הרשות למחקר ופיתוח
מרכז רפואי ברזילי, אשקלון 78278
טל: 08-6746146 פקס: 08-6687805
מייל: Ornitc@bmc.gov.il

בס"ד

יום שלישי 24 ביוני 2015

חוקר נכבד שלום

בכדי להיערך נכונה לרישום מחקרך באתר ה-NIH
אנא הכן את פרוטוקול המחקר שלך בשפה האנגלית לפי המסמך המפורט
יש לענות על כל הסעיפים בכל 11 המסכים
לכשתסיים, מחקרך יהיה בשלב "In Progress"
עליך לעבוד בין השלבים הבאים עד לשלב הסופי Public

In Progress → Entry Completed → Approved → Released → PRS Review → Public

כאשר יתקבל אישור רישום מחקר באתר המידע יהיה ציבורי,
ויזוהה באמצעות מספר מערכת

<u>מסך ראשון</u>

- Organization's Unique Protocol ID
- Acronym
- Study Type:

* Study Type:	○ Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol
	○ Observational participants **not** assigned to intervention(s) based on a protocol; typically in context of routine care
	○ Expanded Access availability of an experimental drug or device outside of a clinical trial protocol

<u>מסך שני</u>

- Organization's Unique Protocol ID
- Brief Title
- Record Verification Date
- Overall Recruitment Status

* Overall Recruitment Status:	--Select--
* § Study Start Date:	Not yet recruiting
* Primary Completion Date:	Recruiting
	Enrolling by invitation
	Active, not recruiting
	Completed
	Suspended
	Terminated (Halted Prematurely)
	Withdrawn (No Participants Enrolled)

- Study Completion Date

The Barzilai University Medical Center, Ashkelon
Hahistadrout St 2, Ashkelon 7830604, Israel
Tel (972)-8-6745555
Fax (972)-8-6736750

המרכז הרפואי האוניברסיטאי ברזילי, אשקלון
ההסתדרות 2, מיקוד 7830604
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פקס 08-6736750

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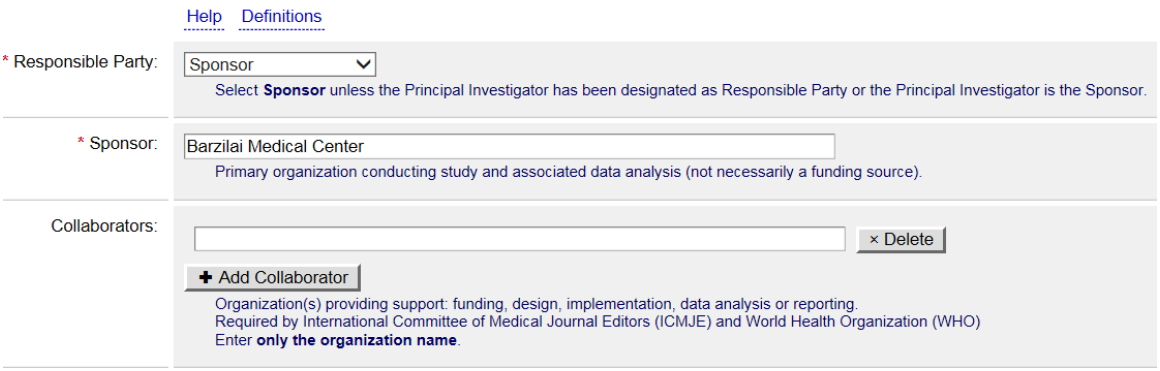
מסך שלישי

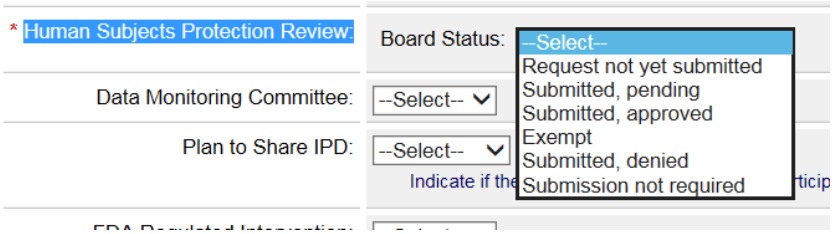
- Responsible Party
- Sponsor
- Collaborators



