

Key Announcements

HRPP Collaborative Review Community Portal

- A free online forum for HRPP and IRB professionals to:
 - Ask questions and share resources related to single IRB and multisite research
 - Participate in discussions and community learning
 - Join a steering committee with minimal time commitments (quarterly meetings and occasional engagement)
 - **Important reminder:** Users must manually enable notifications to receive forum updates.
 - **Sign up here!** (HRPP folks only): https://redcap.link/hrpp_crcp_interest
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Recently Released Features

Relying Site Progress Bar

New onboarding progress tracker showing:

- Study access
- Registration status
- Agreement completion
- Local context progress
- Remaining steps for site activation

Survey Downloads

Relying sites can now directly download completed HRPP and PI surveys.

Development Roadmap

In Progress

- Ability for reviewing IRBs and lead study teams to request edits directly within HRPP and PI surveys.
- Field-level comments and automated notifications for requested corrections.

Planned

- Document history tab organized by document type
 - Dashboard/metrics view for lead study teams
 - Continued API expansion and workflow enhancements
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Featured Topic: EFIC Studies in IREx

Overview - Exception From Informed Consent (EFIC) studies:

- Occur in emergency settings where consent cannot be obtained before treatment.
- Require subsequent consent discussions when feasible.
- Must include community consultation and public disclosure activities before study activation.

EFIC Workflow in IREx

Additional steps beyond a standard IREx study include:

1. Community Consultation Plan (CCP) distribution
 2. Site-specific CCP development
 3. Community engagement activities
 4. Submission of community consultation results
 5. Single IRB review and approval of outcomes
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FitBrain Trial Overview

The FitBrain trial evaluates whether administering Fresh Frozen Plasma (FFP) improves outcomes for patients with moderate-to-severe traumatic brain injury.

Study Characteristics

- Department of Defense funded
 - 8 participating institutions
 - EFIC-designated emergency research protocol
 - Patients randomized to:
 - Standard of care OR Standard of care + 2 units of FFP
 - Treatment must begin within 60 minutes of hospital arrival.
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Lessons Learned Managing an EFIC Study Through IREx

What Worked Well

- Centralized onboarding materials
- Easy dissemination of approvals
- Document version history
- Automated reminders/prompts
- API integration between IREx and Vanderbilt's eIRB System
- Reduced reliance on email attachments and file-size limitations

Challenges

- Unique setup where Northwestern served as lead site, and Vanderbilt Health served as both the Single IRB and a participating site
- Reliance processes varied considerably across participating institutions.
- Study-specific communication often required outside of the standard automated email templates.

Recommendations

- Understand each site's reliance review process early.
- Use IREx prompts/reminders to keep sites moving through onboarding.
- Consider workflow improvements for EFIC studies where one standardized Community Consultation Plan applies across all sites rather than customized templates.