

# Idea Submission Tools and the HVTN Study Proposal Review Process



December 2015

HIV VACCINE  
TRIALS NETWORK

# From hvtn.org, use the Idea Submission Form



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ABOUT

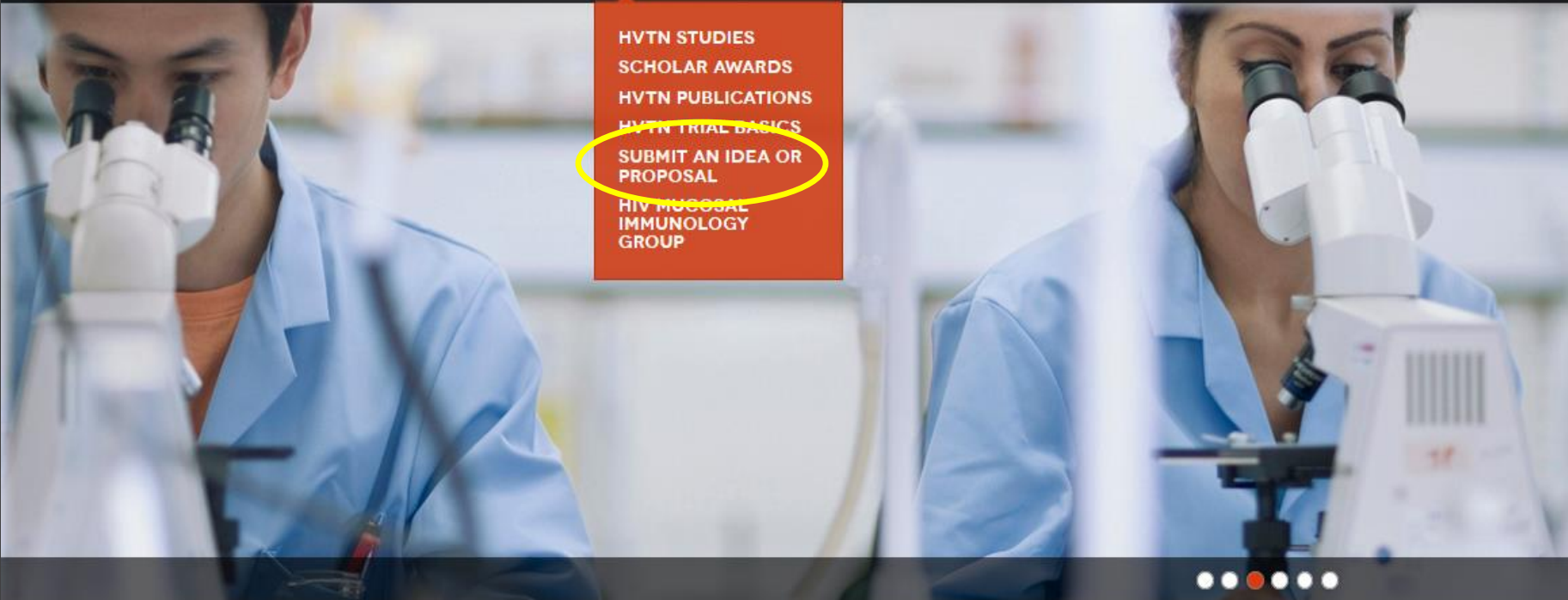
SCIENCE

PARTICIPANTS

TEAM

COMMUNITY

HVTN STUDIES  
SCHOLAR AWARDS  
HVTN PUBLICATIONS  
HVTN TRIAL BASICS  
**SUBMIT AN IDEA OR PROPOSAL**  
HIV MUCOSAL IMMUNOLOGY GROUP



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## SUBMIT AN IDEA OR PROPOSAL

The HVTN's mission is to fully characterize the safety, immunogenicity, and efficacy of HIV vaccine candidates with the goal of developing a safe, effective vaccine as rapidly as possible for prevention of HIV infections globally. As such, we welcome the ideas of the scientific community regarding new proposals for HIV vaccine studies that are not currently being planned or pursued. We also welcome proposals from investigators who would like to use our data and/or specimens collected in HVTN clinical trials to answer questions related to vaccinology, immunology, or HIV/AIDS (see [Ancillary/Exploratory Studies](#)).

