



Fall 2015

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DCRI Site Community Newsletter

Welcome to the Fall edition of our newsletter.

Limited Time: Read about Pragmatic Clinical Trials

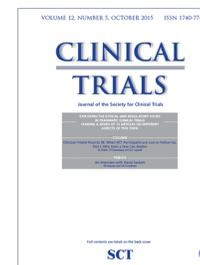
A special series of articles addressing the ethical and regulatory challenges to pragmatic clinical trials is available on the website of the journal Clinical Trials **only until November 15, 2015**.

The 12 articles were sponsored by the NIH Health Care Systems Research Collaboratory with additional support from the Patient-Centered Outcomes Research Institute, and include authors

drawn from the fields of clinical research and patient advocacy, as well as clinicians, bioethicists, and regulatory experts.

[Learn more about the series](#)

[Read the articles](#)



Proposed Changes to the Common Rule

On September 2, 2015, the U.S. Department of Health and Human Services issued a [proposed overhaul of the Common Rule](#) (45 CFR part 46).

Proposed updates include

- Improving informed consent by increasing transparency and by imposing stricter new requirements.
- Generally requiring informed consent for the use of stored biospecimens in secondary research.
- Excluding from coverage under the Common Rule certain categories of activities that should be deemed not to be research, that are inherently low risk, or where protections similar to those usually provided by IRB review are separately mandated (and adding categories of exempt research).
- Changing the conditions and requirements for waiver or alteration of consent.

And more...

Join the conversation on Twitter: @CommonRule2015.

[Provide comments to the proposed rules](#) until December 7, 2015.

New Studies Seeking Sites

Iodinated Contrast Media (ICM) Study (Pediatrics)

Thyroid Function Testing Following Iodinated Contrast Media Administration.

This study will enroll patients up to 3 years of age who are scheduled to undergo a radiologic procedure requiring iodinated contrast media. Thyroid function tests (TFTs) will be obtained prior to the procedure, and within one week after the procedure. Patients with abnormal TFTs will be followed for 1 year.

ClinicalTrials.gov Identifier: TBD

Contact:

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[Site feasibility survey](#)

Furosemide (Pediatrics)

Safety of Furosemide in Premature Infants at Risk of Bronchopulmonary Dysplasia (BPD)

This is a multi-center, randomized, placebo-controlled, dose escalating, double masked, safety study in infants < 29 weeks gestational age at birth, receiving positive airway pressure or mechanical ventilation, and 7 to 28 days postnatal age at time of first study dose.

ClinicalTrials.gov Identifier: [NCT02527798](#)

Sponsor: The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Contact:

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Visit the DCRI Community website for a current list of DCRI studies recruiting sites.

Educational Opportunities



Visit dcri.org for a list of [upcoming workshops and meetings](#).

Ongoing Opportunities

DCRI Research Conference

Join our weekly Research Conference most Tuesdays from noon-1:00 pm Eastern time. Watch live on our [YouTube channel](#) or learn more at <https://dcri.org/education-training/dcri-research-conference>.

NIH Collaboratory/PCORnet Grand Rounds

Grand Rounds is a weekly webinar hosted by the NIH Health Care Systems Research Collaboratory and PCORnet. Visit [the Grand Rounds portal page](#) to see upcoming presentations and view the video and slide archives.

DCRI Education

Focusing on education research and real-time practice improvement.

Learn more at <https://dcri.org/education/site-network-education>.

How to stay connected to the DCRI

Click the icons to connect!



Going to AHA?

Visit us at the [American Heart Association Scientific Sessions](#) Booth #537 in Orlando, Florida on **November 7-11, 2015**.

If you have any comments or suggestions, send an email and let us know what you think. dcricommunity@dm.duke.edu.