DEPARTMENT: Clinical Operations Group – Research	**POLICY DESCRIPTION:** Handling Research Informed Consent Documents (Non-IRB Requirements)
PAGE: 1 of 3	**REPLACES POLICY DATED:** 3/2/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	**REFERENCE NUMBER:** COG.RSH.006 (formerly CSG.RSH.006)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy applies to Company-affiliated facilities (i.e., hospitals, surgery centers, physician practices, administrative offices, etc.) regarding the general (non-IRB related) operational review and handling of research consent documents. The Institutional Review Board (IRB) review of consent forms is governed by the COG.IRB policies. The actual consenting of subjects is also outside of the scope of this policy.

PURPOSE: To provide guidance regarding documenting consent to participate in research (and the content of such consent process), which is usually communication isolated between the researchers, the IRB and the subjects. However, the documentation of such consent is often relevant to healthcare operations. This occurs, among other circumstances, when standard of care must be deviated from for research purposes (thus increasing risk to the subject) and/or for justifying recusal from their case being counted in reported statistics as should have been receiving evidence-based care. Also note that human subjects may not be limited to patients. Often, research is done with staff, providers, visitors and/or others as the subject of the research.

POLICY:

1. Obtaining consent for research is the responsibility of the Principal Investigator and his/her delegates. Unless the facility employs or otherwise engages the Principal Investigator or research staff on its behalf for this purpose, the facility need only verify consent was obtained prior to its performing research interventions with that subject (i.e., alters the care given to a patient, changes staff behavior, etc.). For research involving patients, this is done by placing a copy of the signed consent document onto a patient medical record, noting that the original consent form usually stays with the research records.

2. Prior to implementing any research interventions and unless waived by the IRB in writing, the facility itself must verify that a subject(s) of the research (patients, staff, providers, clinicians, etc.) has consented to participate in the research when the facility is engaged in the research in accordance with the OHRP guidance; which includes the following:
   a. When facility employees or agents intervene for research purposes with any human subjects of the research (patients, staff, providers, clinicians etc.) by performing invasive or noninvasive procedures.
   b. When facility employees or agents intervene for research purposes with any human subject of the research (patients, staff, providers, clinicians, etc.) by manipulating the environment.
   c. When facility employees or agents interact for research purposes with any human subject of the research (patients, staff, providers, clinicians etc.).

3. The facility shall evaluate all patients who are subjects in a clinical trial or other research study that affects their care at the facility as to if they must have a copy of their signed research informed consent placed in their medical record (the original generally remains with the research files maintained by the Investigator). If the patient/subject cannot provide a copy, the facility should contact the investigator (a written authorization is not necessary as this falls under the "Treatment, Payment or Operations" component of HIPAA) to obtain a copy in a prompt manner.
   a. **Copies of signed research consents on the medical record are REQUIRED by this policy:**
      i. when the patient is enrolled in a clinical trial (either prior to arrival or during the course of treatment) for the same condition in which a Core Measure requires a clinical pathway. Note that this is for clinical trials (especially when they affect one or more of the measures) and not observational studies; and/or
      ii. when the facility is performing planned investigational procedures (for example, the protocol requires a) implantation of an investigational device; b) administration of an investigational drug; c) procedure(s) outside of usual care (i.e., for data gathering purposes instead of medical necessity, procedures performed differently because of the protocol, etc.).
   b. **Copies of signed research consents on the medical record are STRONGLY RECOMMENDED** for all other instances where the care a patient receives due to participation in the protocol would have been different than the care they likely would have received absent a research protocol. For example, the facility's care of the patient/subject is incidental to the study (i.e., research data are not collected for planned purposes of research) but they desire to safely continue an investigational therapy to not detriment the patient/subject's participation in a research protocol (i.e., what the FDA considers a "Second Institution").
   c. Nothing in these policies is intended to limit the authority of a physician to provide emergency medical care (even investigational care) to the extent the physician is permitted to do so under applicable Federal, State, or local law.

4. Review of Consent Documents Prior to Planned Engagement In Research
   The facility shall rely on the IRB overseeing the research to assure any documents are in compliance with federal and state laws (which include all accreditation standards) that pertain to human subject protection. The IRB has ultimate authority over the content and specific word-smithing of the research consent documents. With that said, the facility must still provide a cursory review of the consent document, not to validate content or language used, but only to assure that the information provided is consistent with its business operations. Examples of inconsistencies may include statements that obligate the facility to do something that they are not prepared to do (i.e., provide "free care", make special accommodations outside of normal operations, provide extended hours of operation, etc.) or make representations that are inaccurate (i.e., that the facility has

employed the investigator when they have not). Any factual inconsistencies shall be brought to the attention of the investigator and/or the IRB. If the final version is non-negotiable and remains inconsistent with facility operations, then the facility may not accommodate the research.

5. Waiver of Consents in Emergency Settings
   Reference the Special Cases Concerning Investigational Products and Humanitarian Use Devices Policy, COG.RSH.007, for use of investigational products in an emergency situation without consent.

6. IRB Waiver of Consent and/or Waiver of Documentation of Consent
   The IRB has the authority to waive all or some elements of consent as well as waiver of documentation of consent. When the facility is obligated to show consent and the IRB has waived such consent (or documentation of such consent), the facility should have access to a copy of such IRB waiver in writing.

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)