Information and Instructions

for Preparing Proposals

for the

Transportation Research Board's Cooperative Research Programs

Updated May 2024

Note: Text revised since the previous edition of these instructions are highlighted in yellow



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#### I. General Information

Issuance of an RFP does not constitute an award commitment by the National Academy of Sciences' Cooperative Research Programs (CRP) of the Transportation Research Board (TRB), nor does it obligate CRP to pay for costs incurred in the preparation and submission of a proposal.

CRP does not provide pre-proposal briefings or meetings; therefore, proposals submitted in response to a request for proposals (RFP) constitutes the sole opportunity for proposers to present their expertise and qualifications.

Proposals become the property of CRP and are disposed of according to institutional policies.

#### **Nondiscrimination**

Proposers are required to comply with all applicable statutes, regulations, and orders of the U.S. Department of Transportation (U.S. DOT) relative to nondiscrimination in federally assisted programs, and shall not discriminate against any employee or other participant in the research effort because of race, color, religion, sex, or national origin. The successful bidder will be required to provide all required information and will permit access to its books, records, accounts, other sources of information, and its facilities as may be determined by CRP or the U.S. DOT.

## Who Can Respond to a Request for Proposals

There are no restrictions on who may submit a proposal in response to RFPs following a self-appraisal of qualifications to determine whether the respondent possesses, either singly or by teaming with others, the requisite capability and experience necessary to ensure successful completion of the research project. In the instance of a joint venture, a prime contractor must be designated, with justification if the prime contractor will not carry out more than 50 percent of the work (budgeted cost).

CRP research may be conducted by colleges, universities, corporations, research institutions and foundations, or consultants. Each of these entities may submit a proposal as long as it shows the possession of extensive, demonstrated capability coupled with a proven record of experience in the problem area, and no financial conflicts of interest.

CRP also encourages participation of small businesses, minority-owned firms, and women's business enterprises, as contractors or subcontractors for projects.

Although proposers based outside the United States may submit proposals in response to RFPs, and may be able to document possession of sufficient depth of knowledge of U.S. practice in the research subject areas, the complicated logistics involved in site visits and administration of contracts might make it less likely that such organizations will be selected.

#### Research Using Human Subjects

If the research approach includes human subjects testing, proposers should be aware that contracts will be subject to approval by an Institutional Review Board (IRB). This review may be conducted by the National Academies of Sciences, Engineering, and Medicine's IRB, but the National Academies will

delegate the review to the contracting agency's IRB if that agency's process meets all federal requirements for the protection of human subjects.

If an organization cannot use or partner with an external IRB, or if TRB staff believe the project merits extra attention, then TRB staff may ask the National Academies' IRB to conduct a review following its normal procedures. The National Academies; IRB can be contracted by email at <a href="IRB@NAS.EDU">IRB@NAS.EDU</a>. Please review the list of frequently asked questions in <a href="Appendix A">Appendix A</a>.

## **Copyrights**

All data, written materials, computer software, and other information prepared under the contract and the copyrights therein shall be owned by the National Academy of Sciences (NAS, the contracting authority for the National Academies of Sciences, Engineering and Medicine). The contractor and subcontractors will be able to publish this material for non-commercial purposes, for internal use, or to further academic research or studies. The contractor and subcontractors will not be allowed to sell the project material without prior approval by NAS.

By signing a contract with NAS, contractors accept legal responsibility for any copyright infringement that may exist in work done for TRB. Contractors are therefore responsible for obtaining all necessary permissions for use of copyrighted material in TRB's Cooperative Research Programs publications. For guidance on TRB's policies on using copyrighted material, please consult Section 5.4, "Use of Copyrighted Material," in the <u>Procedural Manual for Contractors Conducting Research in the Transportation Research Board's Cooperative Research Programs.</u>

#### Patents and Inventions

The disposition of patents and inventions is the responsibility of the contractor, and its obligations in this regard are set forth in the contract. Appropriate notice to NAS is required of inventions, discoveries, etc., and patent applications.

#### Insurance

Contractors shall be required to maintain either (1) insurance that provides for general liability, automobile usage, and workers' compensation and employer's liability as required by law; or (2) self-insurance that provides the equivalent coverage.

## Disposition of Equipment

Subject to acceptance by the NAS and the terms of the contract, contractors will have the opportunity to make recommendations for the retention or disposition of capital equipment acquired with project funds. If capital equipment was purchased using project funds, the federal government has the right to take possession of the equipment or require reimbursement of some of the funds used for the purchase.

<sup>&</sup>lt;sup>1</sup> http://onlinepubs.trb.org/onlinepubs/crp/docs/CRPProceduralManual.pdf

## Data Rights

The NAS shall have the right to duplicate, use, and disclose in any manner and for any purpose whatsoever all data generated under the contract, whether delivered to the NAS or not, and to authorize others to do so.

#### **II. Selection of Preferred Contractor**

Acceptable proposals (see Section IV for guidance on preparing an acceptable proposal) are sent to the panel that prepared the project statement portion of the RFP for their review. Each panelist evaluates and initially ranks the proposals using the following criteria: (1) the proposer's demonstrated understanding of the problem; (2) the merit of the proposed research approach and methodology; (3) experience, qualifications, and objectivity of the research team in the same or closely related problem area; (4) the plan for ensuring application of results; (5) the proposer's plan for ensuring diversity, equity, and inclusion and participation by Disadvantaged Business Enterprises (DBEs)—small firms owned and controlled by minorities or women; and (6) the adequacy of the facilities and equipment. The panel then reconvenes to collectively and thoroughly discuss the merits of each proposal with the overall goal of recommending the proposal that best conforms to the RFP in a manner most advantageous to the program. The recommendation is usually made by consensus, although a two-thirds vote is sometimes necessary. Panels are encouraged to identify a second-choice proposal if they believe another proposer could also successfully achieve the project objectives.

After the panel meets to review all proposals, the submitter of the panel's recommended proposal is notified. This notification includes the panel's comments on the proposal, to which a response may be required. Minor modifications to the proposal also may be indicated. The notification will also include forms to be submitted on subaward certifications and conflict of interest disclosure, along with a request for documentation to support individual cost rates, indirect cost rates, and wage/salary schedules.

Recommendation by the project panel is not a guarantee of a contract. The NAS will conduct an internal due diligence review and risk assessment. Line items of the budget are examined to determine the reasonableness of the allocation of funds to the various tasks. Proposals that provide for cost sharing at a proposed total cost over and above the total funds available are not encouraged, and the evaluation will be based on the work proposed to be conducted with the advertised funds.

