Monthly IRB-Investigator Meeting

Human Research Protection Office/IRBs

December 17, 2020

COLUMBIA | VAGELOS COLLEGE OF PHYSICIANS AND SURGEONS
OFFICE FOR RESEARCH

Agenda

- HRPO staffing updates
- Home Study Visits
- QA/QI vs Research

HRPO Staffing changes (Sept-Dec 2020)

- Laurence Butaud-Rebbaa, Director for IRB Management
- Sean Hobson, Director for Operations
- Yaritza Collazo, Senior Manager
- Erin Murphy, Assistant Manager

Home Study Visits

Brenda Ruotolo
Executive Director, HRPO

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Key Points to be Covered

- Reasons for offering
- Who may conduct
- Considerations
- IRB coverage

Reasons for offering home study visits

- Facilitate recruitment and retention
- Participants have mobility or other obstacles
- Safety
- Pandemic

Who may conduct home study visits

- Columbia personnel
- Home healthcare agency (HHA) contracted by Columbia
  - Service agreement
- Home healthcare agency contracted by sponsor
  - Clinical trial agreement
- Manufacturer
  - Clinical trial agreement

Considerations

- Optional or required
- Informed Consent
- Engagement and IRB coverage
- Communication
- Documentation
- Liability
- Credentialing
- Licensure
- Training on protocol
- FDA form 1572
- Delegation of authority log
- Responsibility

Engagement

- DHHS concept of engagement of institutions in research
  - In general, an institution is considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain:

    (1) data about the subjects of the research through intervention or interaction with them;

    (2) identifiable private information about the subjects of the research; or

    (3) the informed consent of human subjects for the research.

Applicability of engagement concept at CU

- Columbia applies DHHS 45 CFR 46 to all research
  - Facilitates compliance with NYS PHL Article 24-A (2440-2446) – Protection of Human Subjects
  - NYS Senate S6448, July 2019
- HHA/manufacturer are engaged unless:
  - Conduct same services for non-research situations
  - Exception to engagement for entities that conduct same procedures outside of the research context
- Engagement requires IRB oversight

Engagement

- Federally funded research (45 CFR 46)
- Non-federally funded research if institution commits to applying 45 CFR 46 to all research
- Exception: entities that provide the same services in non-research situations

Exception to engagement

- If HHA provides services in both research and non-research context:
  - Assess whether procedures to be conducted in home visits are consistent with non-research application
  - If procedures are beyond usual clinical care, HHA is engaged and IRB approval is required

Communication and documentation

- Informed consent and documentation thereof
  - If optional must be signature or initials on consent form
- Confirm consent for home study visits before scheduling home visits
- Provide details of home study visits to participants when they become available and obtain feedback after visit
- Communicate with personnel conducting the visit - before and after

Documentation of home study visits

- Document discussions with HHA and participants
- Obtain documentation from HHA of remote visit
- Document all procedures in research records – identify by whom procedures were conducted

*Same for manufacturer if engaged

Form FDA and DOA log

- HHA/manufacturer representatives are not investigators and should not be listed on FDA Form 1572 filed by a Columbia investigator
- Columbia delegation of authority logs should not include HHA/manufacturer representatives, although research records must clearly document by whom each study procedure is performed, whether by Columbia personnel or HHA representatives.

Columbia personnel

When conducting home study visits:

- Are engaged
- Are covered by the IRB approval of the protocol, whether Columbia or IRB on which Columbia is relying
- Credentialing, licensure, training – Columbia responsibility
- Communication as established for on-campus procedures
- Columbia liability coverage
- Documentation as established for on-campus procedures
- Security of data while on site and in transit must be considered and compliant with University policies

HHA (research) contracted by Columbia

When conducting home study visits:

- Are engaged
- Covered by sponsor- or HHA-contracted external IRB or, with reliance agreement in place, by Columbia IRB
- Credentialing, licensure, training – covered in service agreement/contract
- Communication best practices must be observed
- Liability covered in service agreement/contract
- Documentation best practices must be observed
- Security of data while on site and in transit must be considered and compliant with University policies

HHA (research) contracted by sponsor

When conducting home study visits:

- Are engaged
- Covered by Columbia IRB or IRB on which Columbia is relying (considered part of sponsor's protocol) unless other IRB approval is provided
- Credentialing, licensure, training – sponsor responsibility
- Liability covered in service agreement/contract
- Documentation best practices must be observed
- Security of data while on site and in transit must be considered and compliant with University policies