מסך רביעי

Edit Oversight

- FDA-regulated Drug Yes/No
- FDA-regulated Device Yes/No
- FDA IND/IDE Study: Yes/No
- Human Subjects Protection Review:



- Data Monitoring Committee Yes/No
- Plan to Share IPD Yes/No
- FDA Regulated Intervention Yes/No

מסך חמישי

Edit Study Description

- Brief Summary
- Detailed Description

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- Conditions or Focus of Study

Search MeSH, the National Library of Medicine's Medical Subject Headings, for valid condition terms.
If there are no conditions under study, enter brief description of focus of study instead.

- Keywords

מסך שביעי

Edit Interventional Study Design

- Study Type
- Primary Purpose
- Study Phase
- Interventional Study Model:
- Model Description
- Number of Arms

* § Masking:

- [ ] Participant
- [ ] Care Provider
- [ ] Investigator
- [ ] Outcomes Assessor
- [ ] No Masking

Check all roles that are masked or check No Masking.

- Masking Description
- Allocation
- Enrollment

§ Enrollment: Number of Subjects: Type: --Select--

מסך שמיני

Edit Interventions

- Arms
- Intervention Type

No Arms have been specified.]

* Intervention Type: --Select--
* Intervention Name:
[*] Other Names: (if any)
* § Intervention Description:

Drug
Device
Biological/Vaccine
Procedure/Surgery
Radiation
Behavioral
Genetic
Dietary Supplement
Combination Product
Diagnostic Test
Other

Do not repeat information alread

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- Intervention Name

For a drug, use generic name if established.
Use the same name as in the associated Arm/Group Description(s).

- Intervention Description

מסך תשיעי

Edit Outcome Measures

- Primary Outcome Measure

Outcome 1
Title:
Description:
Time Frame:
× Delete Outcome

Edit Eligibility

- Sex
- Gender
- Age Limits
- Accepts Healthy Volunteers
- Eligibility Criteria: Inclusion/Exclusion

מסך עשירי

Overall Contacts

Central Contact Person:

Central Contact Backup:

Overall Study Officials:

מסך אחד עשר

Edit References

- Citations
- Links
- Available Study Data/Documents

בשלב זה יופיע על המסך סיכום המחקר לפי סעיפים

כל סעיף המודגש באדום- מולא באופן שגוי ויש לתקן

The Barzilai University Medical Center, Ashkelon
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ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
Last Update: 01/24/2017 08:33

Study Identification

	Unique Protocol ID:
	Brief Title:
	Official Title:
	Secondary IDs:

Study Status

	Record Verification:
	Overall Status:
	Study Start:
	Primary Completion:
	Study Completion:

Sponsor/Collaborators

	Sponsor:
	Responsible Party:
	Collaborators:

Oversight

	U.S. FDA-regulated Drug:
	U.S. FDA-regulated Device:
	IND/IDE Protocol:
	Human Subjects Review:
	Data Monitoring:
	Plan to Share IPD:

Study Description

	Brief Summary:
	Detailed Description:

Conditions

	Conditions:
	Keywords:

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Study Design

	Study Type:
	Primary Purpose:
	Study Phase:
	Interventional Study Model:
	Number of Arms:
	Masking:
	Allocation:
	Enrollment:

Arms and Interventions

Outcome Measures

Primary Outcome Measure:

1. [Time Frame:]

Eligibility

	Minimum Age:
	Maximum Age:
	Sex:
	Gender Based:
	Accepts Healthy Volunteers:
Inclusion Criteria: - Exclusion Criteria: -	Criteria:

Contacts/Locations

	Central Contact Person:
	Central Contact Backup:
	Study Officials:
	Locations:

References

	Citations:
	Links:
	Study Data/Documents:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

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