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| |  | | --- | | logo copy*1* **UNIVERSITY OF SANTO TOMAS HOSPITAL** RESEARCH ETHICS COMMITTEE 6th Floor St. John Macias O.P. Building  A.H. Lacson St., Sampaloc, Manila 1015 Philippines  Telephone: +63 2 8731-3001 local 2610  Email: [*usth\_irb@yahoo.com.ph*](mailto:usth_irb@yahoo.com.ph)Website*: usthrec.online*  **UNIVERSITY OF SANTO TOMAS HOSPITAL** España Blvd., Manila |   **CASE REPORT ASSESSMENT CHECKLIST FORM** | | | | | | |
|  | | | | | | |
| **Instructions:**  **To the Principal Investigator:** Please indicate in the space provided below whether or not the specified assessment point is addressed by your case report protocol. To facilitate the evaluation of the assessment point, indicate the page and paragraph where this information can be found. Submit this **F28 Form** in Word file format. Please be reminded that for case reports, the **REC F08 Assessment Form**is not applicable.  **To the Reviewer:** Kindly evaluate how the assessment points outlined below have been addressed by the case report protocol & Informed Consent Forms (ICFs). Confirm the submitted information by putting your comments in the space provided under “Reviewers Comments”. Summarize your comments in the space provided and finalize your review by indicating your conclusions under “Recommendation”. Sign and date the space provided for the reviewers. | | | | | | **Receiving Stamp/**  **Date of Submission:**  **CLICK TO ENTER TEXT.** |
| **3** | | | | | | |
| **REC Protocol Reference No.:**  *\*to be assigned by USTH-REC* | **CLICK TO ENTER TEXT.** | | | | | |
| **Protocol No./Title:** | Click to enter text. | | | | | |
| **Principal Investigator:** | Click to enter text. | | | | | |
| **Department/Section** | Click to enter text. | | | | | |
| **TOPICS & CHECKLIST ITEM DESCRIPTION** | | **TO BE FILLED-OUT BY THE**  **PRINCIPAL INVESTIGATOR/ PROPONENT** | | | | **TO BE FILLED-OUT BY THE**  **REC PRIMARY REVIEWER** |
| **Yes** | **No** | **Unable to assess** | **Put page & paragraph where it is found** | **Reviewer’s Comments & Recommendations** |
| 1. **TITLE PAGE** | |  |  |  |  |  |
| * **Title**: The words “case report” should be in the title along with the area of focus | |  |  |  |  |  |
| * **Authors name:** Should not exceed more than six authors | |  |  |  |  |  |
| * **Affiliation:** The names of organizations for each author | |  |  |  |  |  |
| * **Corresponding author:** Write the full name of the corresponding author and all contact details including email and mobile number | |  |  |  |  |  |
| 1. **KEY WORDS** | |  |  |  |  |  |
| * 4-7 key words-include “case report” as one of the key words | |  |  |  |  |  |
| 1. **ABSTRACT** | |  |  |  |  |  |
| * **Background:** what does this case report add to the medical literature? | |  |  |  |  |  |
| * **Case summary:** chief complaint, diagnosis, intervention, and outcome | |  |  |  |  |  |
| * **Conclusion:** what is the main “take-away” lesson from this case? | |  |  |  |  |  |
| 1. **INTRODUCTION** | |  |  |  |  |  |
| * Briefly summarize the background and context of this case report (1-2 paragraphs) | |  |  |  |  |  |
| 1. **TIMELINE** | |  |  |  |  |  |
| * Information from this case report organized into a timeline (table or figure) | |  |  |  |  |  |
| 1. **PATIENT INFORMATION** | |  |  |  |  |  |
| * De-identified demographic and other patient or client specific information | |  |  |  |  |  |
| * Chief complaint | |  |  |  |  |  |
| * Relevant history including past surgeries, family history, and medication history | |  |  |  |  |  |
| 1. **PHYSICAL EXAMINATION** | |  |  |  |  |  |
| * Relevant physical examination findings | |  |  |  |  |  |
| 1. **DIAGNOSTIC ASSESSMENT** | |  |  |  |  |  |
| * Evaluations such as laboratory testing and imaging (PE, lab testing, imaging, surveys) | |  |  |  |  |  |
| * Diagnostic reasoning including other diagnosis considered and challenges | |  |  |  |  |  |
| * Tables or figures linking assessment, diagnosis and interventions | |  |  |  |  |  |
