

DEPARTMENT: Clinical Operations Group – Research	POLICY DESCRIPTION: Research Integration into Healthcare Treatment/Payment/Operations
PAGE: 1 of 5	REPLACES POLICY DATED: 3/1/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	REFERENCE NUMBER: COG.RSH.002 (formerly CSG.RSH.002)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy is applicable to all entities (*i.e.*, hospitals, surgery centers, physician practices, administrative offices, etc.).

PURPOSE: This policy pertains to the oversight of integrating the complexities of research operations into the complexities of healthcare delivery operations. It is not to be confused with the Institutional Review Board (IRB) review of research or a compliance manual for the conduct of research itself.

POLICY:

1. The Facility shall establish a research integration oversight infrastructure customized to the needs of the Facility. There are no regulations or specific instructions directly governing this infrastructure; however, common themes suggest the following:
 - a. Provide a “Single-Point-Of-Entry” contact point convenient for researchers to request to begin a new protocol.
 - b. Educate potential researchers on the Facility process and ongoing communication for changes in the research impacting its integration into healthcare treatment/payment/operations and emphasize the importance of enacting this process as early as possible.
 - c. Although the same person who manages any facility-run IRB may act as a single point of entry into the system, this process is not to be confused with the IRB process. Specifically, the Facility delegates many aspects of human subject protection oversight to an IRB but an IRB is only focused on human subject protection and the IRB committee itself does not address or provide oversight over operational issues (*i.e.*, related to contracting, billing/coding, healthcare operations integration, etc.).
 - d. As opposed to a standing committee to fulfill this purpose, this system could be spearheaded by the contact person who obtains ad-hoc aid from relevant parties depending on the individual needs of the proposed research activity.
 - i. For example, when the protocol requires clinical services, representatives of the services needed should be consulted (radiology, pharmacy, nursing, physician specialist, etc.).
 - ii. For example, when the services involve billing for services or acquisition of supplies (to patient/insurance, sponsor, and researcher), financial individuals should be consulted (CFO, Revenue Integrity, supply chain, etc.).
 - iii. For example, when the services involve release of data, health information management/privacy officials should be involved.
2. Interface with other committees:
This process will interface with the following committees, can decline research for any reason but cannot approve non-exempt human subject research that has not been approved by:
 - a. The IRB overseeing the research;
 - b. If required by regulations, the Facility established Institutional Biosafety Committee (IBC) (as well as the IRB) providing oversight for recombinant DNA studies;
 - c. If required by regulations, the Facility established Radioactive Drug Research Committee (RDRC) (as well as the IRB) providing oversight for radiopharmaceuticals.

DEPARTMENT: Clinical Operations Group – Research	POLICY DESCRIPTION: Research Integration into Healthcare Treatment/Payment/Operations
PAGE: 2 of 5	REPLACES POLICY DATED: 3/1/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	REFERENCE NUMBER: COG.RSH.002 (formerly CSG.RSH.002)
APPROVED BY: Ethics and Compliance Policy Committee	

3. The above is the process designated by the governing body to approve protocols on behalf of the facility. Other committees (*i.e.*, the Board of Trustees, Medical Executive Committee, etc.) are not designed to be pre-approving research entities thus are usually not involved in the review/approvals of individual protocols but can be utilized or be informed if needed.
4. There are four (4) major functions of this process: noting that Feasibility Analysis and Contracting can be done concurrently as part of planned study startup.
 - i. Feasibility Analysis: It is suggested, but not required, that this analysis take no longer than 5 working days from initial request to completion. Each protocols will have unique needs but typical items in a feasibility analysis may include but are not limited to the following:
 1. Ensure that the research is consistent with the mission and values of the Facility;
 2. Review services expected to be performed by the Facility in the support of the research and do the following:
 - a. Ensure that all individuals (physician investigators, advanced practice practitioners, clinical research coordinators, etc.) performing services that require credentialing/privileging are credentialed and privileged to perform the applicable clinical services (Note: if the Facility has a separate “Clinical Investigator” physician privileging category, then assure the physician is so privileged);
 - b. Identify any required deviations from normal policy and assess feasibility of such deviations;
 - c. Identify personnel, equipment, supply, procedure, etc. that are either “above and beyond” usual care or other business interrupts that require separate charges.
 - d. Determine special education needs of involved staff and how this is to be accomplished;
 - e. Determine if any equipment needed for the research will be provided by the researchers and if so, that it follows Facility policies to be brought in;
 - f. For inpatient pharmaceutical distribution, assure that the pharmacy will demonstrate control over the process;
 - g. Establish reimbursement methodology for procedures:

