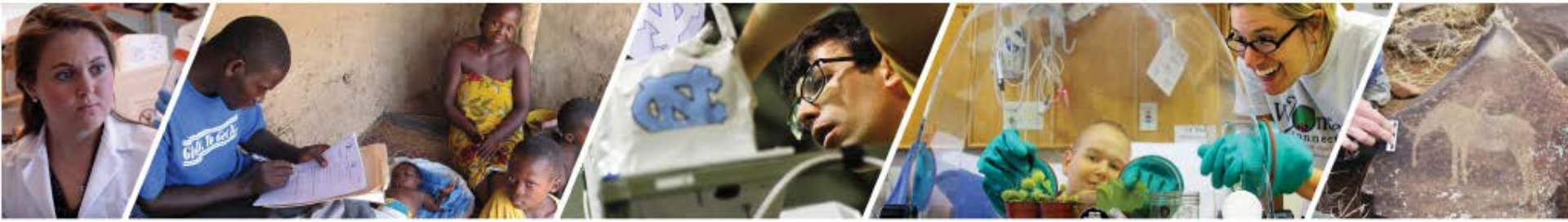
Scientific Review Committee (SRC)

Aim 1: To evaluate clinical research at UNC for scientific merit, feasibility, and validity via protocol development and review

Aim 2: To facilitate IRB review via protocol improvement and documentation of review outcomes

Presentation to UNC IRB Committees, July 2018

Caron Modeas, SRC Coordinator, UNC Office of Clinical Trials



UNC OFFICE OF CLINICAL TRIALS

UNC RESEARCH

SRC Members and Affiliations

Kimberly Brownley, PhD Associate Professor, Dept. of Psychiatry Center of Excellence for Eating Disorders Chair, Committee C and Safety Committee, Office of Human Research Ethics	John Buse, MD, PhD Professor, Medicine Chief, Division of Endocrinology Director, Diabetes Care Center Exec. Associate Dean, Clinical Research
Stephen DeCherney, MD, MPH Professor, Medicine Division of Endocrinology Adjunct Professor of Business, Kenan- Flagler School of Business	Michelle Floris-Moore, MD, MS Associate Professor, Medicine Division of Infectious Diseases Director, Infectious Diseases Fellowship Training Program
Daniel Kaufer, MD Associate Professor, Dept. of Neurology Division Chief, Cognitive Neurology and Memory Disorders Program Co-Director, Carolina Alzheimer's Network	Marianne Muhlebach, MD Professor, Pediatric Pulmonary Medicine Dept. of Pediatrics Division of Pediatric Pulmonology Faculty, NC Children's Airway Center

SRC Members and Affiliations (Continued)

Wanda Nicholson, MD, MPH, MBA
Professor, General OB/GYN
Dept. of Obstetrics and Gynecology
Director, Diabetes and Obesity Core
UNC Center for Women's Health Research

Paul Stewart, PhD
Research Professor, Dept. of Biostatistics
Gillings School of Public Health
Faculty, Biostatistics Team, NC TraCS

Michael Wagner, PhD
Research Professor, Division of Pharmaco-therapy and Experimental Therapeutics
UNC Eshelman School of Pharmacy

Recruiting for SRC members with clinical research backgrounds in:

- *General Surgery*
- *Cardiology*
- *Gastroenterology/Hepatology*
- *Rheumatology/Immunology*

Common Denominator: SRC/IRB FB Review

Clinical research involving **greater than minimal risk**

Exempted from SRC Review

- Industry-sponsored, multi-site trials
- Previous scientific review by an independent entity not involved in the research
- Oncology studies reviewed by the UNC Protocol Review Committee (PRC)
- UNC reliance on an external IRB

Distinctions between SRC and IRB Review

SRC

- Scientific Merit & Importance
- Feasibility
- Clearly Stated Aims
- Relevant Outcome Measures
- Appropriate Data Management & Safety Monitoring Plans
- Statistical Integrity
- Adherence to GCP, FDA & UNC Research Requirements

IRB

- Subjects' Rights & Welfare
- Ethical Conduct in Research
- Appropriate Background & Training of Research Personnel
- Transparency Regarding Risks and Benefits of Participation
- Equal Opportunity & Parity
- Adherence to Federal & State laws, OHRP & UNC Policies

Required Protocol Elements

The Request for SRC Review is accessed at:

