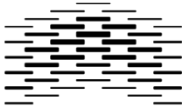


Etter å ha trykket på «**Create**» får du opp dette bildet

* ‡ Organization's Unique Protocol ID:	<input type="text"/>
* ‡ Brief Title:	<input type="text"/>
Acronym:	<input type="text"/> <small>If specified, will be included at end of Brief Title in parentheses.</small>
Official Title:	<input type="text"/> <small>NOTE: Official Title is required by the WHO and ICMJE.</small>
‡ Secondary IDs: (if any)	<input type="button" value="+ Add Secondary ID"/>

Her legger du inn REK-
referansenummer



I «sponsor» delen skal man legge inn HiOA som «sponsor». Stipendiater som registrerer studien ved HiOA og der «principal investigator» ikke er tilsatt ved HiOA, skal velge «sponsor som «responsible party».

Collaborator er samarbeidspartnere/organisasjoner som er involvert i studien.

[Help](#) [Definitions](#)

* ‡ Sponsor:	<input type="text" value="Oslo and Akershus University College of Applied Sciences"/> Primary organization conducting study and associated data analysis (not necessarily a funding source).
* ‡ Responsible Party:	<input style="border: 1px solid black;" type="text" value="Sponsor"/> Select Sponsor unless the Investigator has been designated as Responsible Party per FDAAA.
Collaborators:	<input type="text"/> <input type="button" value="x Delete"/> <input type="button" value="+ Add Collaborator"/> Organization(s) providing support: funding, design, implementation, data analysis or reporting. Enter only the organization name .



Sponsor-delen fortsetter: Dersom «principal investigator» er tilsatt ved HiOA, skal «principal investigator» som hovedregel registreres som «responsible party». Ta gjerne kontakt med FoU seksjonen for nærmere avklaring.

* ‡ Sponsor:
Primary organization conducting study and associated data analysis (not necessarily a funding source).

* ‡ Responsible Party:
Select **Sponsor** unless the Investigator has been designated as Responsible Party per FDAAA.

For Principal Investigator or Sponsor-Investigator only, provide:

Investigator Name [Username]:
Select the investigator's PRS account.
The Investigator Name (i.e., the Full Name from the PRS account record) must be a person's full name for display on ClinicalTrials.gov.
[Investigator not in list?](#) [Incorrect name format?](#)

Investigator Official Title:

Investigator Affiliation:

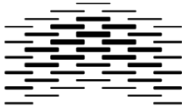
Collaborators:

Organization(s) providing support: funding, design, implementation, data analysis or reporting.
Enter **only the organization name**.



I «oversight» delen skal det legges inn referanse og status i henhold til REK-søknad. Se eksemplet nedenfor.

(‡) FDA Regulated Intervention?:	<input type="text" value="No"/>	Does this trial involve a drug, biologic or device subject to US Food and Drug Administration (FDA) regulations?
* (‡) IND/IDE Protocol?: (Not public)	<input type="text" value="No"/>	FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?
* Board Approval:	Status: <input type="text" value="Submitted, approved"/>	Approval Number: <input type="text" value="2014/726"/>
	If review board does not assign approval numbers, enter date in mm/dd/yyyy format. Send a signed board approval letter to ClinicalTrials.gov (address and instructions).	
* Board Name:	<input type="text" value="Regional Committees for Medical and Health Research"/>	
* Board Affiliation:	<input type="text" value="REC South East"/>	
* Board Contact: (Not public)	Business Phone: <input type="text" value="+4722845511"/>	Extension: <input type="text"/>
	Business Email: <input type="text" value="rek-sorost@medisin.uio.no"/>	
	Business Address: <input type="text" value="REC South East - Sekretariat
P.O.Box 1130, Blindern
0318 Oslo"/>	
Data Monitoring Committee?:	<input type="text" value="No"/>	



Locations

[Help](#) [Definitions](#)

* (‡) Central Contact:

First Name: MI: Last Name: Degree:
Phone: Ext: Email:

Either Central Contact or Facility Contacts are required.

Central Contact Backup:

First Name: MI: Last Name: Degree:
Phone: Ext: Email:

‡ Overall Study Officials:

First Name: MI: Last Name: Degree:
Organizational Affiliation:
Official's Role: --Select--

Her legger du inn kontaktinformasjon til personen administrere/koordinere har all informasjon om studien. Dette kan for eksempel være stipendiat.

Her legger du inn PI for studien

Ved mindre prosjekter kan central contact og PI være den samme