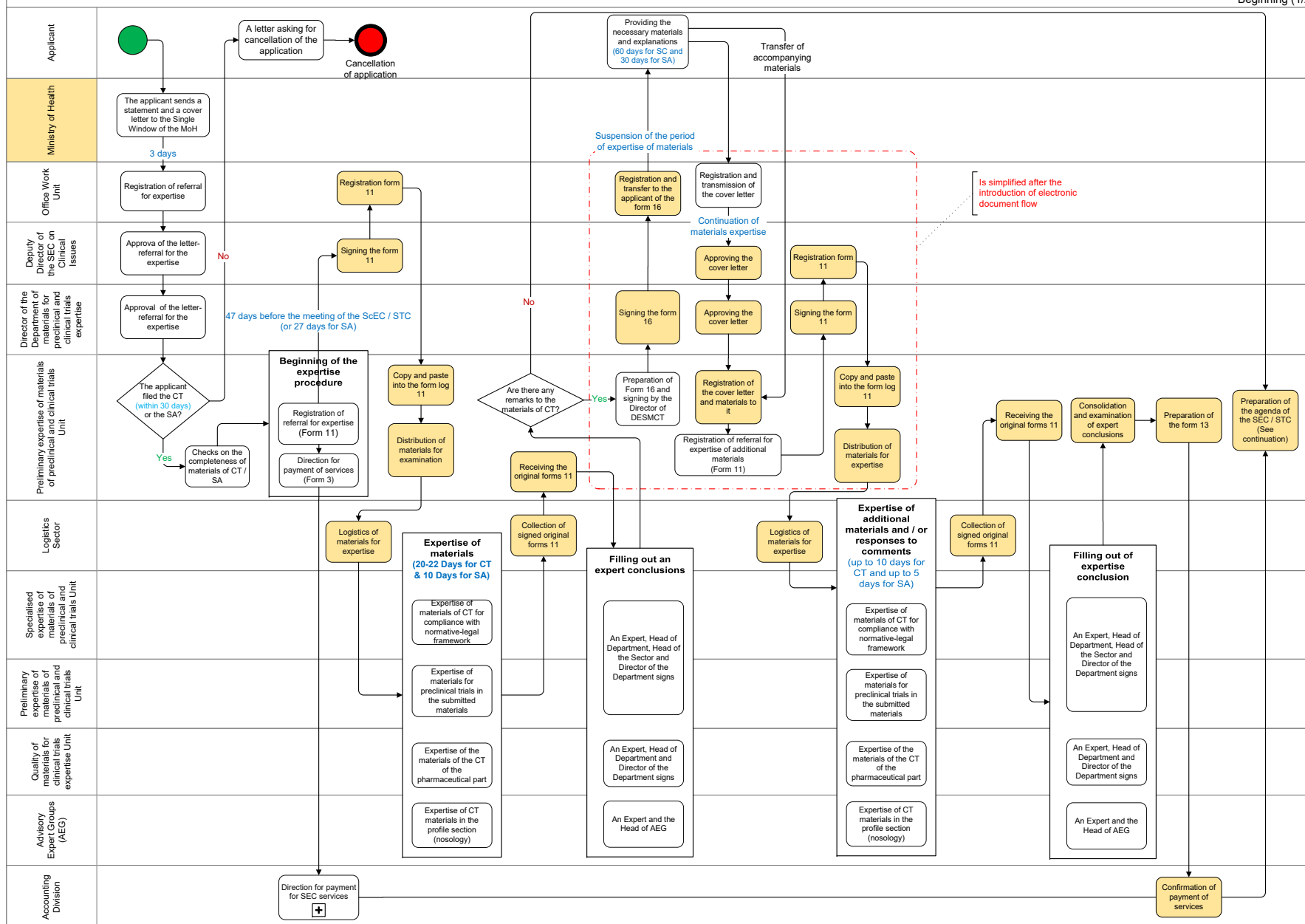


Description of procedure for expertise of materials of Clinical research / Essential amendments

Beginning (1/2)



Applicant	Ministry of Health	Office Work Unit	Director of SEC	Deputy Director of the SEC on Clinical Issues	Director of the Department of materials for preclinical and clinical trials expertise	Preliminary expertise of materials of preclinical and clinical trials Unit	Specialised expertise of materials of preclinical and clinical trials Unit	Scientific Expert Council / Scientific Technical Council	Administration of state registers Unit
<pre> graph TD Start(()) --> D1{Are there any remarks to the CT materials?} D1 -- Yes --> P1[Preparation of the section of the Agenda "Removal of the materials of the CT / SA according to the current legislation"] D1 -- No --> P2[Preparation of the section of the Agenda "Consideration and approval of CT / SA materials"] P1 --> V1[Verification and adjustment of the SEC / STC agenda] P2 --> V1 V1 --> A1[Approving the agenda of the SEC / STC] A1 --> A2[Approving the agenda of the SEC / STC] A2 --> A3[Approving the agenda of the SEC / STC] A3 --> M1[Meeting of the SEC / STC] M1 --> D2{The examination results of the CT / SA are accepted?} D2 -- No --> D3[Direction for expertise of additional materials of CT] D3 --> D1 D2 -- Yes --> P3[Processing results of the SEC / STC meeting] P3 --> S1[Signing a conclusion] S1 --> S2[Signing a conclusion] S2 --> R1[Registration of the cover letter] R1 --> R2[Registration of the cover letter] R2 --> S3[Signing of extracts from the order of the MoH and transfer to the applicant through the Single window] S3 --> S4[Signing of extracts from the order of the MoH and transfer to the applicant through the Single window] S4 --> S5[Signing an order for approval of the CT / SA and making it public on the website of the MoH] S5 --> S6[Signing an order for approval of the CT / SA and making it public on the website of the MoH] S6 --> R3[Receiving of reception-transfer services] S6 --> End(()) End --> A4[Amending in the database "Farmakorishennya" In accordance to approved substantive amendment] </pre>									