Manufacturer

When conducting home study visits:

- Engaged if procedures are only done for research
- If engaged, covered by Columbia IRB or IRB on which Columbia is relying (considered part of sponsor's protocol) unless other IRB approval is provided
- Credentialing, licensure, training – manufacturer responsibility
- Communication best practices must be observed
- Liability covered in service agreement/contract
- Documentation as for on campus procedures is required, if data are shared with study team
- Security of data while in transit must be considered and compliant with University policies

Process

- Describe home study visits in protocol and consent form
- Question will be added in Rascal form
- Complete questionnaire and attach in Rascal
- Provide external IRB approval if applicable
- Determination letter will include notation that HHA is covered as part of sponsor protocol only for study under review and for Columbia site(s)

Guidance for the Evaluation of Research versus Quality Assurance/Improvement Activities in Healthcare Settings

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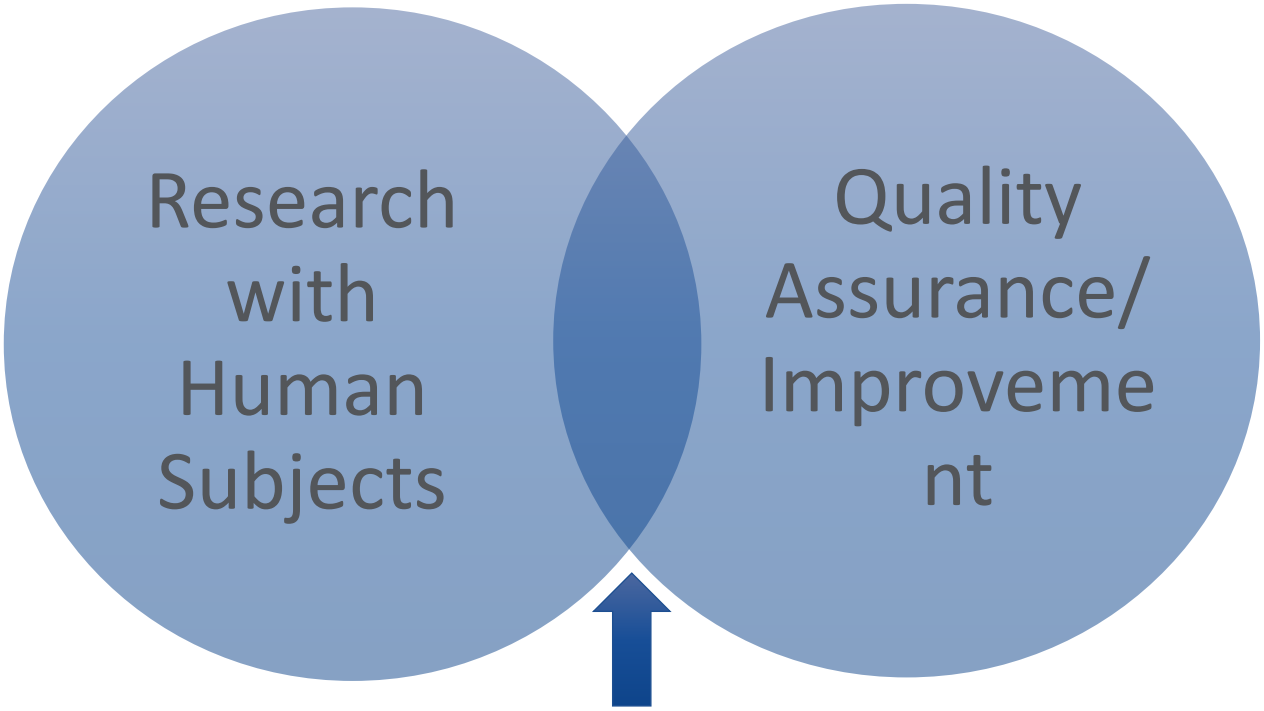
Research vs. QA/QI

- HHS regulations under 45 CFR 46.102 define *Research* as, “a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.”
- There is no regulatory definition for quality assurance (QA) or quality improvement (QI), but often QA/QI are described as “systematic data-guided activities designed to bring about immediate (or nearly immediate) improvements in health care delivery”. (https://www.thehastingscenter.org/briefingbook/quality-improvement-methods-in-health-care)