If Medicare patients are expected to be participants and Medicare is to be billed for routine costs, unless the study is one for investigational devices (to which a and b below are substituted with simply assuring that the clinical trial is listed as a qualifying trial on the CMS website) perform a Medicare Coverage Analysis for services by:

 - a. Determine if the clinical trial is a covered clinical trial per the Medicare Clinical Trials National Coverage Decision;
 - b. Obtain prior approval from the Medicare Contractor, if needed.
 - c. Determine the Routine Costs of the study and if they are allowable by Medicare
 - d. Determine if Medicare is a Secondary Payor
 - i. When the Facility is not the entity receiving the research grant and that research grant is not shared with the Facility, it is suggested to obtain an attestation (which is included in corporate template contracts) from the researcher that these services are not included in the research grant to justify Medicare as a primary payor;

DEPARTMENT: Clinical Operations Group – Research	POLICY DESCRIPTION: Research Integration into Healthcare Treatment/Payment/Operations
PAGE: 3 of 5	REPLACES POLICY DATED: 3/1/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	REFERENCE NUMBER: COG.RSH.002 (formerly CSG.RSH.002)
APPROVED BY: Ethics and Compliance Policy Committee	

- ii. Ensure a plan (prior to billing for services related to a research study) that each line item is analyzed for proper coding as “routine costs” or “Investigational”;
 - iii. If the test article is an investigational device (*i.e.*, under an Investigational Device Exemption from the FDA) follow REGS.BILL.007.
 - 3. Establish a plan to identify referred patients as subjects in research to assure proper coding and billing;
 - 4. Perform a cursory review of the consent form (but not the same review as an IRB - see the Handling Research Informed Consent Documents (Non-IRB Requirements) policy, COG.RSH.006, on Consent Forms) and any HIPAA Authorizations to assure consistency with institutional policy/expectations;
 - 5. Ensure a plan to obtain copies of the any patient signed informed consent documents for scanning into the medical record (see the Handling Research Informed Consent Documents (Non-IRB Requirements) policy, COG.RSH.006);
 - 6. Determine any special storage requests that require lease of space per physician contracting policies;
 - 7. Certify IRB approval, if required by either reviewing it with an Internal IRB or by obtaining a correct (non-expired) approval letter from an External IRB acceptable to the facility;
 - 8. Determine need to obtain or update a Federal-Wide Assurance (see the Human Subject Protection Program Policy, COG.RSH.003).
- ii. Contracting
 - 1. Prior to final approval of the research to take place within the Institution, the Facility shall determine the contract(s) needed, if any, based on study requirements. This may include, but not be limited to, the following:
 - a. Clinical Research/Trial Agreements: For the research sponsor to delineate the non-protocol responsibilities and detail the compensation to the primary investigative coordinating site;
 - b. Facility Use Agreements For Research-Related Services: Corporate template or otherwise negotiated agreement for an external agency to compensate the Facility for research related services. In some cases, the PI must be able to designate and document on an item by item basis which services are study related and which service(s) are part of the normal path of care for the patient;
 - c. Investigator Agreements: Corporate template or otherwise negotiated agreement for the Facility to compensate an independent physician or physician group for providing investigator services;
 - d. Facility Letter (a.k.a. Letter of Indemnification): For the sponsor to indemnify the Facility if the Facility is not indemnified by the Clinical Research/Trial Agreement; and
 - e. Data Use Agreement, Business Associate Agreement: For specific privacy related issues.

