

TUNISIAⁱ

<p>a) Laws governing clinical trials</p> <ul style="list-style-type: none"> - Décret n° 94-1939 du 19 septembre 1994, fixant les attributions, la composition et les modalités de fonctionnement du comité national d'éthique médicale. - Décret n° 2001-2133 du 10 septembre 2001 modifiant et complétant le décret n° 94-1939 du 19 septembre 1994 fixant les attributions, la composition et les modalités de fonctionnement du comité national d'éthique médicale.
<p>b) Ad hoc provisions for paediatric trials</p> <ul style="list-style-type: none"> - A special authorisation is needed for trial involving children
<p>c) Ethics Committees / National Competent Authority</p> <ul style="list-style-type: none"> - Comité national d'Ethique Medicale - DPM (Direction de la pharmacie et des médicaments) du Ministre de la Santé Publique (Competent Authority)
<p>d) Paper or electronic application / existence of a national website</p> <p>Paper submission. No national databases.</p>
<p>e) Procedures for compiling the EU CTA form (e.g. from EudraCT or from the national database)</p> <p>Not applicable.</p>
<p>f) Requested documents to be submitted</p> <ul style="list-style-type: none"> o Cover letter o Application form o List of investigators and corresponding centers o Updated CV of investigators o Contract between the sponsor and contract research organization (if the sponsor has delegated its activities): certified copy o Contract between the sponsor and the coordinating investigator: certified copy o Agreement between the developer and the pharmacist responsible for product management of investigation: certified copy o Summary of the clinical trial protocol (in French) o Clinical Trial Protocol o Investigator's Brochure o Licenses and certificates of GMP o Draft labeling and package for IMPs o List of countries involved o Reference to other opinions from ethics committees in the foreign countries

TEDDY Network is coordinated by:

Consorzio per Valutazioni Biologiche e Farmacologiche
I-27100 PAVIA Via Luigi Porta 14 – Tel. +39 0382 25075
I-70122 BARI Corso Alcide De Gasperi 435 – Tel. +39 080 8641260
www.teddyyoung.net • teddynetwork@cvbf.net

- o Specifications (in duplicate) signed by the sponsor and the coordinating investigator with authentication of signature
- o Information Form and Informed Consent (Arabic and French)
- o Proof of insurance for the duration of the trial
- o Conflict of interest disclosure
- o Conflict of interest disclosure of the coordinator pharmacist

SOURCES: http://www.comiteethique.rns.tn/ethique/representations_internationales.html

ⁱ *This document has been prepared by TEDDY Network as part of its research activity. Information have been derived by questionnaires filled in by researchers and from official national databases where available. It does not replace the official data that can be accessed directly or are provided at the experimental site. The material cannot be distributed nor re-utilised without acquiring a specific preliminary consent from the Network.*

TEDDY Network is coordinated by:

Consorzio per Valutazioni Biologiche e Farmacologiche
I-27100 PAVIA Via Luigi Porta 14 – Tel. +39 0382 25075
I-70122 BARI Corso Alcide De Gasperi 435 – Tel. +39 080 8641260
www.teddyyoung.net • teddynetwork@cvbf.net