**DeSales University Doctor of Physical Therapy Program**



**Case Reports: Participant & IRB Authorization Form**

In health-care, a case-report is a detailed **retrospective** narrative of the clinical presentation, diagnosis, treatment, and outcomes of **no more than 2 patients** (or cases), often with an unusual or novel condition, to be shared for medical or educational purposes. **Consenting** patients are typically managed via the **usual care** that is indicated for their condition regardless of their decision to participate as case-report subjects. A case-report is **not considered a human subject research** in which a researcher conducts an experiment and collects data prospectively, and **it does not involve any human contact**. Thus, information from a case-report **is not considered generalizable medical knowledge**.

If your project **does not meet all the highlighted criteria** of a case-report above, please proceed with submitting a regular IRB application form found at **www.desales.edu**

**Institution Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Institution Location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Institution Type: Outpatient  Hospital  Skilled Nursing/Rehab  DPT Probono **

|  |  |
| --- | --- |
| 1. **CASE-REPORT TEAM MEMBERS:** | |
| **PRINCIPAL INVESTIGATOR (PI):** | |
| **Email:** |  |
| **Phone #:** |  |
| **Faculty:** | CITI Trained: Yes No |
| **CO-PRINCIPAL INVESTIGATOR (CO-PI) 1:** | |
| **Email:** |  |
| **Phone #:** |  |
| **Faculty: Student:** | CITI Trained: Yes No |
| **CO-PRINCIPAL INVESTIGATOR (CO-PI) 2:** | |
| **Email:** | |
| **Phone #:** |  |
| **Student: External**  **Consultant:** | CITI Trained: Yes No |

1. **CASE-REPORT INFORMATION:**
2. **Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
3. **Number of Participants: One Two**
4. **Expected Date of Completion: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
5. **Briefly describe the purpose of this case-report:**
6. **Briefly describe this case-report’s methods and data recording approach:**
7. **What precautions will be taken to ensure the participant(s) privacy & confidentiality is protected? (check all that apply).**

☐ The collection of sensitive information about participants will be retrospective and limited to

the amount necessary to achieve the aims of this case-report, so that no unneeded information will be collected.

☐ All written or electronic private information will be accessible to only personnel involved in this case-report.

☐ All written or electronic records (e.g., consent form, participants’ data) will be kept in a secure place at DeSales University as determined by the PI. Such information will remain stored at DeSales for up to 1 year following the student’s (CO-PI) graduation, and will not be shared with third parties.

☐ All electronic information will be password protected.

☐ Whenever feasible, all personal identifiers will be removed to fully de-identify private information in this case-report and in any of its future dissemination types.

1. **Dissemination Plans: Publication**  **Presentation  None **
2. **IRB REVIEW DECISION:** DeSales IRB has concluded the following**:**
3. **This case-report meets all criteria for an exempt status:** 
4. **Proposed Review Category: Exempt, Category: \_\_\_\_\_\_\_**
5. **This case-report does not meet all criteria for an exempt status** 

**Further Comments: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **PARTICIPANT-1 CONSENT:**

**The participant should be aware that this is a case report in which the following criteria have been met:**

1. The authors will use my private information to create and publish a narrative that relate to my clinical presentation, diagnosis, treatment, and outcomes I experienced during my therapy sessions **in the past**.
2. My personal information is being used because I present an unusual or novel condition, which was treated via the indicated **usual care**. The results of this care will be shared for medical or educational purposes.
3. I am not going to participate in any future research in which an experimental treatment will be conducted.
4. All my private information will be **fully protected, de-identified, and not shared with third parties**.

**Therefore:**

I freely consent to have my personal records reviewed towards the completion of this case-report. I

understand that all my personal information will be de-identified. By signing this consent form I have

not waved any of my legal rights that I otherwise would have as a subject in a research study. I reserve

the right to withdraw my participation from this case-report anytime by communicating my decision with

the DeSales DPT Program at 610-282-1100 Ext:1898

**Participant’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Participant’s verbal consent has been obtained? Yes  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**(Legal representative or guardian if under 18 years of age)**

1. **CLINIC AUTHORIZATION:**

**Clinical Institution Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Clinic Director/Supervising Therapist:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Contact Information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **PARTICIPANT-2 CONSENT:**

**The participant should be aware that this is a case report in which the following criteria have been met:**

1. The authors will use my private information to create and publish a narrative that relate to my clinical presentation, diagnosis, treatment, and outcomes I experienced during my therapy sessions **in the past**.
2. My personal information is being used because I present an unusual or novel condition, which was treated via the indicated **usual care**. The results of this care will be shared for medical or educational purposes.
3. I am not going to participate in any future research in which an experimental treatment will be conducted.
4. All my private information will be **fully protected, de-identified, and not shared with third parties**.

**Therefore:**

I freely consent to have my personal records reviewed towards the completion of this case-report. I

understand that all my personal information will be de-identified. By signing this consent form I have

not waved any of my legal rights that I otherwise would have as a subject in a research study. I reserve

the right to withdraw my participation from this case-report anytime by communicating my decision with

the DeSales DPT Program at 610-282-1100 Ext:1898

**Participant’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Participant’s verbal consent has been obtained? Yes  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**(Legal representative or guardian if under 18 years of age)**

1. **CLINIC AUTHORIZATION:**

**Clinical Institution Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Clinic Director/Supervising Therapist:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Contact Information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**