To submit a proposal, click the idea submission button and fill in the required information. You will be contacted within two weeks of your proposal submission if we require more information. If further development is encouraged by HVTN leadership, we will work with you to establish the appropriate team and guide you on moving the proposal forward.

If you have any questions, or you would like to send additional materials that require formatting, such as graphs or tables, please e-mail [ytn\\_research@hvtn.org](mailto:ytn_research@hvtn.org).

> SUBMIT YOUR RESEARCH IDEA

### IN SCIENCE:

[HVTN STUDIES](#)

[SCHOLAR AWARD](#)

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View a pdf of [submission form](#)

## IDEA SUBMISSION FORM

Name\*

Phone Number\*

Email Address\*

Hypothesis\*

Objectives\*

Brief Description of Your Concept

Verification Code\*

 Refresh

Please type the characters in the box.

Submit Your Idea

Upon submitting your research idea, your idea will be assessed to determine whether or not it is within the scope of the HVTN.

If your idea is deemed within the scope of the HVTN, we will ask you to submit a formal study proposal. For studies requesting existing HVTN specimens and/or data, we will ask you to complete our HVTN Study Proposal Template.



# Completing the HVTN Study Proposal Template

The HVTN is happy to assist investigators in completing a study proposal.

Please contact [vtn.research@hvtn.org](mailto:vtn.research@hvtn.org) for assistance.

## Requested specimens, data and/or analysis

*Please inform us if you require assistance from the HVTN in completing this section.*

*Provide a detailed description of specimens/data required and assays/analyses to be conducted. Please specify the following:*

- 1) *Protocol(s)*
- 2) *Time point(s) or visit(s)*
- 3) *Treatment group(s)*
- 4) *For specimens, provide an overview of assays to be conducted*
  - a. *Provide a more detailed description of assay(s) to be conducted (e.g. drug assays, immunologic and virologic tests).*
  - b. *Provide inclusion or exclusion criterion for sample selection (e.g. participants with positive responses, females only).*
  - c. *Indicate what sample metadata will be required (e.g. treatment assignment, demographics, HLA type)*
- 5) *For study data, provide a detailed analysis plan including the data being requested as specifically as possible. Include the following when describing the request:*
  - a. *Type of data (e.g. assay, clinical, survey)*
  - b. *Sample size and variables needed*
  - c. *Power calculations for primary objectives (if appropriate)*
  - d. *If a specific format for the data is required (e.g. SAS transfer file)*



# Proposal Review Process

Proposal

Feasibility Review

Scientific Review

Regulatory Review

Specimens/data sent



## Feasibility Review

- HVTN works with investigators to fully develop proposal.
- If data and/or specimens requested, availability is confirmed.

## Scientific Review

- Proposal reviewed by relevant Protocol Team Leadership, HVTN Protocol Committee and any additional scientific review committees.
- Reviewers may request changes to proposal.



# Regulatory Review

- Investigator required to:
  - Sign HVTN confidentiality agreement, or already have an active agreement in place.
  - Agree to follow HVTN publication policy, as well as any publication language in relevant clinical trials agreement(s) and site material transfer agreement(s).
  - If requesting specimens, provide IRB/EC approval.
- HVTN complies with any site- and participant-level restrictions/requirements on use of specimens.





# Specimens/data sent

- You do your research.
- Reminder: If presenting/publishing on it, please contact [vtn.research@hvtn.org](mailto:vtn.research@hvtn.org) for inquiries or assistance in complying with publication requirements.



**Thank you**  
**We look forward to working with you!**



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