

D2d Ancillary Study Application Review



Ancillary Study Number _____

Reviewer Name _____

Title of Proposal
(81 character limit)

Principal Investigator _____

Institutional Affiliation _____

1. Non-interference criteria (Burden Assessment)

Please evaluate the ancillary study proposal based on the following criteria:

- *Interference with the conduct of the D2d study* (ancillary studies must not interfere with or negatively influence the D2d study, participants, investigators, resources or the public image of the D2d study).
- *Burden on D2d research staff and D2d resources* (e.g. coordinating center, biological specimens)
- *Reservations or objections to proposed study*

Burden Impact Score:

Please provide a burden impact score to reflect your assessment of the burden on the participants and the conduct of the D2d study, including investigators, research staff and resources. Please use the criteria shown below when deciding on the burden impact score.

Score	Descriptor
Low	Very unlikely that ancillary study will compromise the conduct of the D2d study.
Moderate	Somewhat likely that ancillary study will compromise the conduct of the D2d study.
High	Very likely that ancillary study will compromise the conduct of the D2d study.

Burden Impact Score:

2. Other Important Criteria (Scientific Merit Assessment)

Please evaluate the ancillary study proposal based on the following criteria:

- Scientific merit with broadest range of research questions
- Use of unique characteristics of D2d population and study design
- High ratio of potential impact to participant safety and burden
- Qualifications of ancillary study investigator(s) and key persons, as documented in NIH Biosketches

Scientific Merit Impact Score:

Please provide a scientific merit impact score to reflect your assessment of the likelihood of the ancillary study to contribute to the success of the D2d study. Please use the NIH criteria, shown below, when deciding on the overall scientific impact score.

	Score	Descriptor	Additional Guidance on Strengths / Weaknesses
High Priority	1	Exceptional	Exceptionally strong with essentially no weaknesses.
	2	Outstanding	Extremely strong with negligible weaknesses.
	3	Excellent	Very strong with only some minor weaknesses.
Medium Priority	4	Very Good	Strong but with numerous minor weaknesses.
	5	Good	Strong but with at least one moderate weakness.
	6	Satisfactory	Some strengths but also some moderate weaknesses.
Low Priority	7	Fair	Some strengths but with at least one major weakness.
	8	Marginal	A few strengths and a few major weaknesses.
	9	Poor	Very few strengths and numerous major weaknesses.

Scientific Impact Score:

3. Reviewer Recommendation

Based on your overall assessment of the proposed ancillary study in terms of scientific merit and burden, please provide a recommendation for the subcommittee action.

Recommendation:

Final steps to submission:

Save a copy of this form to your computer.

Click on the "Submit" button and follow the directions to submit electronically. Alternatively, you may attach the file manually to an email and send to: D2d@TuftsMedicalCenter.org.