

<b>DEPARTMENT:</b> Clinical Operations Group - Research	<b>POLICY DESCRIPTION:</b> IRB Initial and Continuing Review of Non-Exempt Research with Human Subjects
<b>PAGE:</b> 1 of 10	<b>REPLACES POLICY DATED:</b> 3/1/12, 9/1/13
<b>EFFECTIVE DATE:</b> February 22, 2019	<b>REFERENCE NUMBER:</b> COG.IRB.007 (formerly CSG.IRB.007)
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

<p><b>SCOPE:</b> This policy applies to all Company-affiliated facility-run Institutional Review Boards (IRBs).</p>
<p><b>PURPOSE:</b> To provide guidance on a systematic review of non-exempt human subject research activities that supports the protection of human subjects and is compliant with state and federal regulations.</p>
<p><b>POLICY:</b></p> <p>The IRB must review all its assigned non-exempt research involving human subjects as defined in the IRB Related Definitions and Common Acronyms Policy, COG.IRB.001. The IRB must assess whether its members have the knowledge, skill and experience to adequately review and approve the submitted research (and secure adequate consultation if they do not) or refer the protocol to a properly experienced IRB.</p> <p><b><u>IRB Review of Research</u></b></p> <p>The IRB (through either a convened board or Expedited Review process) shall review non-exempt research with human subjects under the criteria set forth by federal, State and local regulations as well as the IRB Criteria to Approve or Exempt Human Subject Research Policy, COG.IRB.006.</p> <ol style="list-style-type: none"> <li> <p><b><u>Initial Review</u></b></p> <p>The IRB must conduct initial review of all non-exempt research with human subjects at convened meetings at which a majority of the members are present, unless the research falls into one or more of the categories appropriate for expedited review. Note, the initial review of the treatment (i.e., non-research) use of Humanitarian Use Devices (HUDs) as well as the treatment use of drugs/devices/biologics under an FDA Expanded Access Program (a.k.a. “Compassionate Use”) <u>must</u>, unless waived by FDA, be reviewed initially by a convened board, even if the IRB Chair believes it meets the criteria for Expedited Review. All subsequent reviews of the treatment use of HUDs consistent with IRB approval can be reviewed via expedited review.</p> </li> <li> <p><b><u>Continuing Review</u></b></p> <p>IRBs must conduct substantive and meaningful continuing review of non-exempt research with human subjects at intervals appropriate to the degree of risk, but not less than once per year. Thus, each approval period for research may extend no more than one calendar year after the conditions of IRB review have been met.</p> </li> <li> <p><b><u>Methods of Review</u></b></p> <p>Convened Meeting: Initial and continuing reviews of non-exempt research with human subjects not eligible for expedited review must be conducted by the IRB at convened meetings at which a majority (defined as &gt;50%) of the voting members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas (i.e., a quorum). Approval of research is by a majority vote (&gt;50%) of this quorum. Should the quorum fail during a meeting</p> </li> </ol>

<b>DEPARTMENT:</b> Clinical Operations Group - Research	<b>POLICY DESCRIPTION:</b> IRB Initial and Continuing Review of Non-Exempt Research with Human Subjects
<b>PAGE:</b> 2 of 10	<b>REPLACES POLICY DATED:</b> 3/1/12, 9/1/13
<b>EFFECTIVE DATE:</b> February 22, 2019	<b>REFERENCE NUMBER:</b> COG.IRB.007 (formerly CSG.IRB.007)
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

(e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored.

**4. Expedited Review**

The IRB Chair or his/her designee(s) (who must be an IRB voting member) who is without a conflict of interest, may review research through an expedited procedure if:

- a. The research constitutes a minor change in previously approved research during the period for which approval is authorized (“Minor changes” are defined as not affecting the relationship of likely subject risk to benefit relied upon to approve the protocol; or the rights, safety, or welfare of the human subjects involved in the investigation); or
- b. The research falls within the current categories of the published Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA)’s list of research eligible for expedited review in the *Federal Register*.

