Case Studies, the IRB, and HIPAA
A Guidance Document on the OCF IRB Website

Are case studies research?
The answer to this question determines whether case studies are subject to the IRB. The federal definition of research from 45 CFR 46.102(d) is:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Based on this definition, a single or even a few case studies in an article is not research by the federal definition (in the opinion of the OCF IRB Chair). It is not a systematic investigation of many cases, and scientists would not expect to obtain generalizable knowledge from this type of anecdotal sharing of one or a few cases. It is a scholarly teaching activity that is part of the operations of an academic medical center such as Ochsner Clinic Foundation, and may be a valuable contribution to hypothesis generation for future research.

Do case studies need IRB approval?
No, IRB approval is not needed for one or a few case studies, because they are not considered research. If you are presenting or publishing one or a few case studies there is no need to obtain IRB approval or apply to the IRB Chair for an exempt research ruling. However, if a larger collection of case studies is compiled together, then it may be research according to the federal definition above. Certainly if you are presenting/publishing more than a few case studies, please discuss this with the IRB Chair as to whether this would be considered research under the federal definition, thus requiring IRB review or a determination by the IRB Chair to be eligible as exempt research.

Do case studies need HIPAA authorizations?
HIPAA exempts teaching activities as a part of the Institution’s operations. Therefore, HIPAA authorizations are not needed for case studies that are not considered research. However, if there were a larger collection of cases compiled together that in the view of the IRB Chair was research by the federal definition, then yes, a HIPAA authorization would be required unless it qualified for a HIPAA waiver or used only de-identified information (as defined by HIPAA’s 18 requirements for de-identified data).
Can case studies use personal information in the presentations?
If case studies do not fall under research IRB rules or HIPAA rules, common sense and basic ethical standards apply. There should be the minimum possible use of personal identifiers that is in keeping with the scholarly goals of teaching. The more de-identified the better.

Do case study publications require patient permission?
If case studies do not fall under research IRB rules or HIPAA rules, then this depends on the publisher. Many journals have revised their policies and will not publish a case study without signed patient consent. This reflects the fact that patients are increasingly sensitive to such uses of information about them without their knowledge—whether the author and journal believe the subject of the case report can be identified or not. In one prominent case, the Lancet was subject to legal action from a patient who was able to identify herself in the case report (Smith R. Informed consent: edging forwards (and backwards). BMJ 1998; 316:949-951.). Patients themselves, family members, or other people who know the person can often recognize the individual even though the authors may believe there is no identifying information in the report. The conditions reported are usually rare or atypical making self-recognition even easier.

The best course of action is to assume that individual descriptions may be identifiable and to obtain informed consent for publication. This also serves the goal of maintaining a collaborative relationship with the patient and family. Physicians who have shown case reports to the patient in question have often received useful feedback (and almost always permission), including correction and clarification of what, after all, is fundamental the patient’s story.