The second-choice proposer is notified that it was judged to be a candidate for serious consideration and that its proposal will be held in abeyance during negotiations with the first-choice proposer. In the event that negotiations with the recommended proposer cannot be conducted successfully, TRB may negotiate a contract with the second-choice proposer.

Unsuccessful proposers will be notified, and their proposals will be disposed of in accordance with program policies. A debriefing will be provided to unsuccessful proposers at their request. The debriefing is intended to indicate to the proposers the technical areas in which their proposals were judged weak or deficient and how the weaknesses or deficiencies were factors in their evaluation. The factors constituting the basis for selection of the successful proposer will be identified, but the debriefing will not include a point-by-point comparison of all the elements considered in the evaluation criteria. Neither will there be any revelation of confidential business information, trade secrets, techniques, or

processes of the other proposers, nor will there be any indication of the relative merits or technical standing of the unsuccessful proposers.

## Contract Types

Three types of contracts may be issued: cost-reimbursement, cost-plus-fixed-fee, and fixed-price. CRP encourages the use of fixed-price contracts, although exceptions may be given based on circumstances. Regardless of the contract type, contractors must complete all research tasks and provide all contracted deliverables within the contracted budget amount. Unless specified in the contract, no additional funds will be made available. Proposers should choose the type of contract best suited to their situation. Each type is described below.

- 1. Cost-Reimbursement (CR)—This type of contract provides for payment to the contractor of allowable costs incurred in the performance of the contract, to the extent prescribed in the contract. This type of contract establishes maximum costs for purposes of (a) obligating funds and (b) setting a ceiling, which the contractor may not exceed (except at the contractor's risk) without prior approval. For this type of contract, it is essential that the contractor's cost accounting system is adequate for the determination of costs applicable to the contract and that appropriate review by National Academy of Sciences personnel during performance will provide reasonable assurance that the effort is proceeding satisfactorily.
- 2. Cost-Plus-Fixed-Fee (CPFF)—This is a cost-reimbursement contract providing for payment of a fixed fee to the contractor. Once negotiated, the fixed fee does not vary with actual costs but may be adjusted with written approval as a result of a subsequent change in the work or services to be performed under the contract. For CRP contracts, a fee limit has been established of seven (7) percent of contract costs, exclusive of the fixed fees for the subcontractor, if any. Generally, this form of contract will be used where a cost-reimbursement type of contract is determined to be necessary and there is agreement that the contract may include a contractor fee.
- 3. *Fixed-Price* (FP)—This type of contract provides for a price that is not subject to any adjustment by reason of the cost experience of the contractor in the performance of the contract. It is appropriate when reasonably definite performance specifications (research plans) are available and whenever firm and reasonable prices can be established at the outset of the effort. Monthly and quarterly progress reports, though required, are not to be considered as defined deliverables in the research plan. Payments under a fixed-price contract are made in accordance with a mutually negotiated payment and delivery schedule.

Proposers should specify their preferred contract type should their proposal be selected.

#### III. Research Administration

After the contract is executed, the contractor is expected to pursue the research aggressively and remain on schedule. TRB has developed a Procedural Manual for Contractors Conducting Research in the Transportation Research Board's Cooperative Research Programs 1 that describes the necessary administrative steps leading to successful research. Proposers should ensure that they understand all provisions in the procedural manual before submitting their proposal.

## IV. Instructions for Preparing and Submitting Proposals

#### General

Proposals are invited only in response to the issuance of RFPs by TRB. The cooperative research programs are primarily **applied research** programs that do **not** operate on a grant basis and have no funds available to support unsolicited proposals, however meritorious they may be. The projects are structured to seek practical solutions for critical problems that exist nationwide; therefore, only those proposers already having extensive, demonstrated capability and experience in the subject problem area should submit proposals. Further, it is expected that this high level of capability will be applied in meeting the commitments of the proposal.

#### **Deadlines**

The deadline for *receiving* proposals is shown on the RFP for each project statement. Proposal deadlines are rigid, and extensions are not granted. Without exception, all proposals arriving after the deadline shown on the RFP will be rejected.

Signed copies of proposals are not required.

#### Transmittal

Proposals will be submitted electronically as PDF documents via a link provided in the Request for Proposals.

The full proposal (Items 1-13) must be in a single PDF file.

A letter of transmittal is not required with the proposal package. If a proposer elects to send a transmittal letter, then 1) it must be included in the single pdf file with the full proposal, 2) it must not include information vital to the proposal, and 3) it will be counted against the 60-page limit.

#### Liability Statement

A Liability Statement is included in the RFP (see Figure 1)<sup>2</sup>. For the proposal to be accepted, all fields must be completed, the Liability Statement must be signed by an authorized official of the proposer, and the form shall not be otherwise altered in any way. It should then be scanned and saved as a PDF file and included as Section 13 of the proposal. If a completed and signed Liability Statement is not included in the proposal, or has been altered in any way, the proposal will be rejected.

<sup>&</sup>lt;sup>2</sup> https://www.nationalacademies.org/webdocs/crp-liability-statement-form/CRP-Liability-Statement-Form.pdf?channelToken=b9515dcea9b44b1caeec286a25accf32&download=false&tStamp=1714641498062

#### Presentation

Maximum file size: 10 MB.

Maximum page count: 60 pages, unless otherwise specified in the RFP.

Proposals should be designed for maximum legibility if printed out for review. A minimum 12-point type should be used for text; minimum 10-point type for budgets and captions of tables and figures. All pages should be formatted to print on  $8\frac{1}{2}$ " x 11" paper. If you use color, make sure it will be legible and correctly interpreted if printed in black and white.

All pages of the proposal shall be numbered sequentially.

Proposals must be self-contained and contain all the information outlined in these instructions. Any hyperlinks or URLs included in the proposal will not be considered in the selection process unless they are specifically requested in the RFP.

## Organization of the Proposal

A proposal that does not comply with the instructions in this brochure will not be accepted. It is mandatory that the proposal contain the following information and that it be presented in the order shown below:

- 1. Cover
- 2. Summary Page
- 3. Table of Contents
- 4. Research Plan
- 5. Qualifications and Accomplishments of the Research Team Members
- 6. Conflict of Interest and Use of Proprietary Products
- 7. Equipment and Facilities
- 8. Time Requirements
- 9. Summary of Hours by Task
- 10. Itemized Budget
- 11. Diversity and Inclusion Plan
- 12. Cooperative Features (if appropriate)
- 13. Liability Statement

For the convenience of the reviewers, the first pages of items 4 through 12 should be bookmarked from the table of contents so that information may be located quickly.

