

Principles Guiding the TBI Biospecimen Resource Access Committee (TBI-BRAC) Review

Context: The TBI Biospecimen Resource Access Committee (TBI-BRAC) has the role of evaluating requests for access to a number of biospecimen resources for TBI related research. These resources include those led by the National Institute of Neurological Disorders and Stroke (NINDS).

TBI-BRAC activity is perhaps unique in comparison to other such adjudication committees in that the BRAC includes individual researchers who are exceptionally well acquainted with a Resource, as a result of their role in leading (“RESOURCE INVESTIGATORS”) or managing (“RESOURCE MANAGERS”) the resource. Because of their expertise, these individuals may be very helpful to requesting investigators (“REQUESTORS”) in developing and planning projects. However, such input must adhere to principles of confidentiality of NIH review.

Guidelines:

The TBI-BRAC has the following guidelines for reviewers, Resource Investigators, and Resource Managers:

- Information submitted by Requestors via the BRAC process must remain confidential within the BRAC, as per signed Confidentiality Agreements.
- Requestors are encouraged to reach out to Resource Investigators/Managers to confirm biospecimen availability prior to submission. In addition, Requestors may reach out to BRAC members prior to submission or prior to review for specific information or guidance on funding initiatives, which is acceptable and appropriate. However, if a BRAC member has advised a requestor prior to review, that BRAC member will be recused from review of that particular application.
- BRAC members should not reach out individually to Requestors based on the applications prior to review. Member input to Requestors will be incorporated in the official BRAC recommendations.
- The role of BRAC members is to evaluate the merit of the use of the requested samples for the proposed study. If BRAC members require additional information, that information will be obtained from the Requestor via the BRAC liaison, via NINDS-BRAC@ninds.nih.gov.
- BRAC members may have a research role in applications reviewed by the BRAC. In such cases, that individual must recuse themselves from BRAC review of that application. Some specific situations which may arise include but are not limited to the following:
 - BRAC members who have been invited to collaborate prior to the BRAC review will be excused from that portion of the BRAC discussion and adjudication. Resource Investigators/Managers may provide sample availability information to the BRAC prior to recusing themselves from the discussion.

- It is a breach of confidentiality for a BRAC member or Resource Investigator to unilaterally suggest a collaborative role on a project they are made aware of during the course of their activities as a BRAC reviewer, as the Requestor may feel obligated to do so in order to gain approval.
- It is inappropriate for any BRAC member to suggest remuneration to a Requestor, for any BRAC activities, or to suggest that they be included in percent effort of a grant, based on the information they receive during the course of their BRAC actions.
- BRAC meetings/calls are typically one hour, and related discussions are intended to summarize each reviewer's recommendations. The BRAC members are expected to submit their written comments in advance of the review, and those are considered by all BRAC members.
- Specific Resources may have particular guidelines, procedures, and other requirements. Once BRAC approval is given, individual Requestors will be advised to follow up with the Resource contact(s) in order to be apprised of those.
- Subsequent to BRAC consideration, Requestors will receive a synopsis of the BRAC assessment, as well as contact information for the related Resource Investigators/Managers when appropriate.

Should a BRAC member have any questions at any time regarding BRAC activities, please do not hesitate to email NINDS-BRAC@ninds.nih.gov .