	Human Subjects Research	Quality Improvement
Purpose	designed to develop or contribute to generalizable knowledge	designed to implement knowledge, assess a process or program as judged by established/accepted standards
Starting Point	knowledge-seeking is independent of routine care and intended to answer a question or test a hypothesis	knowledge-seeking is integral to ongoing management system for delivering health care
Design	follows a rigid protocol that remains unchanged throughout the research	adaptive, iterative design
Benefits	might or might not benefit current subjects; intended to benefit future patients	directly benefits a process, system or program; might or might not benefit patients
Risks	may put subjects at risk	does not increase risk to patients, with exception of possible patients' privacy or confidentialty of data
Participant Obligation	no obligation of individuals to participate	responsibility to participate as component of care
Endpoint	answer a research question	improve a program, process or system
Analysis	statistically prove or disprove hypothesis	compare program, process or system to established standards
Adoption of Results	little urgency to disseminate results quickly	results rapidly adopted into local care delivery;
Publication/ Presentation	investigator obliged to share results	QI practitioners encouraged to share systematic reporting of insights

Hastings Center Report July-Aug 2006

Intersection of Research and QA/QI



Research AND Quality Assurance/Improvement

Checklist to Differentiate Quality Assurance/Improvement and Research with Human Subjects

Use the following checklist to determine whether a quality assurance/improvement project also meets the definition of research. Follow the instructions to determine if a submission in Rascal for IRB review is required.	Yes	No
Does the project use existing evidence designed to bring about immediate or nearly immediate improvements in health care delivery within a local health care institution or a setting such as a clinical unit?		
If you answered, "Yes" to the question above, submission in Rascal <u>may not be required</u>. In order to confirm, please complete the following series of questions.		
1) Is the intent of the project to develop or contribute to new knowledge that can be generalized to other populations and/or settings?		
2) Does the project involve collaboration between more than one institution?		
3) Is the project funded by an outside organization that has a commercial or financial interest in the use of the results?		
If you answered "Yes" to any of the questions above, a submission in Rascal for IRB review is required. If you answered "No" to all 3 questions above, a submission in Rascal for IRB review is not required.		

Examples of Quality Improvement/Assurance Activities

- A radiology clinic uses a database to help monitor and forecast radiation dosimetry. **This practice has been demonstrated** to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected.

Examples from OHRP FAQs: (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html)

Examples (continued)

- A clinic increasingly utilized by geriatric patients implements a **widely accepted** capacity assessment as part of routine standard of care in order to identify patients requiring special services and staff expertise. The clinic expects to audit patient charts in order to see if the assessments are performed with appropriate patients, and will implement additional in-service training of clinic staff regarding the use of the capacity assessment in geriatric patients if it finds that the assessments are not being administered routinely.

Examples from OHRP FAQs: (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html)

Statement for Journal Submissions

- Intent to publish the results of a project does not, by itself, mean that results would be generalizable (i.e., research) or require review by an IRB.
- Statement for Journal Submissions found within the guidance can be submitted alongside your QA/QI project manuscript.
  - Some journals/conferences may accept this in place of an official IRB determination.
- Many journals and conferences may still require an official IRB determination prior to acceptance of a manuscript or a presentation.
  - Submission in Rascal will be needed.

Additional Considerations

- QA/QI activities, such as looking at outcomes evaluation or development of clinical guidelines or protocols to support the core functions of treatment and payment of health care activities, may fall under the category of “health care operations” where HIPAA Authorization or Waiver of Authorization may not be necessary.
  - Consult with Privacy Office (privacy@cumc.columbia.edu)
- If a report of eligible patients or patient data will be obtained from the Tripartite Request Assessment Committee (TRAC), the TRAC request form can be submitted via https://webapps.nyp.org/trac after IRB approval or assessment that IRB review is not required.
- If PHI will be disclosed to an entity outside of CU, the proper data use agreements endorsed by the Office of Sponsored Projects Administration must be in place prior to the release. https://research.columbia.edu/mta-dua

Questions?

If you have questions related to this guidance, or if you are uncertain if your project meets the definition of human subjects research, please feel free to contact Rafael Santos at rs3275@columbia.edu.

Questions?