

CPP Ile de France XI

Committee of Personnel Protection

Saint-Germain-en-Laye, May 17, 2018

CHRU de BESANCON
Ingrid TISSOT
2 place St Jacques
25030 BESANCON CEDEX

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| Title of the essay: | « Prévention du diabète de novo après transplantation par un traitement court par vildagliptine dans la période précoce suivant une transplantation rénale » |
| Promotor: | CHRU DE BESANCON |
| Coordinator: | Pr Didier DUCLOUX |
| Promotor ref.: | PRODIG |
| IDRCB number : | 2016-002023-28 |
| Réf. CPP : | 17039 |

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| Request for an opinion, valid authorization, on a category 1 search | x |
| Request for an opinion, valid authorization, on a category 2 search | |
| Request for an opinion, valid authorization, on a category 3 search | |
| Request for an advisory opinion on a substantial change of purpose in the use of a collection of elements human biological (art. L. 1211-2 of CSP) | |
| Request for an Advisory Opinion on a draft declaration of constitution of a collection of human biological samples (art. L. 1243-3 of CSP) | |

| Examined documents | Version number and date |
|--|-------------------------|
| Notice Mail | 2017/06/19 |
| Additional document | November 20, 2017 |
| Insurance | 2017/06/19 |
| Formulaire de demande | 2017/06/19 |
| Protocole | V4 of 2017/09/26 |
| Summary | V1 of 2017/06/19 |
| Summary of product characteristics | Attachment |
| Investigators' CV | Attachment |
| List of investigators | V2 of 2017/11/20 |
| Information Form and Patient Informed Consent Form | V3 of 2018/04/19 |
| Certificate of identity | 2017/03/08 |
| ReTRANSQOL and EQ-5D questionnaires | Attachment |
| Justification of the adequacy of the means | V1 of 2017/06/19 |

Michèle CATZ, présidente – Sabine de la PORTE, Vice-présidente – Jean-François LAIGNEAU, Secrétaire
 Anne-Elisabeth DECARIS, Assistante
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I received the changes requested at the meeting of SEPTEMBER, 14 2017, concerning the research project referenced above.

Participated in the deliberation :

I – FIRST COLLEGE

Annie DURAND
Agnès GUIBERT
Gérard LOEB
Kolia MILOJEVIC
Sabine de la PORTE

Hospital Pharmacist
Biostatistician
Doctor
Biostatistician
Searcher

II - SECONDE COLLEGE

Christine GHESTEM
Odile LACHAUD
Olivier LANTRES
Christine STOUFFLET

Association of the families of Vésinet
Representative UDAF 78
Lawyer
Philosopher

No deliberative member of the committee is affected by a conflict of interest.

Therefore I give the FAVORABLE OPINION of our Committee for this research. Please believe, Madam, the assurance of my best feelings.

Michèle CATZ, chair of the meeting.