## **Details of Essential Content**

#### 1. Cover

The cover (1<sup>st</sup> page of the proposal) shall contain the program name and project number (e.g., NCHRP 01-01), the title of the project, the name of the submitting proposer, and a "Limited Use Document" clause. For guidance, an example of the desired information and layout of the cover is shown in <u>Figure 2</u>.

## 2. Summary Page

The summary page shall immediately follow the cover and shall include the information arranged as shown in Figure 3.<sup>3</sup> Note that the summary page shall contain the project number and title; the name, address, and telephone number of the proposer submitting; the name and address of any proposer with which a joint venture is proposed, if such is the case; the name and title of the person formally submitting the proposal; the name(s) and title(s) of the person(s) who actually wrote the proposal; the name(s), address(es), telephone number(s), and e-mail address(es) of the PI(s) assigned to the project; the name, address, telephone number, and e-mail address of the responsible administrative officer authorized to bind the proposer contractually for the project and to approve the expenditure of project funds; the amount of time proposed to complete the research; the total amount of the budget contained in the proposal; and the proposed contract type and amount of fixed fee, if any (refer to Section 10(k) of this document for fixed-fee limitations).

#### 3. Table of Contents

Provide bookmarks from each item in the table of contents to the appropriate section of the proposal.

#### 4. Research Plan

The research plan shall describe in detail how the research objective will be accomplished, including the submission of acceptable final deliverable(s). The plan ultimately becomes a part of the contract by reference of the proposal; therefore, it should describe in a specific and straightforward manner the proposed approach to the solution of the problem described in the project RFP. It should be concise yet include sufficient detail to describe completely the proposed approach to solving the problem. Research methodology shall be described in sufficient detail to permit evaluation of the probability of success in achieving the objectives. It is emphasized that no pre-proposal briefings or meetings with TRB staff or panels are conducted during proposal evaluation and selection. The proposal, therefore, constitutes the one and only opportunity for the proposer to state its case. The research plan shall be subdivided into the following sections:

- a. *Introduction*. The introduction to the research plan should provide a concise overview of the proposer's approach to conducting the research. It should describe (1) the manner in which the expertise and experience of the proposed team will be used in the research and (2) the availability and application of special data, facilities, contacts, or equipment needed. The introduction should highlight the linkages of the proposed team's capabilities to the project tasks and the manner by which the proposed plan will satisfy the objectives.
- b. *Research Approach*. This section should be used to describe how the objectives will be accomplished through a logical, innovative, and rational plan. The plan shall describe each phase or task of the proposed research in sufficient detail to allow an informed assessment of the likelihood of success.
- c. Anticipated Research Results. The research plan shall contain specific statements describing the anticipated research results and how their application could be promoted. Section 4(c) should include: a summary of the anticipated product(s) (e.g., mathematical models, design techniques, field or laboratory test procedures, or guidelines for recommended practice); a description of their applicability to improving current practice; and an implementation

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<sup>&</sup>lt;sup>3</sup> http://onlinepubs.trb.org/onlinepubs/crp/docs/ProposalPrep Fig3.docx

**plan**. Although the plan will likely evolve during the project, proposers should identify their initial thoughts on activities to promote product application, including the audience or "market," a realistic assessment of impediments to successful implementation, future activities necessary for successful implementation, and criteria for judging the progress and consequences of implementation. If the nature of a project is such that it is known initially that the results will not be amenable to immediate implementation into practice, this section should include recommendations for the additional work necessary to reach the implementation stage.

## 5. Qualifications and Accomplishments of the Research Team Members

Name, address, telephone number, and pertinent background information must be provided for the PI bearing primary responsibility for the project. The same information is required for other research team members participating to a significant degree. The proposal must describe how the academic, industrial, and/or research experiences of each research team member relates to the project to be undertaken. Short resumes, focused only on information relevant to the project, may be included in this section.

Proposals shall describe relevant past accomplishments of proposed research team members in the same or closely related problem area of the project to be undertaken. Include accomplishments only if the proposed team members contributed in a significant way to the success of those efforts. This description should include details concerning all known instances of application to practice of the proposer's research products. If no knowledge of such accomplishments exists, this should be stated.

In typical CRP projects, the principal investigator is an employee of the prime contractor, and the prime contractor is responsible for the majority of the time and budget. However, it is permissible to propose variations from this practice. If the team proposes a principal investigator who is not an employee of the proposed prime contractor, or if the proposed prime contractor is proposed to conduct less than 50% of the total effort (by time or budget), then this section should include: (1) n explanation of why this approach is appropriate and (2) a description of how the proposed prime contractor will ensure adequate communication and coordination with their subcontractors throughout the project.

## 6. Disclosure: Conflict of Interest and Use of Proprietary Products

- a. Section 6(a) must present information relevant to possible sources of financial or organizational conflict of interest that could be perceived as jeopardizing an objective approach to the research effort, and proposers must disclose any such circumstances. If there are none, each Proposal shall contain a certification that no conflict of interest exists. Proposals with a Research plan that includes a conflict of interest for any Investigator or related parties will not be considered for award. If a conflict of interest develops or becomes known during the conduct of research, the contract is subject to termination. A detailed definition and examples of Conflict of Interest can be found in the CRP Conflict of Interest Policy for Contractors in Appendix B. Successful proposers will be required to submit an Investigator Conflict of Interest and Disclosure Form for each named member of the research team as a prerequisite for contract negotiations.
- b. Proposers must all ensure that there are no financial conflicts of interest with members of the project panel. To avoid a potential conflict and rejection of the proposal, you must ensure that

none of the prime or subcontractors are currently employing and compensating any member of the panel.

c. Use of proprietary materials. CRP research projects may not evaluate, compare, or rank any proprietary products as part of the research that might provide those products with a competitive advantage or disadvantage. If proprietary products must be tested during the research, they will not be identified by name in any materials presented, published, or otherwise distributed. They must be described in generic terms according to their design and performance characteristics.

## 7. Equipment and Facilities

This section shall describe any equipment or facilities available to the proposer that are considered necessary to complete the research. The proposer should identify any arrangements that will be made to borrow or rent necessary equipment. Letters of commitment should be included to indicate the availability of equipment. Rental rates should be included in the budget. In the case where it is anticipated that project funds will be used to purchase additional equipment, these expenses are to be listed under "capital equipment."

