**ROTEIRO PARA ELABORAÇÃO DE RELATÓRIO FINAL 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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**DADOS DOS SUJEITOS**

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

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

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

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

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

cada centro e no total:

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

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7. Principais razões de retirada/descontinuação:

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

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9. Total de eventos sérios ocorridos em cada um dos centros participantes e no

total:

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

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11.Houve pedido de indenização 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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