No other initial/continuing approvals or other actions can be taken by the Chair without meeting such criteria. The full IRB shall be informed at or by the next convened meeting (usually as an FYI item in the agenda) of all requests that received Expedited Review approval since the last meeting, the basis for doing so and their dispositions. An Expedited Reviewer cannot disapprove research requests on behalf of the IRB, thus any request that is not approvable under Expedited Review or not otherwise approved by an Expedited Reviewer must be referred to the convened board for final determination. While an Expedited Reviewer may refer to the convened board any activity under their review, if such activity a) falls into one of the regulated categories of Expedited Review deemed by the HHS Secretary as minimal risk and b) the Expedited Reviewer (in whole or in part) is referring to the convened board due to reasons of overturning the presumption of minimal risk in these categories, the Expedited Reviewer must justify and document the reasons to the convened board as to why the research activity deemed as minimal risk is, in fact, greater than minimal risk.

**PROCEDURE:**

**A. Initial Review**

- 1. In conducting the initial review of proposed research, IRBs must obtain information in sufficient detail and with sufficient time to make the determinations.
  - a. Documents should include at a minimum:
    - i. the full protocol;
    - ii. a proposed informed consent or request for waiver of consent (or waiver of documentation of consent);
    - iii. the investigator’s brochure or product labeling as applicable;
    - iv. subject surveys/questionnaires, as applicable;
    - v. any recruitment materials including advertising intended to be seen or heard by subjects as applicable (Note: According to the FDA, IRB review and approval of

<b>DEPARTMENT:</b> Clinical Operations Group - Research	<b>POLICY DESCRIPTION:</b> IRB Initial and Continuing Review of Non-Exempt Research with Human Subjects
<b>PAGE:</b> 3 of 10	<b>REPLACES POLICY DATED:</b> 3/1/12, 9/1/13
<b>EFFECTIVE DATE:</b> February 22, 2019	<b>REFERENCE NUMBER:</b> COG.IRB.007 (formerly CSG.IRB.007)
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

listings of clinical trials on the internet is not required when the system format limits the information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information); and

- vi. any other material submitted to the IRB and/or determined to be necessary for the protection of human subjects.
  - b. Unless a Primary Reviewer system (not to be confused with Expedited Review) is used, all members should receive a copy of the complete documentation. These materials are to be received by members sufficiently in advance of the meeting date to allow review of this material. If the IRB uses a Primary Reviewer system, the Primary Reviewer(s) should do an in-depth review of all pertinent documentation listed above. All other IRB members should at least receive and review a protocol summary (of sufficient detail to make the determinations required under federal regulations and IRB policy, the proposed informed consent document, and any recruitment materials, including advertisements intended to be seen or heard by potential subjects). In addition, the complete documentation should be available to all members for review at their request.
2. Except for determinations pursuant to a Limited IRB Review required by 45 CFR 46.104(d)(7), determinations for approval of regulated non-exempt research by the IRB must meet the following criteria:
- 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;
  - 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 in the absence of 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. Similarly, the IRB should not consider payment to research subjects as a benefit for purposes of this evaluation;
  - 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. See the IRB Required Additional Protections For Vulnerable Subjects/Children Policy, COG.IRB.009;
  - d. Unless meeting such criteria for waiver or partial waiver, informed consent will be sought from each prospective subject or the subject's legally authorized representative, in

<b>DEPARTMENT:</b> Clinical Operations Group - Research	<b>POLICY DESCRIPTION:</b> IRB Initial and Continuing Review of Non-Exempt Research with Human Subjects
<b>PAGE:</b> 4 of 10	<b>REPLACES POLICY DATED:</b> 3/1/12, 9/1/13
<b>EFFECTIVE DATE:</b> February 22, 2019	<b>REFERENCE NUMBER:</b> COG.IRB.007 (formerly CSG.IRB.007)
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

accordance with, and to the extent required by statute. See the IRB Review of Research Informed Consent and Its Documentation Policy (COG.IRB.008);

- e. Unless meeting such criteria for waiver, informed consent will be appropriately documented in accordance with, and to the extent required by, statute. See Policy COG.IRB.008;
- f. When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects;
- g. When appropriate, the research plan makes adequate provision to protect the privacy of subjects and to maintain the confidentiality of data; and
- h. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards shall be included in the study to protect the rights and welfare of these subjects.