## 8. Time Requirements

The time required to complete the research project shall be clearly stated in the proposal. Proposals will not be rejected if the proposed time does not match the time specified in the RFP; however, the proposer must justify any deviation from the RFP. In addition, a schedule shall be included that shows each phase or task of the work, when that phase or task will begin, how long it will continue, and when it should end. The timetable should clearly delineate the points in time at which interim deliverables and final deliverables (other than monthly and quarterly progress reports) are planned.

## 9. Summary of Hours by Task

A summary table shall be included listing **each key member of the research team, including consultants and contractors**, their role in the study, level of effort (expressed as the percentage of their time on the project over the proposed project period), and their number of hours by task. The example detailed in <u>Figure 4</u><sup>4</sup> should be followed as closely as possible. Actual hours should be shown rather than months or dollars. In addition, it is preferred that only one table be submitted rather than separate tables by task.

## 10. Itemized Budget

The estimated cost for the project should be based on the proposed performance period. Specific forms—<u>Figure 5</u><sup>5</sup> (for the proposed prime contractor) and <u>Figure 6</u><sup>6</sup> (one for each borrowed personnel, consultant, or subcontractor)—shall be used to reflect phase and/or task costs to the extent feasible. Proposals will not be accepted where budgets are in excess of the amount shown in the RFP, and budgets that provide for cost sharing at a total cost over and above the total funds available are not encouraged.

<sup>&</sup>lt;sup>4</sup> http://onlinepubs.trb.org/onlinepubs/crp/docs/ProposalPrep Fig4.xls

<sup>&</sup>lt;sup>5</sup> http://onlinepubs.trb.org/onlinepubs/crp/docs/ProposalPrep Fig5.xls

<sup>&</sup>lt;sup>6</sup> http://onlinepubs.trb.org/onlinepubs/crp/docs/ProposalPrep Fig6.xls

Full justification must be provided if the proposed prime contractor will conduct less than 50% of the work (budgeted costs). All budget information should be suitable for printing on 8½" x 11" paper. If a budget page cannot fit on a single 8½" x 11" page, it should be split over multiple pages. It is recommended that proposers use the Excel templates provided at the links above.

The format in Figure 5 should be used to reflect the costs of the proposed prime contractor only and include the following:

- a. Salaries and Wages. Each principal employee of the proposed prime contractor to participate in the performance of the project shall be identified by name, with role, unloaded hourly rate, and cost presented in the format specified in the terms of Figure 5. It is recognized that the internal policies of some agencies prevent strict conformance with this requirement. If the proposer does not break out indirect costs, but instead uses commercial wage rates, those rates should be shown in the budget and supporting documentation for those rates should be provided. Acceptable documentation includes, but is not limited to, proposer's published rate scale; or a copy of a contract or invoices documenting that the proposed labor rates have been paid by a federal/state/local government entity or other large, well-known institution.
- b. *Borrowed Personnel*. Summarize the reimbursement to other employers for salaries and wages paid by them to their employees released for, and directly engaged in, the performance of the subject research, plus federal and state payroll taxes and related employee benefit plan costs. Use Figure 6 to provide a detail breakout of these costs.
- c. *Consultants*. Summarize the costs for services of independent consultants deemed necessary for accomplishment of the research. Use Figure 6 to provide a detail breakout of these costs.
- d. *Subcontracts*. Summarize the costs for services of subcontractors deemed necessary for performance of a portion of the research. Use Figure 6 to provide a detail breakout of these costs.
- e. Capital Equipment. List items with a value in excess of \$5,000 per unit required for the conduct of the research. Any unit costing more than \$5,000 is subject to approval in advance of purchase. Only equipment needed for the research project and to be used exclusively for the research project may be included; general use equipment shall not be approved. Contractors are encouraged to consider other means of acquiring capital equipment, such as leasing.
- f. *Materials and Services*. Identify materials, supplies, and other articles, including the cost of processing; testing; rental of apparatus and equipment from others; preparing, editing, and reproducing deliverables, including the final deliverables for submission to TRB; and services not provided for in Items a, b, c, and d above. After the final deliverables have been received and accepted, their publication is the responsibility of TRB. Accordingly, the budget should provide only for preparing the number of copies as described in the RFP. If the RFP does not specify the number of copies, assume the number of copies specified in Section IV, "Research Administration," under the subsection entitled "Deliverables." Publication is the responsibility of TRB; publication costs should not be included in the proposer's cost estimate.
- g. *Communications and Shipping*. Include costs for telephone and Internet services, postage, freight, express, etc.
- h. Travel. Identify transportation costs plus the per diem allowance for lodging, meals, and

incidental expenses established by the U.S. General Services Administration (GSA), for persons working directly on the subject research. Details per trip should include number of travelers, estimated transportation (airfare, train, etc.), and per diem. While all travel shall be conducted in accordance with the research proposer's stated travel policies, travel expenses shall not exceed the prevailing federal travel regulations for such travel. Most projects include at least one meeting between key members of the research team and the project panel and CRP Program Officer; the travel costs for the research team should be included. Approval of individual trips is not required except for costs of travel to scientific and technical meetings.

- i. *Employee Benefit Plan Costs and Payroll Taxes*. Include costs of insurance and employees' pension and retirement plans and federal and state payroll taxes for employees working directly on the subject research. The current costs and taxes should be extrapolated on the basis of previous years' trends to provide the best estimates possible over the entire contract period.
- j. Overhead. Include an allowance for overhead costs determined in accordance with the proposer's usual method of accounting and generally accepted accounting principles. The current overhead rate should be extrapolated on the basis of previous years' trends to provide the best estimate possible for the anticipated contract period. Specify the rate and the base on which the overhead is applicable and include a statement supporting this rate. A negotiation agreement or statement from a federal, state, or local government agency is acceptable for this purpose. A fixed overhead rate is preferred, and the proposer may be asked to agree to fixed indirect rates. The funding allocated for the project does not allow for upward adjustment of indirect rates. If the proposer does not agree to fixed indirect rates, an upward adjustment will require a reallocation of the budget without an increase in funding.
- k. Fixed Fee. In the event the proposer desires to undertake work on this project on a cost-plus-fixed-fee (CPFF) basis, the budget shall include a line item showing the fixed-fee percentage and amount. The fixed fee, which is subject to negotiation, cannot exceed seven (7) percent of contract costs exclusive of the fixed fees for the subcontractor, if any. The subcontractor's fixed fee is also limited to seven (7) percent. The contractor is required to submit in the proposal a justification for the amount(s) included in the budget (e.g., a statement of the complexities of administration).

