

DEPARTMENT: Clinical Operations Group – Research	POLICY DESCRIPTION: Research Activity Records and Reports
PAGE: 1 of 3	REPLACES POLICY DATED: 3/1/12
EFFECTIVE DATE: September 1, 2013	REFERENCE NUMBER: COG.RSH.010 (formerly CSG.RSH.010)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy applies to all Company-affiliated facilities supporting research (i.e., hospitals, surgery centers, physician practices, administrative offices, etc.). Note that Institutional Review Boards (IRBs) and Investigators have separate requirements for reporting and record-keeping.

PURPOSE: This policy provides guidance regarding the information that should be maintained by the facility in its support of research. Proper maintenance of these items will be of great assistance in regulatory and accreditation surveys as well as internal and external audits.

POLICY:

1. Records

- a. Protocol List. The facility shall at all times have a current database (a sample spreadsheet is available through the Responsible Executive for Clinical Research) containing the following minimum fields that can easily report the following:
 - i. **Sponsor:** This is the agency sponsoring the costs of the protocol. This is usually a pharmaceutical/device company or a branch of NIH (i.e., NIDA, NIA, NCI). Other sponsors may include AHRQ, The Joint Commission (TJC), JDRF etc.. If the facility is being paid by a third party, the third party payer is not the sponsor. For example: Suppose Dr. Smith (not an HCA entity) is contracted to perform a Pfizer study in his office and using the HCA-affiliated facility only for certain procedures. Dr. Smith is paid by Pfizer and in turn pays the HCA-affiliated facility a portion of the grant. In this case, Pfizer remains the Sponsor of the protocol. Dr. Smith will be who our contract is with and identified later in the database as appropriate. NOTE: If there is no evident funding for the research (i.e., the protocol was generated by an in-house physician or nurse) the Sponsor is the one underwriting the funding (i.e., if the Facility is underwriting the cost, put HCA-[FACILITY NAME], if an independent physician is underwriting the cost, put his or her name);
 - ii. **Sponsor Protocol ID (if applicable):** If the protocol is sponsored by industry pharmaceutical/device companies, a federal agency or other commercial sponsor, they will have assigned it a unique ID number (a.k.a. Protocol Number). Often protocols have “nicknames” for quick identification but this is not the same thing (there is a separate field for Nicknames). NIH-funded grants will have a grant number. NOTE: If the activity pertains to a Humanitarian Device Exemption (HDE), use the HDE number for this field. For a product under the FDA’s Expanded Access Program, using the FDA number (i.e., the IND or IDE number) will suffice unless there is none, then something to the effect of “Expanded Access” will suffice. NOTE: This is not the IRB number of the study (see below). NOTE: This number is not the same as the NCT number issued by ClinicalTrials.gov. Although the NCT number is a unique number, not all studies will be listed on that database;

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- iii. Protocol Nickname (if applicable): As mentioned earlier, many protocols have Nicknames (“SAPPHIRE study”). This field would be used for that purpose. If none, put NONE or N/A;
 - iv. Protocol Title: This is the FULL and unabbreviated formal title of the protocol;
 - v. Principal Investigator: Provide full name and credentials for the principal investigator as listed on his or her clinical license at the local site. For example- “Jane Doe, M.D.” or “John Smith, PhD.” NOTE: If a protocol is being run independently by more than one Principal Investigator, a second record with its own unique identifier is required- this should not be confused with a Sub-Investigator working under the supervision of the Principal Investigator but reflects the instances where two investigators are not working together yet are conducting the same research protocol independent of each other;
 - vi. IRB: This is the IRB overseeing the study. If exempt, then documentation such as “Exempt” will suffice.
 - vii. Initial IRB Approval Date: Date of Initial IRB approval (or date Exempt determination was made). If not approved, put “Not Approved;”
 - viii. Next IRB Continuing Review Due Date: This is the most recent date of termination of the IRB approval. This date will be updated at each continuing review extension. If the activity was exempt, “N/A” will suffice;
 - ix. IRB Closure Date: The date the study is closed out by the IRB. This will be blank until the protocol is closed by the IRB; and
 - x. Other fields if/as determined by the facility (e.g., NCT registration number, who the contract is with, any Contract Research Organization, specialty, age restrictions, vulnerable populations).
- b. Protocol Folder: Protocol related documents should be filed in a protocol-centric manner.
- i. Each protocol folder (paper or electronic) should be labeled, generally at a minimum, with the following:
 1. Protocol Sponsor;
 2. Sponsor’s Protocol Number (and nickname if applicable); and
 3. Principal Investigator’s Name (space permitting).
 - ii. Each folder should contain the following, as applicable:
 1. Copies of Protocols (approved or otherwise) and their subsequent proposals and approved revisions;
 2. Copies of Consent Forms/protected health information (PHI) Authorizations (approved or otherwise);
 3. Copies of all IRB approvals showing approval dates and expirations of the research
 4. Copies of all contracts involving the facility;
 5. Significant facility correspondence pertaining to the protocol;

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<p>6. Any justifications for Exempt Determination (or determinations that an activity is not research with human subjects) made by Institutional Officials in lieu of an IRB review according to Institutional Policy; and</p> <p>iii. When a Facility runs an internal IRB or contracts with an external IRB, duplicate filings are not necessary for those documents kept and readily producible by the IRB.</p> <p>c. The records required by this policy must be retained in accordance with the longer of: the Records Management Policy, EC.014; three years after the research has been completed; or through contractual obligation by the research sponsor.</p> <p>d. Records are accessible for inspection and copying at reasonable times and in a reasonable manner by authorized representatives of DHHS or FDA, other authorized governmental auditors (i.e., CMS), internal audit or the corporate Responsible Executive for Clinical Research.</p> <p>2. Reporting and Reports</p> <p>a. Notification of the presence of external auditors and investigations are subject to the reporting requirements of the Regulatory Compliance Notification Policy COG.RAS.001.</p> <p>Adverse events experienced by patients in clinical research protocols must be documented in the medical record by the appropriate clinical staff according to facility policy as any other non-research related adverse events are. Note that is the Principal Investigator’s responsibility to provide the reporting of adverse events to IRBs, data safety monitoring boards and/or the study sponsor.</p> <p>REFERENCES:</p> <ol style="list-style-type: none"> 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. Records Management Policy, EC.014 4. Regulatory Compliance Notification Policy COG.RAS.001
