughout the study.

One or both IRB specific criteria below must be met to be designated as "Key Personnel" on a BRI IRB submission:

f. Must make a *direct* and *significant contribution* to the data;
g. Must *contribute to the scientific development or execution* of the project in a *substantive and measureable* way.

- *Who **MUST** be listed? Principal Investigator (PI).*
- *Who **SHOULD** be listed if appropriate criteria (a-g) are met? Sub-Investigators, primary study coordinator (If study is still enrolling and/or intervention is ongoing.)*
- *Who **SHOULD NOT** be listed (unless appropriate criteria (a-g) are met)? Research Assistants, backup coordinators, people with only an occasional role in the research (e.g. on-call providers, hospital staff, nurses, residents, back up study coordinators that MAY see a subject on trial), IDS pharmacy staff, etc.*

All human subjects research personnel meeting the CRP criteria above (*a-e*) will undergo various training requirements based on their role in a research study. BRI IRB will only track and require ethics and GCP training for those personnel meeting both CRP *and* IRB criteria above (*a-g*), prior to approving said personnel for a study. Unless personnel meet both CRP *and* IRB criteria above (*a-g*), they are not required to be listed as "Key Personnel" on IRB submission documents.

The Principal Investigator (PI) is responsible for determining who should be considered "Key Personnel" based on the above criteria for each study. The IRB does not make a judgment on the level of engagement of said individual beyond what is reported on the IRB application. There are different scenarios where the extent of referrals by personnel would and would not be considered "engaged" based on their role in the study. If the PI chooses to list an individual as "Key Personnel" it is their prerogative. The IRB will not determine what level of engagement each person listed would have and then determine who would have to do training. As such, **ALL** personnel designated as "Key Personnel" on IRB submissions are required to complete training for Ethics and GCP.

For further assistance and clarifications on exceptions and exemptions for qualified personnel, please see regulatory guidance below and our training instructions/guidance at the following link: CITI Ethics and GCP.

BENAROYA RESEARCH INSTITUTE
Virginia Mason

References to Guidance from Federal Regulations:

1. Office For Human Research Protections (OHRP):

   - "…an institution holding an OHRP-approved Federalwide Assurance (FWA) is responsible for ensuring that its investigators conducting HHS-conducted or -supported human subjects research understand and act in accordance with the requirements of the HHS regulations for the protection of human subjects." http://www.hhs.gov/ohrp/policy/faq/investigator-responsibilities/obtain-training-protection-human-subjects.html

2. OHRP: Institutions would be considered "engaged" in human subjects research (and would need an Assurance) if their nonexempt involvement includes the following:

   …

   (3) Institutions whose employees or agents interact with living individuals *for research purposes* (e.g., engaging in protocol-dictated communication or interpersonal contact; conducting research interviews; obtaining informed consent). (See Example (B)(3) below for certain informational activities that do not constitute "engagement" in research and do not require an Assurance.)

   …

   (B) Institutions would not be considered "engaged" in human subjects research (and would not need an Assurance) if their involvement is limited to the following:

   …

   (3) Institutions whose employees or agents (i) inform prospective subjects about the availability of research; (ii) provide prospective subjects with written information about research (which may include a copy of the relevant informed consent document and other IRB-approved materials) but *do not obtain subjects' consent or act as authoritative representatives* of the investigators; (iii) provide prospective subjects with information about contacting investigators for information or enrollment; or (iv) obtain and appropriately document prospective subjects' permission for investigators to contact them (e.g., a clinician provides patients with literature about a research study, including a copy of the informed consent document, and tells them how to contact the investigator if they want to enroll; a clinician provides investigators with contact information about potential subjects after receiving explicit permission from each potential subject). http://www.hhs.gov/ohrp/policy/engage08.html

3. Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions - Statement of Investigator (Form FDA 1572):

   - Page 10, question #31 ~ "Should research nurses, other nurses, residents, fellows, office staff, or other hospital staff be listed in Block #6?

     "Hospital staff, including nurses, residents, or fellows and office staff who provide ancillary or intermittent care but who do not make a direct and significant contribution to the data do not need to be listed individually. It is not necessary to include in this block a person with only an occasional role in the conduct of the research, e.g., an on-call physician who temporarily dealt with a possible adverse effect or a temporary substitute for any research staff (ICH E3 Section 6). http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0406-gdl.pdf

4. FDA Guideline for Industry Structure and Content of Clinical Study Reports:

   - Page 6, B ~ "Any other person carrying out observations of primary or other major efficacy variables, such as a nurse, physician's assistant, clinical psychologist, clinical pharmacist, or house staff physician. It is not necessary to include in this list a person with only an occasional role, e.g., an on-call physician who dealt with a possible adverse effect or a temporary substitute for any of the above. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073113.pdf

5. National Institutes of Health (NIH):

   - "Senior/key personnel are defined as the PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition." http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch1.htm#def_senior_key_personnel