

Checklist to Determine Research Application Type

If PHCC research approval is required, apply the following checklist to determine the appropriate application form.

- A.** Does the activity involve a clinical case report or case series describing one to three PHCC-registered patients?
- **Yes:** Submit a **PHCC Case Report Research Application**.
 - **No:** Proceed to B.
- B.** Is the activity considered **non-human subject research** and involves either:
- PHCC as a research site; or
 - A PHCC investigator and a non-PHCC research site?
- **Yes:** If a non-human subject determination letter is required, submit a **PHCC Non-Human Subject Research Application**.
 - **No:** Proceed to C.
- C.** Is the activity considered **human subject research** involving:
- PHCC as a research site only
 - A PHCC investigator and a non-PHCC research site; or
 - A PHCC investigator conducting research independently or in collaboration with one or more institutions that are not parties to the National IRB Reliance Agreement?
- **Yes:** Submit a **PHCC Human Subject Research Application**.
 - **No:** Proceed to D.
- D.** Is the activity considered **human subject research related to health** and involves a **PHCC Principal Investigator (PI)** and one or more non-PHCC research sites that are parties to the **National IRB Reliance Agreement**?
- **Yes:** Submit a **National Reliance Research Application – Reviewing IRB**, where PHCC IRB will be the **Reviewing IRB**.
 - **No:** Proceed to E.
- E.** Is the activity considered **human subject research related to health** and involves a **PHCC Site Investigator (SI)** and one or more non-PHCC research sites that are parties to the **National IRB Reliance Agreement**?

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- **Yes:** Submit a **National Reliance Research Application – Relying IRB**, where PHCC IRB will be the **Relying IRB**.
- **No:** A PHCC research application is not required.

Notes

Case Report	A retrospective description and analysis of the clinical presentation, diagnosis, treatment, management, and outcomes of one to three patients with a unique, unusual, novel, or educational clinical condition, intervention, or outcome that provides valuable clinical insights for healthcare practice.
Human Subject Research	Research involving living individuals where a researcher gathers data through direct interaction, intervention, or by using identifiable private information/biological specimen.
Non-Human Subject Research	Research that does not involve human subjects. Example include research involving case reports, anonymized datasets, systematic reviews etc.