Date and Time
Place:

Call to order Time: _____

Present (18 members, 10 for quorum):

☐ Berg	☐ Honess - Alt	☐ Riker	☐ Wilcox
☐ Chessa	☐ Hinkens	☐ Ryan	
☐ D'Amato	☐ Hyrkäs	☐ Tack	
☐ Hall	☐ Larsen	☐ Trott	
☐ Harrison	☐ Morton	☐ Verdi	
☐ Higgins	☐ Nesbitt - Alt	☐ Vogel	

Ad Hoc: _____

_____

Absent: _____

Guests: _____

_____

_____

Adjourned Time:

_____ Excused at: _____

_____ Excused at: _____

_____ Excused at: _____

Excused at:

Dr. Larsen will remind all Board members to recuse themselves from any deliberation and voting on any study submitted to the IRB in which they have a potential or perceived conflict of interest. This includes, but is not limited to: service as a principal investigator, co-principal investigator, sub-investigator: receiving funding from the study; serving in a supervisory or subordinate role with the principal investigator of the study; serving as a mentor/trainee relationship with the principal investigator; a family member of the principal investigator.

Pre-meeting business

Review of Minutes from Previous meeting (s)

□ Accept as is	□ Accept with Revisions*	□ Revise & Resubmit*	*See minutes for revisions
Requested change to the minutes:_____ Minutes of this meeting recorded by:_____			

□ Accept as is	□ Accept with Revisions*	□ Revise & Resubmit*	*See minutes for revisions
Requested change to the minutes:_____ Minutes of this meeting recorded by:_____			

A. New protocols

1.

Research Coordinator:

Sponsor/Funder:

Investigator: Presenter (if not PI)

Primary and Secondary Reviewers:

Committee Review included, but was not limited to the following areas:

Investigator	□ Investigator has a CV on file at the IRB office □ Investigator has no conflict of interest that would compromise the integrity of the study
Population	□ Study does not specifically target a vulnerable population □ Study targets a vulnerable population □ Investigator is sensitive to the ethical issues surrounding research involving vulnerable subjects
IC	□ Written informed consent will be obtained from the subjects □ This study may enroll children: written informed consent will be obtained from the child's parent or guardian □ Verbal assent will be obtained when appropriate □ This study may enroll adults who are not competent to provide informed consent: written informed consent will be obtained from the subjects legally authorized representative
ICF	□ Consent document accurately describes the important aspects of this study □ The consent document is likely to be understood by study participants □ The following revisions to the consent document are required for final study approval:
BirthControl	□ Pregnancy is an exclusion criteria for this study □ Women of childbearing potential may participate in this study □ Subjects are instructed not to become pregnant during the study □ Birth control is recommended □ This study may involve men who may be sexually active □ Sexually active men are advised to use a condom during sexual intercourse
Recruitment	Subjects will be recruited from:_____ □ The person recruiting subjects will not be the subject's health-care provider □ The person recruiting subjects will be the subject's health-care provider □ A research advertisement will be used □ The method and form of advertisement are acceptable
Genetics	□ This study involves testing for genetic markers that are known to predict for the development of disease
Tissue	□ This study involves the storage of tissue for future research

	□ Tissue samples are linked to personal identifiers □ The procedures for collecting, storing, and controlling access to tissue samples appear to be adequate to protect the rights of research participants
Cost/Payment	□ This study does involve increased costs to participants relative to a research alternative □ The increase in cost is ethical in this situation and adequately explained in the consent document □ This study provides reimburse or payment to subjects for their participation in the study □ The level and schedule of reimbursement/payment is reasonable in relation to study procedures □ The investigator is sensitive to the issues of coercion and undue influence □ Subjects for whom the payment is likely to be coercive will be excluded from the study
Risks	□ The risks and discomforts of the research participation were thoroughly evaluated □ Risks are minimized by study design □ The main risks of research participation are adequately summarized in the consent document
Benefits	□ Participation in this study will not directly benefit research participants □ This study may benefit people in the future □ Participation in this study may directly benefit research participants □ Altruism is the main reason that someone would participate in this study □ Risks of research participation are reasonable in view of potential benefits
Privacy	□ Provisions to protect the privacy of subjects and the confidentiality of data are adequate □ Study design provides for ongoing monitoring for the purpose of identifying unexpected results that would indicate a need for study revision □ Data oversight will be performed by: □ PI □ Sponsor □DSMB □ CR Division

Presentation: Background and History θ Standard Therapy θ Phase θ Methods and Study Design θ
Known Side Effects / Anticipated Side Effects θ Results of Prior Human and Animal Studies θ
Patient Population θ Inclusion/Exclusion Criteria θ
Other: _____

Questions: _____

_____

_____

_____

Action Items:

Decision:

Vote: # Voting: # For: # Against:

Abstained: Name(s):

B. **Amendments: Full Board**

1.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	# Against:
	# Abstained:	Name(s):	

2.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	# Against:
	# Abstained:	Name(s):	

3.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	# Against:
	# Abstained:	Name(s):	

4.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	# Against:
	# Abstained:	Name(s):	

C. Continuing Review: Full Board

1.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	# Against:
	# Abstained:	Name(s):	

2.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	
	# Abstained:	Name(s):	

3.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	# Against:
	# Abstained:	Name(s):	

4.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	# Against:
	# Abstained:	Name(s):	

5.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	# Against:
	# Abstained:	Name(s):	

C. Continuing Review: Full Board

6.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	# Against:
	# Abstained:	Name(s):	

7.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	# Against:
	# Abstained:	Name(s):	

8.

Action Items:			
Decision:			
Vote:	# Voting:	# For:	# Against:
	# Abstained:	Name(s):	