



Enhancing Human Subject Research Through Communication and Education

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Researcher frustration



- Inconsistent IRB reviews may be contradictory and are time consuming for sponsors of multi-center research.
- Researchers (and subjects) may be excluded from multi-center studies by delays in or “outside the norm” IRB review.

Most researchers and IRBs agree however that local IRBs are essential, and that a move towards centralized IRBs may be worrisome.



The Need

- The creators of **IRBNet** recognized the need for a more organized and collaborative system of research design and IRB review.
- **Dartmouth College** and the **Children's Hospital of Philadelphia** received NIH funding to collaborate on the development of a national, centralized and secure, networked IRB system.

Specific aims of IRBNet

- Educate researchers through “best practice” guidance in the development of protocol and consent forms.
- Facilitate communication among IRBs in the review of multi-centered trials
- Streamline the information required for IRB review





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COMMUNICATION

STUDY MANAGER

NEWS

2 Modules

- Study Manager
- Communication

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STUDY MANAGER

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In the Study Manager, users can:

- Attach completed protocols and consent forms
- Create and edit protocol and consent forms using the Study Designer
- Submit studies for review
- Share their study with other users...

Multi-Centered Studies

- Lead PI (or sponsor)
 - creates protocol and documents using Study Designer, or uploads completed documents
 - chooses researchers to share with from registered list of researchers from participating organizations
- Local PI
 - Automatic e-mail notification is sent to each user, documents are copied across, and only local site information needs to be added
 - Documents “translated” into local format if data elements available
 - Each user then submits documents to local IRB for review
- Lead/Local IRB Review
 - Participating IRBs can search for and share review information
 - No more re-entering all data for each institution, only local data



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The Communication Module:

- Allows IRB administrators to communicate and collaborate when reviewing studies locally and multi-site.
- Reduces IRB workload and paperwork by helping researchers to develop “best practice” studies before submission.

In the Communication Module, IRBs can

- Search and view other IRB decisions on multi-centered studies.
- Input new studies and their review status at the local site. (i.e. pending, approved, etc.)
- Communicate with other IRBs to discuss review decisions.



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Communication Module



- **Click on a study title to view documents and enter IRB review status.**
- **Communicate your local IRB decision** with participating IRBs.
- **Search** for review decisions completed by other IRBNet users.
- For reviewed studies go [here](#).

| Study Title | Local P.I. | Submission Date | IRBNet ID |
|--|----------------------|-----------------|-----------|
| Healthy Teen Project | Ardis L. Olson, M.D. | 03/18/2004 | 15427-1 |
| Double-blind, placebo, pneumonia study | Dr. Barney Rubble | 03/15/2004 | 03281-1 |
| Using biomarkers to improve the prediction of death for CABG surgery | Gerald T. O'Connonr | 02/04/2004 | 04026-1 |

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Communication Module

Study Review Details

| Study Details | |
|------------------------------|----------------------|
| Study Title | Healthy Teen Project |
| Local Principal Investigator | Ardis L. Olson, M.D. |
| Submission Date | 03/18/2004 |
| Submitted by | Cheryl Bush |
| IRBNet ID | 15427-1 |



IRB Reference Number

Review Status Approved
 Deferred
 Exempt
 Not Approved
 Simple Minor Revisions

Review Date

Expiration Date

Share review information with IRBs

Post review comments to IRBNet

Send comments to Researcher

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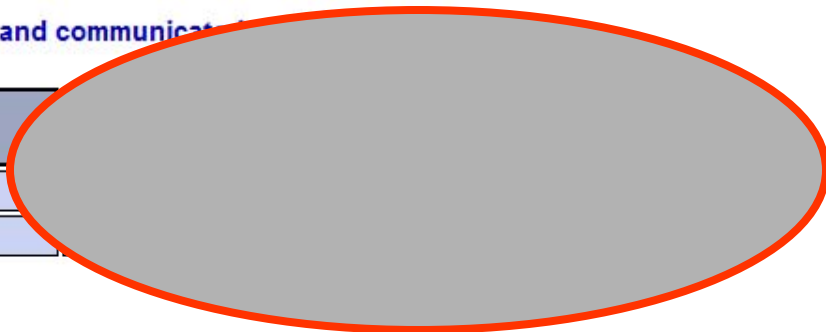
Communication Module



- Click on a **Study Title** to view study and review details.

You may **search** again or **enter a new study and communication**

Study Title



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Communication Module

Study and Review Details

| Study Details | |
|------------------------------|-------------------------------------|
| Study Title | Antihistamine effects on rhinovirus |
| IRBNet ID | 01588-1 |
| Local Principal Investigator | Rali Fanelli |

| Review Details |
|----------------|
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If this study has been submitted to your IRB, then you r



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Access restricted to valid IRBNet account holders.

Information obtained from this site may only be used for Academic and Review purposes.

Activity on this site is monitored.

Improper use will result in loss of access to the system.

Welcome to IRBNet!

The IRBNet mission is to establish an effective means of communication and streamline the exchange of information between researchers, IRBs and sponsors.

IRBNet Features:

IRBs: can receive study materials, communicate IRB decisions to local researchers and communicate with other IRBs in multi centered studies.

Researchers: can create protocols and consent forms, share study materials with IRBNet users and submit studies to their local IRB for review.

Sponsors: can attach study materials, give researchers access to study materials and view IRB decisions regarding multi-centered studies.

Click [here](#) to learn more about the IRBNet.

IRBNet was developed by Dartmouth College in collaboration with the Children's Hospital of Philadelphia.

Explore IRBNet for yourself! Please provide feedback.

WWW.IRBNET.ORG