DEPARTMENT: Clinical Operations Group – Research	**POLICY DESCRIPTION:** Access to Records for Research or Research Monitoring Purposes (Non-IRB Requirements)
PAGE: 1 of 2	**REPLACES POLICY DATED:** 3/1/12
EFFECTIVE DATE: September 1, 2013	**REFERENCE NUMBER:** COG.RSH.008 (formerly CSG.RSH.008)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy applies to all Company-affiliated facilities (i.e., hospitals, surgery centers, physician practices, administrative offices, etc.) as clinical data gathered may be needed for a planned or unplanned research study. This may be information directly gathered for a research endpoint (or adverse events that should be noted as part of the research) or standard research data that would be used for other kinds of research such as observational, outcome, quality improvement or other kinds of research.

PURPOSE: To provide guidance regarding balancing the rights to individual privacy with the rights of researchers to access private information. Researchers must adhere to the federal and local privacy laws and be consistent with any individual authorizations.

POLICY:

1. Use and Disclosure through Authorization
    a. Language pursuant to an Authorization To Use/Disclose PHI for research purposes is usually combined with research consent forms as allowed by federal law but may occasionally be in a stand-alone form. Such language may not mirror the facility template release forms for non-research purposes but should still be consistent with laws and facility policy. If the language is not consistent with facility policy, the facility may request an authorization consistent with facility policy prior to releasing Protected Health Information (PHI).
    b. Access to records shall be granted according to such authorizations. This includes providing access for investigators and their research coordinators. This also includes promptly providing read-only access for research monitors (i.e., a monitor agent of the research Sponsor) and regulators (i.e., the FDA) to monitor/audit the records pertaining to the specific study they are monitoring/auditing.
    c. Note, that in the event an individual withdraws an authorization, HIPAA allows for continued access to research data gathered under that authorization.
    d. Note, in the event several authorizations for research are combined (as in for a clinical trial with one or more unconditioned activities requiring Opting-In such as a pharmacogenomics banking sub-study), absent clarity on which component is withdrawn, the entire authorization should be considered withdrawn.
2. Use and disclosure without Authorization. There are separate compliance policies (HIM.PRI.001 through HIM.PRI.013) that address the use and disclosure of individually identifiable data for research purposes.

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REFERENCES:

1. Patient Privacy Program Policies, HIM.PRI.001 – HIM.PRI.013
2. IRB Related Definition and Common Acronyms Policy, COG.IRB.001
3. Clinical Operations Group Research Policies in the COG.RSH series (COG.RSH.001 through COG.RSH.010)
4. FAQs concerning credentialing of Clinical Research Associates (a.k.a. “CRA” or “Monitor”) [January 16, 2013]