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EUDRACT - LIST OF ADDITIONAL FIELDS CONTAINED IN EUDRACT (REASONS FOR NEGATIVE OPINIONS OF THE ETHICS COMMITTEE)

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1. INTRODUCTION

In accordance with point 3.3. of Commission Guidance 2009/C28/01[1], where a negative opinion bas been issued by an Ethics Committee, the information on the trial will be published, together with a field indicating the reason for the negative opinion.

To this end, EudraCT is going to contain the following fields.

2. LIST OF REASONS

- Relevance of the Clinical Trial
- Evaluation of the anticipated benefits and risks
- Investigators and staff
- Facility in a monocentre-trial
- All facilities in a multicentre-trial
- Facility/ies (one or more, but not all, in a multicentre-trial)
- Inclusion and exclusion criteria
- Control group
- Recruitment procedure
- Patient Information Sheet and consent form and procedure
- Measures to minimise pain, discomfort and fear
- Insurance and/or indemnity (injury or death / liability)
- Compensations to subjects
- Compensations to investigators
- Agreement between sponsor and site
- Inclusion of persons incapable of giving informed consent or other vulnerable populations
- Data protection and confidentiality
- Compliance with GCP
- Fulfilment of administrative requirements
- Other (Please specify - free text)
- Not Specified

[1] http://ec.europa.eu/health/documents/eudralex/vol-10/index_en.htm