**ROTEIRO PARA ELABORAÇÃO DE RELATÓRIO DE SUSPENSÃO DE ESTUDOS CLÍNICOS UNICÊNTRICOS E MULTICÊNTRICOS – CEP/HPP**

**DADOS DO PROJETO**

1. Registro CONEP:

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2. Título do projeto:

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3. Razões da suspensão:

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4. Análise do CEP sobre as razões da suspensão:

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**DADOS DOS SUJEITOS**

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

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

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

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

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5. Total de sujeitos efetivamente incluídos no estudo (após a randomização) centro/

em cada centro:

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

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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**

1. 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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