The costs for borrowed personnel, consultants, and subcontractors should be reflected using Figure 7. One table should be provided for each entity.

All fiscal, budget, and other pertinent information must be part of the full PDF proposal.

Cost analysis of proposals will be conducted by the project panel in coordination with the Office of Contracts and Grants to determine the reasonableness of the proposed itemized budget. A determination of the need for a pre-award audit for financial accountability purposes will be made on a case-by-case basis.

All proposed costs shall be in accordance with applicable government costs allowability requirements. Refer to OMB Circular A-21, "Cost Principles for Educational Institutions"; Circular A-87, "Cost Principles for State, Local and Indian Tribal Governments"; and Circular A-122, "Cost Principles for Non-profit Organizations." Institutions of higher education and other nonprofit recipients are required to meet all applicable audit requirements of OMB Circular A-133, "Audits of States, Local Governments, and Non-Profit Organizations."

## 11. Diversity and Inclusion Plan

The Transportation Research Board recognizes that an inclusive and diverse organization is fundamental to fulfilling the National Academy of Sciences Congressional Charter and the TRB Vision and Mission. An inclusive and diverse environment enhances innovation and creativity in all areas of TRB and is important for cultivating an equitable and supportive atmosphere. Diversity may relate to gender, racial, and ethnic profiles as well as other socio-demographic aspects, such as geographic representation, education, management level, and length of professional career.

CRP further recognizes that our research contractors are likely to be most successful and produce results relevant to all potential users when they bring diverse perspectives and experiences to their teams and research plans. TRB also encourages participation by certified DBEs; however, it does not have a minimum DBE requirement.

Item 11 of the proposal shall describe:

- a. Diversity among the research team members,
- b. How the proposed team will bring a diverse and inclusive approach to the research,
- c. Organizational policies or programs that the proposed prime contractor or any subcontractors have in place to promote and enhance diversity and inclusion.
- d. Participation in the team by DBEs. Proposers must describe their plan for DBE participation in Item 11, including a copy of the certification of each DBE (if a DBE is certified in multiple jurisdictions, **provide documentation from only one jurisdiction**). Include the anticipated dollar amount and the percentage of DBE participation relative to the total project budget. Use Figure 7 to break out the dollar amount for each DBE on the team. If a proposer's team does not include a DBE, a statement to that effect must be included in Item 11.

#### 12. Cooperative Features

If assistance in the form of personnel, data, or equipment is required from other organizations, agencies, or individuals (whether public or private), describe the plans for obtaining such assistance. Such cooperative features could include paid subcontractors, unpaid volunteer participants, donations or loans of equipment or data, or agreements to provide access to roads or other facilities. A letter of intent from agencies or individuals agreeing to provide these cooperative arrangements should be included in the proposal.

Federal, state, transit agency, or airport employees included in proposals to conduct research must also include a letter signed by appropriate authority stating that the employee's agency is aware of the proposal and approves of the employee's participation in the proposed research.

## 13. Liability Statement

See information on Figure  $1^2$ .

#### **Final Notes**

It is expected that proposers will have studied the foregoing instructions and will have complied fully with them. Failure to do so, if not warranting outright rejection, will certainly raise serious questions as to how well the proposer would handle a complex research project and would, therefore, seriously

jeopardize the chances of being selected to conduct the work. In matters that require further clarification, proposers should contact the CRP Program Officer with technical questions regarding the RFP. The name and telephone number of the staff member assigned to each project are noted on the RFP.

# Please remember that proposals must conform to the following minimum requirements or will be automatically rejected:

- 1. Proposals must be fully uploaded to the link provided in the RFP before the deadline shown on the RFP.
- 2. Proposals must include a complete, accurate, signed, and otherwise unmodified PDF copy of the Liability Statement.
- 3. Proposal budgets must not exceed the available funds stated in the RFP.
- 4. Proposals must not exceed the page limit or file size specified in the RFP.

Nothing set forth herein shall waive any provision of the contract terms and conditions, which shall be controlling and take precedence with respect to any conflicting provision included in this document.

## **Abbreviations**

ACRP Airport Cooperative Research Program

BTSCRP Behavioral Traffic Safety Cooperative Research Program

CFR Code of Federal Regulations

CPFF Cost-Plus-Fixed-Fee

CR Cost-Reimbursement

CRP Cooperative Research Programs

DBE Disadvantaged Business Enterprise

FP Fixed-Price

GSA General Services Administration

HHS U.S. Department of Health and Human Services

IRB Institutional Review Board (aka the Committee to Review Studies Involving Human

Subjects)

NAS National Academy of Sciences (the contracting authority for the National Academies of

Sciences, Engineering, and Medicine)

NCHRP National Cooperative Highway Research Program

NRC National Research Council

OMB Office of Management and Budget

RFP Request for Proposals

TCRP Transit Cooperative Research Program

TRB Transportation Research Board

## **Figures**

The figures in this section are provided for visual reference. If links to fillable PDF forms or spreadsheets have been provided above, those files should be used.

## Cooperative Research Programs

## **Liability Statement**

Revised May 2024

Project	[Project Title or # from RFP]
Title or #:	[Troject Time of a jroin Tull]

The signature of an *authorized representative of the prime proposing agency* is required on the following unaltered statement in order for the TRB to accept the agency's response for consideration. **Responses submitted without this executed and unaltered statement by the response deadline will be summarily rejected.** An executed, unaltered statement indicates the agency's intent and ability to execute a subaward that includes the provisions below.

For reference, click here to download an example of a completed Liability Statement.

**NOTE**: The "authorized representative of the prime proposing agency" <u>must</u> be an individual who has authority to enter into a contract on behalf of the proposing agency indicated below.

