

Checklist to Determine if Research Approval Is Required

To determine if a PHCC research approval is required, the below checklist must be applied:

- A. Is the activity a systematic investigation designed to contribute to generalizable knowledge? If yes, go to B. If no, go to I.
- B. Activity is research. Does the research involve obtaining information or biological specimens relating to living individuals? If yes, go to C. If no, go to H.
- C. Does the research involve interaction or intervention with individuals or use of identifiable data/biological specimens? If yes, go to F. If no, go to D.
- D. Do the data or biological specimens contain direct or indirect personal identifiers that permit an individual(s) to be identified? If yes, go to F. If no, go to E.
- E. Were the data or biological specimens originally recorded with personal identifiers but from which the identifiers are subsequently removed, obscured, coded or otherwise modified such that the identity of the individual(s) may reasonably be ascertained using available information and means? If yes, go to F. If no, go to G.
- F. Activity is human subject research. Submit research application for review and approval by PHCC Institutional Review Board (IRB).
- G. Activity is non-human subject research. Submit research application for review by PHCC IRB office if a non-human subject determination letter is required. Otherwise proceed in accordance with applicable PHCC requirements.
- H. Is the activity a clinical case report or case series involving one to three patients? If yes, submit a case report application. If no, go to I.
- I. Activity does not require research approval. Determine whether any other institutional, operational, quality improvement, audit, publication, data access, or administrative approvals are required. Examples include:
 - *Anonymized data requested for intentions other than research dissemination, such as audits, evaluations, and reports.*
 - *Quality assurance/improvement projects /organizational effectiveness studies.*

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Flowchart to Determine if Research Approval Is Required

