Case Studies/Series Guidance

Summary

Guidance to determine whether a case study or case series requires IRB review.

Guidance

A case study tends to highlight one or a few *particular* cases for purposes of demonstration or discussion rather than for purposes of drawing generalized conclusions.

Below are some criteria that tend to be representative of either case studies or research; this list is to be used as a guide not as a definitive determination. Note that CHOA has used five case studies as a threshold above which we normally wish to review the project as "research."

Standard case studies usually do not require consent or HIPAA Authorization. However, if the case study or series include a patient or patients with an extremely rare condition, which may cause their information to be identifiable by association, HIPAA Authorization and Consent is recommended. In addition, if you will be using a photo from the patient, you may obtain their consent using a consent form for that purpose.

If you are unsure if a case study or series is research, submit to the IRB (irb@choa.org) for a NHSR determination or call for guidance. If you are unsure if a case study or series requires HIPAA Authorization, contact the Privacy Office.

Common Elements	
Case Study	**Research**
Report on 5 or fewer subjects	Report on more than 5 subjects
Not meant to be a representative sample (not drawing conclusions)	Drawing conclusions about a broader population based on the reported cases (even if not statistically significant; e.g. pilot studies can be "research")
Reported/Published without attempting to draw broader conclusions	Reported/Published in a way that suggests broad findings or recommendations