**B. Conditional Approvals**

For minor clarifications or modifications, the IRB may provide Conditional Approval to the investigator accompanied by specific instructions provided:

1. The investigator is informed of the specific and unambiguous changes required for the research to be approved. For example: “Make Consent form meet all Federal Requirements” is not specific enough to be a minor clarification whereas instructing the investigator to “Add ‘a minor skin rash that lasts 3-7 days has been noted in approximately 10% of subjects’ in the risk section and change ‘if you withdraw from the study, it will not affect your care at this institution’ to ‘if you withdraw from the study before it is over, you do not lose any rights or benefits to which you are otherwise entitled,’” is more specific and unambiguous.
2. The investigator is informed that he/she cannot begin this research (or requested change in research) until the conditioned changes have been made; and
3. That the IRB (as a committee or through their designee) must validate the conditioned changes were made prior to the investigator conducting the research (or implementing the requested change in research).

Only when the IRB stipulates specific revisions requiring simple concurrence by the investigator may IRB support staff or a non-voting member validate the change. Otherwise, the IRB Chair or another IRB member designated by the Chair should be the ones to subsequently approve the revised research activity on behalf of the IRB under an expedited review procedure. If and when the IRB requests substantive clarifications or modifications regarding the research, the approval of the proposed research should not be given conditionally but should be **deferred to a future meeting** upon receipt of responsive material. Generally, if the changes have been submitted timely (e.g. 30 days for minor changes, 90 days for major changes involving external collaborators but extended time may be appropriate as determined by the IRB), it is suggested that the IRB re-review the submission to accompany any new information that might alter their previous approval.

<b>DEPARTMENT:</b> Clinical Operations Group - Research	<b>POLICY DESCRIPTION:</b> IRB Initial and Continuing Review of Non-Exempt Research with Human Subjects
<b>PAGE:</b> 5 of 10	<b>REPLACES POLICY DATED:</b> 3/1/12, 9/1/13
<b>EFFECTIVE DATE:</b> February 22, 2019	<b>REFERENCE NUMBER:</b> COG.IRB.007 (formerly CSG.IRB.007)
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

**C. Determination of Continuing Review Date**

Until the research activity reaches a point where continuing review is no longer needed (see criteria for Closure of IRB Oversight below) the IRB shall conduct continuing review on each study at an interval appropriate to the degree of risk, but not to exceed one year. The re-approval deadlines run from the date when all conditions for approval have been met (i.e., when the protocol was approved by the convened board or Expedited Reviewer and not when the investigator receives notification). If the IRB granted Conditional Approval, the time runs from the date the IRB verified that the conditions of approval were met. For protocols that were deferred and later approved at a subsequent meeting, time runs from the date that approval was actually given and not the first meeting the protocol was presented and deferred. The IRB may utilize an option of “Fixed Anniversary Dates” as described in federal guidance.

**D. Continuing Review**

In conducting continuing review of research not eligible for expedited review, all IRB members should receive at least the following:

1. A copy of the full protocol or protocol summary;
2. A status report on the progress of the research that includes:
  - a. The number of subjects accrued;
  - b. A summary of any adverse events or unanticipated problems involving risks to subjects or others;
  - c. Any withdrawal of subjects from the research and reasons for withdrawal;
  - d. Any complaints about the research;
  - e. A summary of any relevant literature, findings obtained thus far;
  - f. Amendments or modifications to the research since the last review;
  - g. Any relevant multi-center trial reports;
  - h. Any other relevant information, especially information about risks associated with the research; and
3. A current copy of the informed consent document being used.

