**ELABORAÇÃO DE RELATÓRIO DE**

**SUSPENSÃO DE ESTUDOS CLÍNICOS**

**UNICÊNTRICOS E MULTICÊNTRICOS**

**DEVE SER DIGITADO**

**DADOS DO PROJETO**

1. Registro CONEP: \_\_\_\_\_\_\_\_\_\_\_\_\_ Registro: CEP/UNIMAR: \_\_\_\_\_\_\_\_\_\_\_\_

2. Título do projeto: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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3. Razões da suspensão: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**DADOS DOS SUJEITOS**

1. Total de sujeitos recrutados no centro/ em cada centro: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Total de sujeitos incluídos no centro/ em cada centro: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. Total de sujeitos selecionados para randomização centro/ em cada centro: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. Total de sujeitos excluídos na randomização centro/ em cada centro: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5. Total de sujeitos efetivamente incluídos no estudo (após a randomização) centro/em cada centro: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6. Total de sujeitos retirados/descontinuados centro/ em cada centro: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

7. Todos os centros participantes suspenderam o estudo? Se não, justifique.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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8. Houve registro de eventos adversos graves por parte dos pesquisadores em algum centro participante?

* Se sim, em qual(is) centro(s)? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* Qual(is) foi(ram) o(s) eventos adversos? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* Qual a conduta tomada? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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9. Algum sujeito buscou compensação por danos causados por este estudo em algum dos centros participantes?

* Se sim, em qual (is) centro(s)? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* Qual (is) foi (ram) o (os) dano(s)? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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* Qual a conduta tomada? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**DADOS DA SEGURANÇA DOS SUJEITOS MEDIANTE SUSPENSÃO DO ESTUDO**

* Informar como foi feito o acompanhamento dos sujeitos de pesquisa (mencionar quais as medidas de proteção tomadas em relação aos sujeitos que foram realizadas). \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Marília, ............. de ..................................... de 2.00\_\_

Assinatura e Carimbo do Pesquisador Principal

RG // CR // Fone Institucional // E-mail