Activities that Require IRB Review

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Case Reports / Limited Case Series

Activity	Description	IRB Review Required?
Case Report	A description (i.e., publication or presentation) of the clinical characteristics or treatment(s) provided to **three or fewer** patients that share a common condition, which did not involve activities defined as research.	**No**, when the activity is limited to 1-3 patient records.
Limited Case Series	A description (i.e., publication or presentation) of the clinical characteristics or treatment(s) provided to **four or more patients** that share a common condition. This activity constitutes "research".	**Yes**, when the activity involves 4 or more patient records.

For case reports or presentations that involve AV Recordings, "Consent for Collection and Sharing of Images and/or AV Recordings for External Use" must be used.

NOTE: If the Case Report involves *1-3 patients*, but the journal you intend to submit to *requires proof of IRB review*, then you will need to submit for IRB review prior to initiation of any data collection activities

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Other Activities that Require IRB Review*

Activity	Description
Case Studies	An intensive, prospective, systematic investigation of a single individual, group, community, or some other unit.
Clinical Investigations	Experiments using a test article in one or more human subjects.
“Compassionate Use” of an investigational drug or device	Physician determines an unapproved drug or device is the best treatment for a patient and meets the required criteria.
Data / Specimen Repositories or Registries	Storage of tissue, blood, genetic material, or data that is identifiable or de-identified.

*This is a simplified list. For a complete list, please see *GUIDANCE: Activities that Require IRB Review (HRP-004)* (available via https://www.sharp.com/research/upload/Guidance-Activities-That-Require-IRB-Review.pdf)

Contact the SHC IRB Office for any questions regarding activities that require IRB review: research@sharp.com

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