At least one member of the IRB (i.e., a Primary Reviewer) should also receive a copy of the complete protocol including any modifications previously approved by the IRB. Furthermore, upon request, any IRB member should have access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting.

Each study must be reviewed at a frequency proportionate to its risks but not to exceed annually. Although the IRB can re-review research at any time, particularly in the presence of new information pertaining to the risk/benefit ratio, at the time continuing review is due, the IRB has the scheduled opportunity to continue approval for a set time period not to exceed one calendar year, to request consent or study modifications, or to suspend or terminate the approval of the research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects. The IRB’s action must be reported in writing promptly to the investigator, sponsor and appropriate governmental agency as required.

<b>DEPARTMENT:</b> Clinical Operations Group - Research	<b>POLICY DESCRIPTION:</b> IRB Initial and Continuing Review of Non-Exempt Research with Human Subjects
<b>PAGE:</b> 6 of 10	<b>REPLACES POLICY DATED:</b> 3/1/12, 9/1/13
<b>EFFECTIVE DATE:</b> February 22, 2019	<b>REFERENCE NUMBER:</b> COG.IRB.007 (formerly CSG.IRB.007)
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

Local IRB procedures must concisely define the above requirements for the evaluation for continued approval of each study by the IRB. Additionally, IRB policies must include the following:

- The criteria for research that needs verification from sources other than the investigators that no material changes had occurred since previous IRB review;
- That the current consent document, if applicable, is still accurate and complete;
- That any significant new findings that arise from the review process and that may relate to participants' willingness to continue participation will be provided to participants.

**E. Expiration of IRB Approval**

When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB (regardless of the reason which could include the investigator not submitting the request timely or the inability of the IRB to review the research timely), IRB approval expires automatically and the non-exempt research activity requiring IRB oversight must stop except for where the IRB finds that it is in the best interest of the individual subjects to continue to participate in the research interventions or interactions until their orderly termination. No new enrollment can occur. Such expiration of IRB approval does not need to be reported to the OHRP or FDA as it is not a suspension or termination of IRB approval, however serious or continuing noncompliance with regulations still must be reported (e.g., an investigator continuing to perform the research after repeatedly being notified of IRB approval expiration).

The IRB may develop a local SOP outlining the required timeframes for submittal and effectively communicate it to the Principal Investigator, however the Principal Investigator is ultimately responsible for assuring that the IRB receives the information timely and the IRB is responsible for assuring that information is distributed to its members for the meeting timely and that a quorum is present.

**F. Process for Reviewing Changes to Ongoing Research During the Approval Period**

The IRB may use expedited review procedures to review minor changes in ongoing previously-approved research during the period for which approval is authorized. An expedited review may be carried out by the IRB Chair or one or more experienced reviewers designated by the Chair from among the voting IRB members.

When a proposed change in research study is not minor (e.g., procedures involving increased risk or discomfort are to be added), then the IRB must review and approve the proposed change at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects to which the IRB must be informed of the change following its implementation and should review the change to determine that it is consistent with ensuring the subjects' continued welfare.

Each protocol revision should be incorporated into the written protocol and that revision date/version should be prominently placed to appropriately allow for version control. A similar

<b>DEPARTMENT:</b> Clinical Operations Group - Research	<b>POLICY DESCRIPTION:</b> IRB Initial and Continuing Review of Non-Exempt Research with Human Subjects
<b>PAGE:</b> 7 of 10	<b>REPLACES POLICY DATED:</b> 3/1/12, 9/1/13
<b>EFFECTIVE DATE:</b> February 22, 2019	<b>REFERENCE NUMBER:</b> COG.IRB.007 (formerly CSG.IRB.007)
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

dating/version methodology should occur for the informed consent revisions. This is to assure that the most current set of documents always is being utilized.

Review of a change in a protocol does not ordinarily alter the date by which continuing review must occur. This is because continuing review is a review of the full protocol activity, not simply to change a portion of it.