Prime Proposing Agency:	[Prime Proposing Agency is the name of your company or organization. <b>NOT the</b> National Academy of Sciences, Engineering, and Medicine, ACRP, TCRP, NCHRP, BTSCRP, etc.]								
Name & Title:	[Individual with Contracting Authority for Prime Proposing Agency]								
Signature:									

#### SUBAWARDEE LIABILITY

- (a) The parties agree that the subawardee and its employees and agents ("Subawardee") will be primarily responsible for performing the work required under the subaward, and shall therefore be legally responsible for, and shall indemnify and hold the Academy harmless for all claims asserted against the Academy, its committee members, officers, employees, and agents, by any third parties, whether or not represented by a final judgment, if such claims arise out of or result from Subawardee's negligent or wrongful acts in performing such work, including all claims for bodily injury (including death), personal injury, property damage, and other losses, liabilities, costs, and expenses (including but not limited to attorneys fees).
- (b) With respect to entities of State government that are subject to State law restrictions on their ability to indemnify and hold harmless third parties ("Restricted State Entities"), the obligation to indemnify and hold harmless the Academy in Paragraph (a) shall apply to the full extent permitted by applicable State law. In addition, each Restricted State Entity executing this subaward represents and warrants that no part of any research product or other material delivered by such Restricted State Entity to the Academy ("Work Product") shall include anything of an obscene, libelous, defamatory, disparaging, or injurious nature; that neither the Work Product nor the title to the Work Product will infringe upon any copyright, patent, property right, personal right, or other right; and that all statements in the Subawardee's proposal to the Academy and in the Work Product are true to the Subawardee's actual knowledge and belief, or based upon reasonable research for accuracy.
- (c) The term "wrongful act" as used herein shall include any tortious act or omission, willful misconduct, failure to comply with Federal or state governmental requirements, copyright or patent infringement, libel, slander or other defamatory or disparaging statement in any written deliverable required under the subaward, or any false or negligent statement or omission made by Subawardee in its proposal to the Academy.
- (d) The obligations in paragraph (a) of this clause to indemnify and hold harmless the Academy shall not extend to claims, damages, losses, liabilities, costs, and expenses to the extent they arise out of the negligent or wrongful acts or omissions of the Academy, its committee members, officers, employees, and agents.
- (e) Both the Academy and Subawardee shall give prompt notice to each other upon learning of the assertion of any claim, or the commencement of any action or proceeding, in respect of which a claim under this paragraph may be sought, specifying, if known, the facts pertaining thereto and an estimate of the amount of the liability arising therefrom, but no failure to give such notice shall relieve the Academy or Subawardee of any liability hereunder except to the extent actual prejudice is suffered thereby.
- (f) The Academy and Subawardee agree to cooperate with each other in the defense of any claim, action, or legal proceeding arising out of or resulting from Subawardee's performance of the work required under this subaward, but each party shall control its own defense. The Academy shall also have the option in its sole discretion to permit Subawardee or its insurance carrier to assume the defense of any such claims against the Academy.
- (g) The obligations under this clause survive the termination, expiration, or completion of performance under this subaward.

## Figure 2

## **Example Cover Page**

#### NCHRP1

## **Project Number**

(Insert appropriate project number, e.g., 02-04, 05-07A, 10-12(02).)

## **Project Title**

(as shown on RFP)

# TRANSPORTATION RESEARCH BOARD NAS-NRC LIMITED USE DOCUMENT

This proposal is for use of recipient in selection of a researcher to conduct work under the National Cooperative Highway Research Program.<sup>2</sup> If the proposal is unsuccessful, it is to be returned to the NCHRP.<sup>1</sup> Proposals are regarded as fully privileged, and dissemination of the information included therein must be approved by the NCHRP.<sup>1</sup>

## **Proposer Name**

<sup>&</sup>lt;sup>1</sup> The appropriate program acronym should be used (i.e., NCHRP, TCRP, ACRP, or BTSCRP).

<sup>&</sup>lt;sup>2</sup> The appropriate program title should be used.

## Figure 3

# **Example Summary Page**

## **SUMMARY PAGE**

NCHRP¹ Project (Use number	on project statement RFP)
"(Title as shown on project stat	ement RFP)"
Proposer:	(Name that will appear on contract; include address and phone number)
Person Submitting Proposal:	(Name and title)
Proposal Written by:	(Name and title)
Proposal Date:	
Principal Investigator:	(Name and title, address, telephone number, and e-mail address)
Administrative Officer:	(Name and title, address, telephone number, and e-mail address)
Proposed Contract Period: (In r	months)
Total Contract Amount:	\$
Proposed Contract Type:	(Cost-reimbursement, cost-plus-fixed-fee, or fixed-price)
Fixed-Fee Portion at%:	\$ (Only if proposing a cost-plus-fixed-fee contract)

<sup>&</sup>lt;sup>1</sup> Use the appropriate program acronym (i.e., NCHRP, TCRP, ACRP, or BTSCRP).

Figure 4
Effort By Tasks (Hours and Costs) XCRP Project No. XX-XX

			Hours							
Names of Principal Staff Members	Role in Study	Time (%) Over Contract Period **	Task 1	Task 2	Task 3	Task 4	Task 5	Total	Hourly Rate (\$)	Cost
PRIME (Company Na	me)									
J. Smith	Proj Principal	3.1%	8	16	16	8	16	64	\$ 85.00	\$ 5,440.00
S. Jones	Principal Investigato	33.2%	24	120	240	150	160	694	\$ 70.00	\$ 48,580.00
E. Gonzalez	Jr. Planner	36.7%	24	160	300	122	160	766	\$ 60.00	\$ 45,960.00
R. Kim	Admin	6.5%	16	24	16	40	40	136	\$ 35.00	\$ 4,760.00
Subtotal			72	320	572	320	376	1660		
										\$ -
BORROWED PERSO	NNEL 1 (Company N	lame)								\$ -
M Martinez	Researcher	4.0%	8	20	20	20	16	84	\$ 40.00	\$ 3,360.00
K. Bala	Researcher	34.5%	40	120	200	200	160	720	\$ 40.00	\$ 28,800.00
T. Richards	Jr. Planner	19.3%	12	60	150	100	80	402	\$ 60.00	\$ 24,120.00
P. Lee	Admin	3.1%	8	8	8	20	20	64	\$ 35.00	\$ 2,240.00
Subtotal			68	208	378	340	276	1270		\$ -
										\$ -
SUBCONTRACTOR 1	` ' '									\$ -
M. Huange	Legal Advisor	1.9%	4	10	10	8	8	40	\$125.00	\$ 5,000.00
H McDonnell	Engineer	16.3%	20	60	100	80	80	340	\$ 75.00	
A. Robinson	Transp. Planner	9.9%	6	30	80	50	40	206	\$ 70.00	\$ 14,420.00
G. Thomas	Admin	1.4%	4	4	4	10	8	30	\$ 35.00	\$ 1,050.00
Subtotal		29.5%	34	104	194	148	136	616		\$ -
										\$ -
SUBCONTRACTOR 2	` ' '									\$ -
R Colon	Research Specialist	8.0%	16	40	40	40	32	168	\$ 45.00	\$ 7,560.00
Subtotal			16	40	40	40	32	168		\$ -
										\$ -
GRAND TOTAL PRO	JECT		190	672	1184	848	820	3714		\$191,290.00
Notes:										Contract
* Include Subcontract	ors and Consultants									months
** Total hours divided	by 174 hours/month	divided by conti	act month	ns.						<u>12</u>