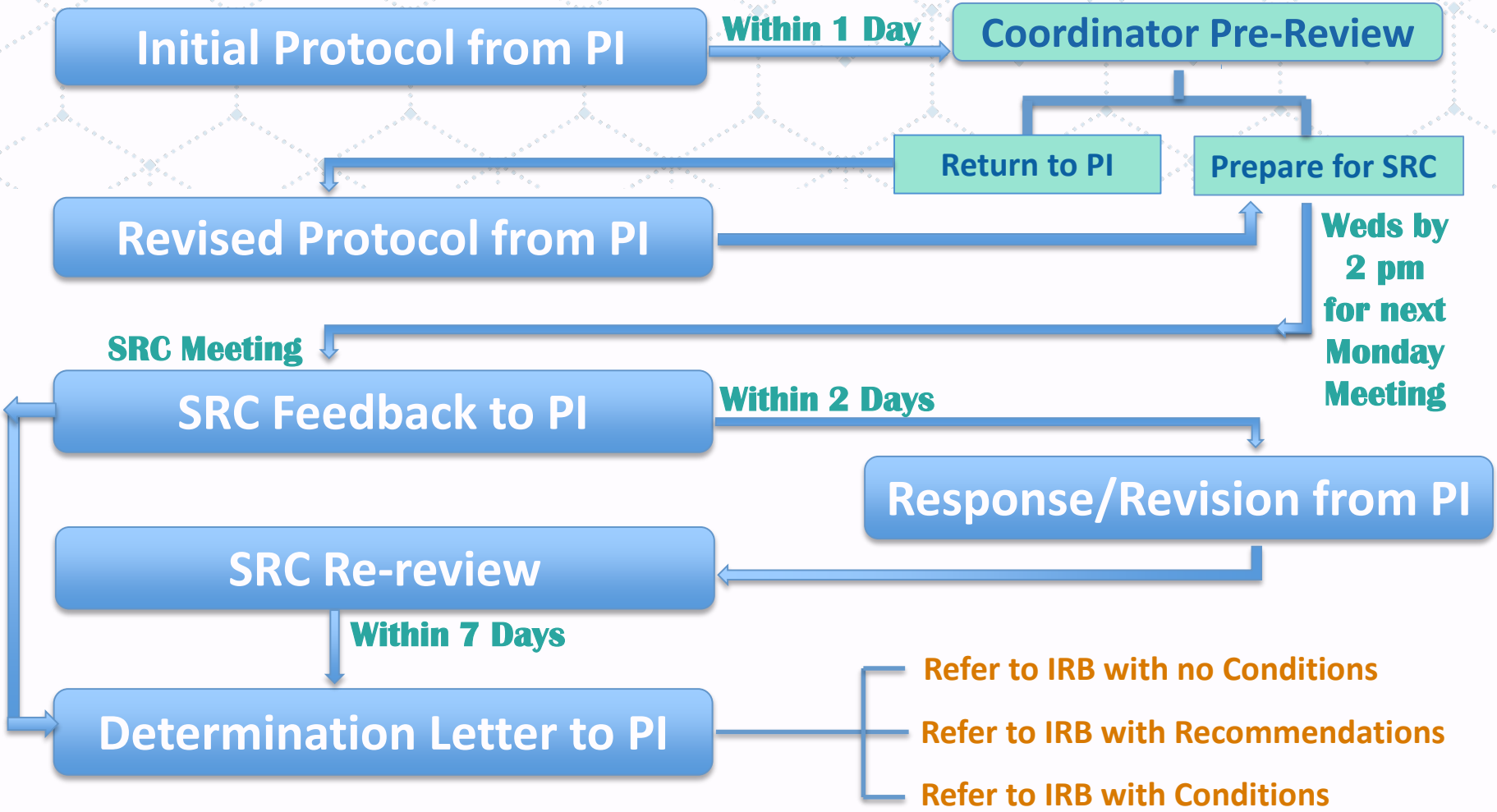
https://apps.research.unc.edu/src/index.cfm

The site describes the requirements for a full protocol to include:

Objective(s)	Background/Rationale
Study Design	Eligibility Criteria (Inclusion/Exclusion)
Outcome Measure(s)/Endpoint Justification(s)	Data Management
Safety Monitoring/Management Plan	Statistical Analysis/Sample Size Justification
Abbreviations/Acronyms (defined)	References

The SRC site also provides links to: training and consultation resources, statistical guidelines, and protocol templates (Interventional, Registry/Repository, Observational, and Retrospective Study Designs)

SRC Review Process and Timelines



Examples of SRC Determination Letters

...with no Conditions

Dear Dr. XX:

Thank you for providing your response to the SRC reviewers' comments. The modifications made to the protocol have been accepted by the reviewers. You may proceed with your IRB application for this study.

Please ensure the following documents are included with your submission:

- This cover letter
- The reviewer comments (attached)
- Protocol version/date: XX

…with Recommendations

Dear Dr. XX:

Thank you for providing the above noted protocol for scientific review. The protocol was reviewed on XX by the Scientific Review Committee with a primary, secondary, and biostatistical review. The reviewers have provided comments (attached) that the Committee encourages you to consider when finalizing your protocol; we hope you find these helpful.

You may proceed with your IRB application for this study. Please ensure the following documents are included with your submission:

- This cover letter
- The reviewer comments (attached)
- Protocol version/date: XX

…with Conditions

Dear Dr. XX:

Thank you for providing your response to the SRC reviewers' comments. The modifications made to the protocol thus far have been accepted by the reviewers. Contingent upon incorporation of final recommendations, you may proceed with your IRB application for this study.

Please ensure the following documents are included with your submission:

- This cover letter
- The reviewer comments (attached)
- Protocol version: XX