**G. Closure of IRB Oversight**

An IRB may close a study at the request of the Principal Investigator, at the demand of the Institution’s administration, or upon its own accord. The IRB will review all study closure notifications/requests received (by the PI, the sponsor or otherwise), and if needed, request additional information from the investigator if questions arise or additional verification that IRB closure is met. “Closure” for purposes of this section is related to the closure of IRB oversight of the non-exempt human subject research activities engaged in by the overseen Principal Investigator. After IRB closure, it is likely that additional study activities will take place at the local Institution (albeit unless transferred to another IRB, non-exempt research with human subjects may not continue to be engaged in by the overseen Investigator) or elsewhere (as in a study involving multiple centers where the Institution has completed their engagement in non-exempt research activities but other centers or a third party sponsor may continue non-exempt activities under their own independent IRB oversight). The notification/request for natural closure should, at a minimum, contain enough information to attest that the below criteria are met. A more detailed “final report” from the investigator is not required unless otherwise demanded by the IRB.

**Natural Closures:** Given the higher risk nature of FDA governed research, the FDA has more strict criteria for closure of IRB oversight than all other research.

- a) For FDA governed research: Generally, an FDA governed study no longer needs IRB oversight when the following criteria is reached :
  - i) the research is permanently closed to the enrollment of new subjects by the Principal Investigator;
  - ii) all subjects enrolled by the Principal Investigator have completed all research-related interventions;
  - iii) there are no planned long-term follow-up data gathering activities on subjects enrolled by the Principal Investigator; AND
  - iv) the Principal Investigator has completed all his/her data analysis (or, as may be the case in a sponsored multicenter study, the Principal Investigator is not conducting the data analysis).
- b) For all other research: Unless an IRB determines otherwise (i.e. why Continuing Review is necessary for the protection of human subjects), Continuing Review of research is not required by the IRB (i.e. neither by convened board nor Expedited Review) in the following circumstances:
  - i) Research eligible for Expedited Review (as initial review or continuing review) in accordance with the criteria from Expedited Review;

<b>DEPARTMENT:</b> Clinical Operations Group - Research	<b>POLICY DESCRIPTION:</b> IRB Initial and Continuing Review of Non-Exempt Research with Human Subjects
<b>PAGE:</b> 8 of 10	<b>REPLACES POLICY DATED:</b> 3/1/12, 9/1/13
<b>EFFECTIVE DATE:</b> February 22, 2019	<b>REFERENCE NUMBER:</b> COG.IRB.007 (formerly CSG.IRB.007)
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

- ii) Research reviewed by the IRB in accordance with the Limited IRB Review option as required for IRB Exempt Status;
- iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
  - (1) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - (2) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

**Administrative Closures:** The IRB or Institution administration may also administratively close IRB oversight of the research at any time and for any purpose. This type of closure is not considered a “termination” that triggers regulatory reporting requirements but simply an administrative closing (noting that the Institution itself may also initiate this administrative closure). In these instances, should it be the desire of the Institution to allow the Investigator to continue with non-exempt research activity, the IRB should cooperate with the transition to another qualified IRB in a manner that assures uninterrupted IRB oversight. Examples of situations when administrative closure of a study generally occur are as follows:

- a) The investigator/staff are no longer affiliated with institution.
- b) the Institution itself is no longer engaged in the research (although research activity may continue elsewhere).
- c) The Institution Official or IRB chooses to transition oversight to an external IRB.
- d) It is determined by the Institution or IRB that the IRB is currently (or expected to be) no longer able to give adequate oversight (i.e. due to change of membership, change of IRB resources etc.).

**Non-IRB Administrative Monitoring:** After closure of local IRB oversight, should additional research activity continue (e.g. activities that do not need continuing review such as long term follow-up or data analysis in a non-FDA governed study, activities deferred to the oversight of external IRBs etc.), the Institution may desire to maintain an accounting of such continuations to which this responsibility may be assigned to the IRB Coordinator at the Institution’s convenience. When this occurs, such periodic queries from the IRB Coordinator regarding study continuance are not to be construed as or considered requests for Continuing Reviews by the IRB but merely an operational request on behalf of the Institution. The IRB Coordinator may also request an affirmation that the remaining activities have not changed in a manner that would require IRB oversight.

