

**Annex 2: Documents to be submitted to the DRCI (Délégation à la Recherche Clinique et à l'Innovation: Delegation for Clinical Research and Innovation)**

(Preferably in electronic format, if not then on paper)

**At the earliest possible date (as of submission of the authorization request to the competent authority and/or notice of the CPP (Committee for the protection of Individuals))**

**Necessary and essential documents to be sent the file to the coordinator and to the Coordinator's DRCI:**

1. Protocol (in French or English)
2. Summary of Protocol in French
3. All complementary information which might not be listed in the French summary, necessary for working out the schedule of additional expenditures (each line of the schedule updated). Format chosen by the promoter.
4. Copy of the delegation of proxy in the event of monitoring by the CRO<sup>1</sup>
5. Name and title of the person signing the agreement
6. Name and address for billing purposes

**Necessary and essential documents to be sent to each DRCI and to each investigator at the other centres after having obtained the validated schedule from the coordinating centre**

1. Protocol (in French or English)
2. Summary of Protocol in French
3. All complementary information which might not be listed in the French summary, necessary for working out the additional expenditure schedule (each line of the schedule updated). No format is imposed.
4. Copy of the delegation of proxy in the event of monitoring by the CRO
5. Name and title of the person signing the agreement
6. Name and address for billing purposes
7. Schedule of additional expenditures validated by the coordinating centre

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<sup>1</sup> Contract research organisation, sub-contracted service provider that industrial promoters turn to.

## Before opening the centre

### Documents to be sent by the promoter to each DRCI before opening the centre (installation):

1. CPP acceptance
2. Afssaps (French Health Products Safety Agency) authorisation

## In the event of an amendment bringing about a change in the schedule of calculation of additional expenditures

### Documents to be sent in the context of this procedure, to the coordinator and to the coordinator's DRCI in the event of amendment bring about a change in the schedule of calculation of additional expenditures:

1. a letter from the promoter indicating the existence of an amendment num. ...
2. an amended protocol or the amendment (English or French)
3. summary of the amendment/ changes in French
4. all complementary information leading to revision of the schedule of additional expenditures. Format chosen by the promoter

### Necessary and essential documents to be sent to each DRCI and to each investigator in the event of amendment after having obtained the validated schedule from the coordinating centre:

1. a letter from the promoter indicating the existence of an amendment num. ...
2. an amended protocol or the amendment (English or French)
3. summary of the amendment/ changes in French
4. all complementary information leading to revision of the schedule of additional expenditures. Format chosen by the promoter
5. additional expenditures schedule validated by the coordinating centre