Figure 5
Prime Contract Budget Detail XCRP Project No. XX-XX\*

		T	ask 1		Task 2	T	Task 3		1	Task 4		Т	ask 5		Total	
(a) Salaries and Wages (Prime)																
	Direct															
	Hourly															
Name Role in Study	Rate	Hours	Cost	Hours	Cost	Hours	(	Cost	Hours	(	Cost	Hours	Cost	Hours		Cost
			\$ -		\$ -		\$	·		\$	-		\$ -		\$	-
			\$ -		\$ -		\$	-		\$	-		\$ -		\$	-
			\$ -		\$ -		\$	-		\$	-		\$ -		\$	
			\$ -		\$ -		\$	-		\$	-		\$ -		\$	-
Subtotal		1	\$ -	1	\$ -		\$	-		\$	-		\$ -		\$	-
			·		1.								•			
(b) Borrowed Borrowed (0)																
(b) Borrowed Personnel (2)		<b>!</b>			1.6								•			
Entity Name 1		_	\$ -	4	\$ -		\$	-		\$	-		\$ -		\$	-
Entity Name 2		_	\$ -	1	\$ -	ı	\$	-		\$	-		\$ -	ı	\$	-
Subtotal			\$ -		\$ -		\$			\$	-		\$ -		\$	-
(c ) Consultants (2)		<del>                                     </del>		1												
Entity Name 1			\$ -	1	\$ -		\$			\$	-		\$ -		\$	-
Entity Name 2		1 !	\$ -	1	\$ -	1	\$	-		\$	-		\$ -	1	\$	-
Subtotal		1	\$ -	1	\$ -	1	\$	-		\$	-		\$ -	1	\$	
			•		1 .								•			
(d) Subcontracts (2)		Ì														
Entity Name 1			\$ -		\$ -		\$	-		\$	-		\$ -		\$	-
Entity Name 2		1	\$ -	1	\$ -	1	\$	-		\$	-		\$ -	1	\$	-
Subtotal			\$ -	1	\$ -	1	\$	-		\$	-		\$ -	1	\$	-
		'			1.											
(e) Capital Equipment (Prime)																
Item 1		l .	\$ -		-	<b>.</b>	\$	-		\$	-		\$ -		\$	
Item 2		-	\$ -	-	\$ -	4	\$	-		\$			\$ -	1	\$	
Subtotal		-	\$ -	-	\$ -	1	\$	-		\$	-		\$ -	1	\$	
Cubicital			<u> </u>		Ψ -		Ψ			Ψ			•		Ψ	
(f) Materials and Services (Prime)																
Item 1			\$ -		\$ -		\$	-		\$	-		\$ -		\$	-
Item 2			\$ -	1	\$ -	1	\$	-		\$	-		\$ -	1	\$	-
Item 3		1	\$ -	1	\$ -	1	\$	-		\$	-		\$ -	1	\$	-
Subtotal			\$ -		\$ -		\$	-		\$	-		\$ -		\$	-
(g) Communications and Shipping (Prime)																
Item 1		<del>                                     </del>	\$ -	<del></del>	T\$ -	<del>                                     </del>	\$	-		\$			\$ -	-	\$	
Item 2		4	\$ -	-	\$ -	ł	\$	-		\$	-		\$ -	ł	\$	
Item 3		<b>-</b>		1		1	\$			\$				1	\$	
Subtotal		-	\$ - \$ -	ł	\$ -	ł	\$	-		\$	-		\$ -	ł	\$	-
Subiotal			ş -	1	Φ -		ą	-		ą			<b>3</b> -		φ	
(h) Travel (Prime)																
Trip 1 Description			\$ -		\$ -		\$	-		\$	-		\$ -		\$	-
Trip 2 Description		1	\$ -	1	\$ -	1	\$	-		\$	-		\$ -	1	\$	-
Trip 3 Description		1	\$ -	1	\$ -	1	\$	-		\$	-		\$ -	1	\$	-
Subtotal			\$ -		\$ -		\$	-		\$	-		\$ -		\$	-
(i) Employee Benefit Plan & Payroll Taxes (Pri	me)		\$ -	1	\$ -		\$	-		\$	-		\$ -		\$	-
					1											
(j) Overhead (Prime)			\$ -	-	\$ -		\$			\$	-		\$ -		\$	-
(k) Fixed Fee (Prime)(3)	Rate: 7.00%		\$ -	1	\$ -		\$	-		\$	-		\$ -		\$	-
CRAND TOTAL DROJECT	•		•		1.6		•			•			•		•	
GRAND TOTAL PROJECT			\$ -		\$ -		\$	-		\$	-		\$ -		\$	-
		tract months.														

<sup>(2)</sup> Use Figure x to provide detail for borrowed personnel, consultants, and subcontractors.

(3) Maximum fee of 7%, exclusive of fixed fees for subcontractors.

<sup>\*</sup>Use this form for prime contract only.

Figure 6

## Borrowed Personnel, Consultant, and Subcontract Budget Detail XCRP Project No. XX-XX\*

<b>Entity Name:</b>	

Salaries and Wages		Task 1		7	Task 2	Task 3		Task 4		Task 5		
Name	Role in Study	Loaded Hourly Rate**	Hours	Cost	Hours	Cost	Hours	Cost	Hours	Cost \$ -	Hours	Cost
				\$ - \$ -		\$ - \$ -		\$ - \$ -		\$ - \$ -		\$ - \$ -
Subtotal				\$ - \$ -		\$ -		\$ -		\$ - \$ -		\$ -
Capital Equipment Item 1 Item 2 Subtotal				\$ -		\$ -		\$ -	1	\$ -		\$ -  \$ -
Materials and Services Item 1 Item 2 Item 3 Subtotal				\$ - \$ - \$ - \$ -		\$ - \$ - \$ - \$ -		\$ - \$ - \$ - \$ -		\$ - \$ - \$ - \$ -		\$ - \$ - \$ - \$ -
Communications and S Item 1 Item 2 Item 3 Subtotal	Shipping			\$ - \$ - \$ - \$ -		\$ - \$ - \$ - \$ -		\$ - \$ - \$ - \$ -		\$ - \$ - \$ - \$ -		\$ - \$ - \$ - \$ -
Travel Trip 1 Trip 2 Trip 3 Subtotal				\$ - \$ - \$ -		\$ - \$ - \$ -		\$ - \$ - \$ -		\$ - \$ - \$ -		\$ - \$ - \$ - \$ -
TOTAL (Salaries & Wag	ges plus Expenses)			\$ -		\$ -		\$ -		\$ -		\$ -

<sup>\*</sup>Use this form for borrowed personnel, consultants, and subcontractors, one form per entity.

