# **ROTEIRO PARA ELABORAÇÃO DE RELATÓRIO DE SUSPENSÃO DE ESTUDOS CLÍNICOS UNICÊNTRICOS E MULTICÊNTRICOS**

**DADOS DO PROJETO**

1. Registro CONEP:
2. Título do projeto:

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1. Razões da suspensão:

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

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

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

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

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

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1. Todos os centros participantes suspenderam o estudo? Se não, justifique.

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

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* Se sim, em quais centros?

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* Quais foram os eventos adversos?

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* Qual a conduta tomada?

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

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* Quais foram os danos?

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* Qual a conduta tomada?

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1. DADOS DA SEGURANÇA DOS SUJEITOS MEDIANTE SUSPENSÃO DO ESTUDO
2. 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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