

DEPARTMENT: Clinical Operations Group - Research	POLICY DESCRIPTION: IRB Criteria to Approve or Exempt Human Subject Research
PAGE: 1 of 3	REPLACES POLICY DATED: 3/1/12, 9/1/13
EFFECTIVE DATE: February 22, 2019	REFERENCE NUMBER: COG.IRB.006 (formerly CSG.IRB.006)
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: This policy applies to all Company-affiliated facility-run Institutional Review Boards (IRBs).
PURPOSE: To provide the guidance for IRBs to either exempt or approve human subject research.
<p>POLICY:</p> <p>IRB Exempt Determinations</p> <ol style="list-style-type: none"> 1. The facility must have a procedure compliant with the Research Activities Not Needing IRB Oversight or Certification of IRB Review Policy, COG.RSH.005, to make IRB exempt determinations. Should the IRB be faced with making this determination in lieu of the Institutional Official, the IRB will follow similar steps as indicated in that policy. 2. The IRB 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 should be used: <ul style="list-style-type: none"> 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? <ol style="list-style-type: none"> 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? <ol style="list-style-type: none"> i. If NO, then IRB oversight is not necessary but other laws still apply (e.g., HIPAA, Stark Laws). ii. If YES, does the research involve “human subjects” as defined by federal law and references in Policy COG.RSH.001? <ol style="list-style-type: none"> a) If NO, IRB oversight is not necessary but other laws still apply (e.g., HIPAA, Stark Laws). b) If YES, does the research meet any of the statutorily exempt categories put forth by OHRP law (45 CFR 46.104)? <ol style="list-style-type: none"> i. If NO, IRB oversight is required. ii. If YES, then the research is exempt from IRB review but other laws still apply (e.g., HIPAA, Stark Laws). <p>Criteria To Approve Research</p> <ol style="list-style-type: none"> 1. In order to approve clinical investigations or other research with human subjects, the IRB must make the following eight (8) determinations required by regulations: <ol style="list-style-type: none"> a. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

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- b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
 - c. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
 - d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by, regulations and policy.
 - e. Informed consent will be appropriately documented in accordance with, and to the extent required by, regulations and policy.
 - f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 - h. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
2. Discussions on controverted issues pertaining to these criteria and their resolution must be documented in the minutes.
3. Any reason not to approve research pertaining to the above criteria will be given to the researcher in writing. Denial of research for reasons not pertaining to human subject protection (e.g., inadequate funding, operational difficulties) are administrative in nature and generally should be deferred to the facility's administrative review process, leaving the IRB focusing on human subject protections. The facility can always deny supporting IRB-approved research for any reason but cannot support non-exempt human subject research that is not approved by an IRB.

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REFERENCES:

1. IRB Related Definition and Common Acronyms Policy, [COG.IRB.001](#)
2. Clinical Operations Group Research Policies in the COG.IRB series (COG.IRB.001 through COG.IRB.011)
3. Guiding Documents and Definitions Policy, [COG.RSH.001](#)
4. Research Activities Not Needing IRB Oversight or Certification of IRB Review, [COG.RSH.005](#)