DEPARTMENT: Clinical Operations Group – Research	**POLICY DESCRIPTION:** Research Activities Not Needing IRB Oversight or Certification of IRB Review
PAGE: 1 of 2	**REPLACES POLICY DATED:** 3/1/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	**REFERENCE NUMBER:** COG.RSH.005 (formerly CSG.RSH.005)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: All Company-affiliated facilities (i.e., hospitals, surgery centers, physician practices, administrative offices, etc.).

PURPOSE: For certain kinds of research, federal regulations allow the Institutional Official to certify that research activity undertaken by the Institution does not need (internal or external) Institutional Review Board (IRB) oversight, or if it does need IRB oversight, when the institution does not need to certify that IRB oversight occurred. Note: This policy does not alleviate any Internal IRB from their documentation requirements should they review research. Such requirements are under the COG.IRB policies.

POLICY:

1. The Institutional Official or his/her designee may determine that certain research does not need oversight by an IRB; however, the Institutional Official may not overrule a previous decision by an IRB which the facility submitted the research to for review on its behalf.

2. The Institutional Official or his/her designee may rely on materials submitted by the investigator and/or other valid opinions that research does not need IRB oversight or certification of IRB oversight.

3. To determine if research activity needs IRB oversight, the following decision tree shall be used:
   Q: Is the activity considered a “clinical investigation” as defined by federal law and referenced in the Guiding Documents and Definitions Policy, COG.RSH.001?
   a. If YES, IRB oversight is required.
   b. If NO, is the activity otherwise considered “research” as defined by federal law and referenced in Policy COG.RSH.001?
      i. If NO, then IRB oversight is not necessary but other laws still apply (i.e., HIPAA, Stark Laws, etc.).
      ii. If YES, does the research involve “human subjects” as defined by federal law and references in Policy, COG.RSH.001?
         a) If NO, IRB oversight is not necessary but other laws still apply (i.e., HIPAA, Stark Laws, etc.).
         b) If YES, does the research meet any of the statutorily exempt categories put forth by OHRP law (45 CFR 46.104)?
            1) If NO, IRB oversight is required.
            2) If YES, then the research is exempt from IRB review but other laws still apply (i.e., HIPAA, Stark Laws, etc.).

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4. For research involving multiple institutions, if IRB oversight is required for the overall research, the facility must determine if it individually needs to certify IRB review. Is the facility "engaged in the research" according to the guidance put forth by OHRP?
    a. If NO, then the facility may (at its option) certify review but it is not required.
    b. If YES, then the facility must certify IRB review.

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)