| * Prognostic characteristic where applicable | |  |  |  |  |  |
| 1. **INTERVENTIONS** | |  |  |  |  |  |
| * Types of therapeutic intervention (pharmacologic, surgical, preventive) | |  |  |  |  |  |
| * Intervention detailed methods and duration | |  |  |  |  |  |
| * Explanation to intervention outcome | |  |  |  |  |  |
| * Other concurrent interventions | |  |  |  |  |  |
| 1. **FOLLOW-UP AND OUTCOMES** | |  |  |  |  |  |
| * Clinician assessment | |  |  |  |  |  |
| * Important follow-up diagnostic evaluations | |  |  |  |  |  |
| * Assessment of intervention adherence and tolerability, including adverse events | |  |  |  |  |  |
| 1. **DISCUSSION** | |  |  |  |  |  |
| * Strengths and limitations in your approach to this case | |  |  |  |  |  |
| * Compare your results with previous reported cases (optional) | |  |  |  |  |  |
| * Specify how this case report informs practice or guidelines | |  |  |  |  |  |
| * How does this case report suggest a testable hypothesis? | |  |  |  |  |  |
| 1. **CONCLUSION** | |  |  |  |  |  |
| * State clearly the main conclusion of the case report and provide a concise statement and explanation of the importance and relevance | |  |  |  |  |  |
| 1. **PATIENT PERSPECTIVE** | |  |  |  |  |  |
| * When appropriate report the patient experience in his own word and his message | |  |  |  |  |  |
| 1. **ETHICAL CONSIDERATIONS** | |  |  |  |  |  |
| * **Ethical Guidelines:** Declaration of Helsinki require that participants (or their legal guardians) provide consent when their personal information or medical history is used for research purposes, even in case reports. | |  |  |  |  |  |
| * **Ethical Compliance:** Statement that the case report protocol is reviewed and approved by the USTH-REC. | |  |  |  |  |  |
| * **Informed Consent Process:** | |  |  |  |  |  |
| * Before any data collection or publication, obtain explicit, informed, and voluntary consent from the participant (or their legal representative). | |  |  |  |  |  |
| * Ensure the participant was fully informed of the nature and purpose of the case report, the procedures involved, potential risks and benefits, and their right to withdraw at any time. | |  |  |  |  |  |
| * Clear documentation of the consent process, including the date, time, and method of obtaining consent and preferred language that the participant will understand. | |  |  |  |  |  |
| * **Confidentiality and Privacy:** | |  |  |  |  |  |
| * Statement of compliance to Data Privacy Act of 2012 | |  |  |  |  |  |
| * **Protecting Identity:** Take all necessary steps to protect the participant's identity and maintain confidentiality throughout the case report process. | |  |  |  |  |  |
| * **Anonymization:** Consider anonymizing the data or using pseudonyms to further protect the participant's privacy | |  |  |  |  |  |
| * **Data Security:** Implement secure storage and handling practices for all data collected | |  |  |  |  |  |
| 1. **Conflict of Interests:** Disclosure for each author of any potential conflicts of interest (financial, professional, or personal) that may influence the case report. | |  |  |  |  |  |
| 1. **INFORMED CONSENT** | |  |  |  |  |  |
| * Written consent was obtained from the patient for publication of this case report. A copy of the written consent is available for review. | |  |  |  |  |  |
| 1. **ADDITIONAL INFORMATION** | |  |  |  |  |  |
| * Author contribution | |  |  |  |  |  |
| * Author information | |  |  |  |  |  |
| * Acknowledgement | |  |  |  |  |  |
| * References | |  |  |  |  |  |
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| **To be filled-out by the REC Primary Reviewer** | | | | |
| *Summarize your assessment review comments in this space provided:* | | | | |
| **RECOMMENDATION:** | |  | **FOR CLARIFICATORY INTERVIEW** | |
|  | **APPROVED** | |
|  | **MINOR REVISIONS** | |
|  | **MAJOR MODIFICATIONS** | |
|  | **DISAPPROVED**  **State Reasons for Disapproval:** | |
| **REC REVIEWER:** | Name & Signature:  **CLICK TO ENTER TEXT.** | | | Date: |