DEPARTMENT: Clinical Operations Group – Research	POLICY DESCRIPTION: Research Integration into Healthcare Treatment/Payment/Operations
PAGE: 4 of 5	REPLACES POLICY DATED: 3/1/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	REFERENCE NUMBER: COG.RSH.002 (formerly CSG.RSH.002)
APPROVED BY: Ethics and Compliance Policy Committee	

- f. Conditions for Receipt and Use of Data for Specific Research Purposes: For institutional confidentiality, publications etc.
 2. Note that some agreements (specifically those with referral sources or physician owned entities) are required to be reviewed and approved by the Facility operations counsel according to such policy prior to execution.
 3. All other agreements (*i.e.*, with clinical trial sponsors or site management organizations) should be reviewed by the Corporate Responsible Executive for Clinical Research at the corporate office prior to execution. The Corporate Responsible Executive for Clinical Research may take the lead, with assistance from the Facility, in finalizing agreement language with the sponsor (or other contracting entity).
 4. The Facility shall determine what activities are billable and its charges for such activities.
 5. The recommended, but not required, target turnaround time in sending a signed copy (or a request for changes) is no more than five (5) working days from the date the Facility received the contract correspondence from the other party.
 6. Only authorized individuals can sign on behalf of the facility, per Facility policy.
 7. A copy of all executed contracts should be readily accessible (*i.e.*, kept according to the Access to Records for Research or Research Monitoring Purposes policy, COG.RSH.008 as well as Records Management Policy EC.014). Additional copies (including the original) may be kept elsewhere per Facility policy.
 8. Contract amendments shall follow the same procedures as stated above.
 9. Contracts that involve the setting up of industrial accounts will be forwarded to the appropriate personnel to set up such accounts.
- iii. Final Facility Approval Of Study
 1. A Facility can decline research participation/support (even research approved by an IRB or exempt from IRB review) for any reason. However, if the research is not exempt from IRB oversight and/or the IRB has not yet approved or has disapproved the research, then the Facility may not allow the research to take place.
 2. Investigators should be informed that while the clinical study may have obtained the required IRB approval (or Exempt determination), it is the Facility that makes the final determination if it is operationally and financially feasible for the activity to be conducted at the Facility. A Facility may decline an IRB approved (or Exempt) study for any reason such as inadequate financial support, lack of appropriate capacity to ensure protocol compliance, inconsistency with mission and values etc.
 3. For planned studies, it is strongly suggested that the Facility send a written communication uniquely identifying the study notifying the investigator that the study may begin and identifying any parameters on that final approval (noting that any parameters cannot be inconsistent with the IRB approval).

DEPARTMENT: Clinical Operations Group – Research	POLICY DESCRIPTION: Research Integration into Healthcare Treatment/Payment/Operations
PAGE: 5 of 5	REPLACES POLICY DATED: 3/1/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	REFERENCE NUMBER: COG.RSH.002 (formerly CSG.RSH.002)
APPROVED BY: Ethics and Compliance Policy Committee	

iv. Patient Encounters

1. Early Recognition of Patients as Research Subjects. For planned research, this is ideally done prior to referring for services of planned research (*i.e.*, the researchers calling to set up the appointment/admission noting that it is a research appointment/admission). Unplanned research-related encounters necessitate a plan for early identification through mechanisms such as identification at registration or through nursing assessment.
2. Protocol Reconciliation.
 - i. When patients identify themselves as research participants, the Facility determines what research protocol they are on and if it affects care at the Facility. The usual categories include:
 1. Planned Research Encounter: This is for a planned protocol per the above procedure.
 2. Unrelated Study: When the patient is participating in a study unrelated to his/her care at the Facility and such participation does not alter his/her care at the Facility. Under this circumstance, the Facility usually does nothing.
 3. Second Institution: When the study is unrelated to the patient encounter with the Facility BUT the Facility must alter its usual care to accommodate the protocol (*i.e.*, a hospital making accommodations for the subject to continue taking investigational drugs they were prescribed as an outpatient). In this circumstance, the Facility usually does not need to certify IRB review BUT may need to obtain a copy of the subject's signed consent form to justify any deviation from an evidence-based pathway.
 4. Unplanned Protocol: A protocol in which the facility is engaged but the startup procedure was not enacted as it should have been and now must be enacted (*i.e.*, a patient admitted to the hospital to get an investigational implant where the hospital was never informed by the investigator until the patient arrived).
3. Proper Coding and Billing for Research-Related Services. See the REGS.BILL policies.

REFERENCES:

1. IRB Related Definition and Common Acronyms Policy, [COG.IRB.001](#)
2. Clinical Operations Group Research Policies in the COG.RSH series (COG.RSH.001 through COG.RSH.010)
3. Outpatient Self-Administered Drugs Policy, [REGS.BILL.003](#)
4. Stat, Call Back, Stand-by and Handling Charges Policy, [REGS.BILL.006](#)
5. Billing for Investigational Devices Policy, [REGS.BILL.007](#)