**Case Reports: IRB and HIPAA Requirements**

A case report is information collected and presented on one or more individuals to highlight an interesting experience, observation, treatment, presentation, relationship, or outcome. It typically (but not always) results from a retrospective review of the individual’s record.

 **START HERE**

**Does the activity involve using a drug, device, diet supplement, or biologic?**

**\* How do I decide?**

Use the Flagler Hospital Case Report Algorithm to decide whether your activity is research as defined by federal human subjects regulations. This is a self-determination process that does not require IRB review unless you are uncertain.

**\*\*Research**

A systematic investigation designed to develop or contribute to generalizable knowledge, regardless of whether or how the activity is funded. Some scholarly activities are not considered research by this definition.

**Not research**

**Submit application to the Flagler Hospital IRB; approval required before preparing case report**

**Research \*\***

**Purpose of the case report, as determined by you?\***

**Request a waiver of HIPAA authorization**

 **No**

**Proceed with the case report**

**Use the consent form provided to obtain HIPAA authorization from the patient or patient’s representative, & proceed with case report**

**Yes**

**Does the use require an IND or IDE from the FDA, or does it involve the use of any drug outside of medical practice, or will the results be submitted to the FDA?**

**Submit application to the Flagler Hospital IRB; approval required before preparing case report**

 **Yes**

**Can all HIPAA identifiers be removed from the case report so that there is no reasonable risk of patient identification in the case report?**

**No**

 **Yes**

**Will the patient or representative authorize the use of PHI for the case report**

**Not research; IRB review not required**

 **One**

 **No**

**Two or more**

**Yes**

 **Number of cases**

**No**