**ROTEIRO PARA ELABORAÇÃO DE RELATÓRIO FINAL DE ESTUDOS CLÍNICOS UNICÊNTRICOS E MULTICÊNTRICOS**

**DADOS DO PROJETO**

1. Registro CONEP:

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1. Título do projeto

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**DADOS DOS SUJEITOS**

1. Total de sujeitos recrutados em cada centro e no total:

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1. Total de sujeitos incluídos no estudo em cada centro e no total:

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1. Total de sujeitos selecionados para randomização em cada centro e no total:

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1. Total de sujeitos excluídos na randomização em cada centro e no total:

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

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1. Total de sujeitos retirados/descontinuados em cada centro e no total:

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1. Principais razões de retirada/descontinuação:

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1. Total de sujeitos que concluíram o estudo em cada centro e no total:

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1. Total de eventos sérios ocorridos em cada um dos centros participantes e no total:

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1. Condutas adotadas em relação aos eventos dos eventos adversos graves;

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1. Houve pedido de indenização por danos causados por este estudo em algum dos centros participantes?

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

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* Quais foram os danos?

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* Qual a conduta tomada?

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