**H. Documentation of Research Review**

Review activities must be documented in detail. Such documents (e.g., meeting minutes) must be sufficient to demonstrate thorough protocol review, analysis, discussions, actions with rationales and the ultimate determinations by the IRB.

An IRB must notify the investigators and the institution in writing of its decision to approve or disapprove research activity or of modifications required to secure IRB approval of the research



<b>DEPARTMENT:</b> Clinical Operations Group - Research	<b>POLICY DESCRIPTION:</b> IRB Initial and Continuing Review of Non-Exempt Research with Human Subjects
<b>PAGE:</b> 9 of 10	<b>REPLACES POLICY DATED:</b> 3/1/12, 9/1/13
<b>EFFECTIVE DATE:</b> February 22, 2019	<b>REFERENCE NUMBER:</b> COG.IRB.007 (formerly CSG.IRB.007)
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

activity. If the IRB decides to disapprove a research activity, it shall include in the written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

If a research protocol that involves an exception to the informed consent process is submitted for initial IRB review and the IRB determines that the protocol does not meet the criteria contained within the regulations or because of other relevant ethical concerns, then the IRB shall promptly notify the investigator in writing. The written notification shall include a statement of the reasons for the IRB's determination.

**I. Charging for IRB Review**

It is acceptable to charge market rates for IRB review. The amount and collection of charges is independent of any decisions the IRB makes. Any charges to physicians/physician-owned-entities/referral sources shall fall under legal compliance policies requiring approval by Operations Counsel.

**J. Interaction with Other Research Related or Institutional Committees**

**1. Data Safety Monitoring Boards**

Sponsor-Investigators with a high volume of self-sponsored research projects should establish an independent data monitoring committee for those self-sponsored protocols to exercise oversight of the clinical investigation and the informed consent process. An independent sponsor may also establish Data Safety Monitoring Boards. Information from these committees should be provided to the IRB in order to perform continuing review.

**2. Radioactive Drug Research Committee (RDRC)**

The RDRC is responsible for the review of basic science research protocols using radioactive drugs in humans. Among other things, the RDRC evaluates the radiation dose and qualifications of the administrator of the radiopharmaceutical, proper licensure of the facility and appropriate quality of the radiopharmaceutical. Membership and operational requirements are dictated at 21 CFR 361.1. The IRB works in conjunction with the RDRC and approval by both boards is required for study commencement. Additionally, the IRB and RDRC must coordinate the review of adverse events (AEs) that may be caused by radiation to assure all AEs are reviewed and both boards may benefit from the other's knowledge, experience and role.

**3. Institutional Biosafety Committees (IBC) and Recombinant DNA Advisory Council (RAC)**

For certain kinds of genetic research, the IRB must work in conjunction with these committees to protect the human subjects. BOTH IBC and IRB approval must be obtained to conduct the research. The IRB relies on the IBC to assure that Biosafety Levels are appropriate and maintained throughout the study (such as security, insect/rodent protection plan in physical locations where vectors are prepared) as well as NIH's RAC has reviewed and approved the protocol. Usually, IBC approval and IRB approval are applied for

<b>DEPARTMENT:</b> Clinical Operations Group - Research	<b>POLICY DESCRIPTION:</b> IRB Initial and Continuing Review of Non-Exempt Research with Human Subjects
<b>PAGE:</b> 10 of 10	<b>REPLACES POLICY DATED:</b> 3/1/12, 9/1/13
<b>EFFECTIVE DATE:</b> February 22, 2019	<b>REFERENCE NUMBER:</b> COG.IRB.007 (formerly CSG.IRB.007)
<b>APPROVED BY:</b> Ethics and Compliance Policy Committee	

simultaneously to prevent delays in the research from starting; however, the IRB cannot approve research until it has received final approval from the IBC.

**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)