<sup>\*\*</sup>Including direct costs, indirect costs, and fixed fee (up to 7%).

Figure 7

Diversity and Inclusion Participation Plan

Proposer	Date
Program and Project Number	

	Relationship to	Prime (Check One)		
Company Name	Prime	Subcontractor	DBE Certifying Body	Budgeted Amount (\$)

Instructions: In the table above, list each DBE on your team, its relationship to the lead proposer, the DBE certifying body, and the dollar amount budgeted.

Please attach DBE certification.

## Appendix A. Institutional Review Board Transportation Research Board (TRB) Cooperative Research Programs (CRP) Frequently Asked Questions

This document is designed to illustrate responsible conduct for research on human subjects and to provide a brief overview of Institutional Review Board (IRB)<sup>A1</sup> protections. The document is not exhaustive, and simply provides basic background information on IRB and confidentiality protocols. Links to sources and additional information are provided at the end of the document.

#### **Contents**

What is research on human subjects?	24
What sorts of harm can arise from research on human subjects?	25
What is an Institutional Review Board?	26
When does a project need IRB review?	28
What happens if my institution does not have an Institutional Review Board?	27
What happens if/when IRB regulations are not followed?	27
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## What is research on human subjects?

As defined in federal regulations (see "What is an IRB" below), "human subjects" are living individuals "about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information." An example of an intervention is a field test of driver reaction to different traffic signs; an example of an interaction is a survey.

Other examples of research on human subjects could include before-and-after attitudinal assessments of people who attended workshops or webinars if the intent is to publish the results, present them at a professional meeting, or otherwise use them to advance generalizable knowledge. Research like this, as well as stand-alone questionnaires and interviews, *may* be exempt from further IRB review *unless* individual human subjects can be directly identified or identified through personal information linked to them (e.g., names, phone numbers, addresses) and disclosure of their responses could place them at risk of criminal/civil liability or damage their financial standing, employability, or reputation. (NSF)

Some interactions with human subjects are not considered "research with human subjects" under federal regulations, and there is no need in these cases to seek an exemption or approval from an IRB. Such research includes before-and-after assessments that are intended solely for internal use (e.g., responses to questions on how well meeting logistics worked to improve future meetings). Such research also

<sup>&</sup>lt;sup>A1</sup> An Institutional Review Board (IRB), or research ethics committee, provides core protection for human research participants through advance and periodic independent review of the ethical acceptability of proposals for human research. (Grady, 2015)

includes interviews or surveys conducted with individuals who are providing factual information on behalf of their organization.

## What sorts of harm can arise from research on human subjects?

Some typical examples of harms that can arise from research on human subjects include:

- Harms commensurate with daily life (these do not require special protection):
  - *Mere inconvenience* when a survey or other research interaction is administered at an inconvenient time or place or simply takes a long time to administer.
- Harms that have the potential for serious effects (which IRBs should examine):
  - *Emotional or psychological harm*, for example, when a research interaction causes upset, or worries about a breach of confidentiality.
  - Social harm due to stigma or other negative social outcomes of breach of confidentiality.
  - Physical harm if revelations about others get back to those persons, particularly when researchers study domestic violence, gang activity, political activity in a conflict zone, or other phenomena concerning violence-prone individuals.
  - Financial harm if revelations result in loss of employment or insurance coverage.
  - Legal harm when illegal activities are disclosed.
  - *Moral harm* when participation in research strengthens subjects' inclinations to behave unethically.

#### What is an Institutional Review Board?

IRBs are administrative bodies established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which an IRB is affiliated.

The IRB is charged with the responsibility of reviewing, prior to its initiation, all research (whether funded or not) involving human participants. The IRB is concerned with protecting the welfare, rights, and privacy of human subjects. (Oregon State, 2019)

Federal regulations give the IRB the authority to: approve, disapprove, or modify research; conduct continuing reviews; observe and verify changes to research; suspend or terminate approval; and observe the consent process and the research procedures.

Three core principles serve as the foundation for regulations and guidelines. They are: respect for persons, beneficence, and justice. The application of these principles occurs through informed consent, A2 assessment of risks and benefits, and selection of subjects.

<sup>&</sup>lt;sup>A2</sup> Informed consent is "a legally-effective, voluntary agreement that is given by a prospective research participant following comprehension and consideration of all relevant information pertinent to the decision to participate in a study." (National

Every institution that receives federal funding for research with human subjects must establish an IRB "in accord with and for the purposes expressed in" Title 45 Code of Federal Regulations (CFR) Part 46. This set of regulations includes four subparts. Subpart A, better known as "the Common Rule," describes the required protections for all human subjects and provides the overall rule of ethics in the United States for research involving human subjects. Subparts B-D provide additional protections for pregnant women, human fetuses, neonates, prisoners, and children. The regulations do not specify additional protections for other vulnerable groups (e.g., mentally disabled, economically/educationally disadvantaged), but they do require investigators to include additional safeguards in projects to protect their rights and welfare "when some or all of the subjects are likely to be vulnerable to coercion or

The National Academies has its own Institutional Review Board, but the Office of Legal Counsel has determined that TRB Cooperative Research Programs should generally have the IRB of the organization to which TRB has contracted the research conduct the IRB review when human subjects are involved. For exceptions, see below under "What happens if my institution does not have an Institutional Review Board?"

#### When does a project need IRB review?

undue influence." (45 CFR 46.111)

A project needs IRB review if there is a systematic collection of quantitative or qualitative information that is intended to contribute to generalizable knowledge *and* the project involves human subjects. IRBs are to evaluate all protocols based on consideration of: (1) risk to subjects; (2) adequacy of protection against these risks; (3) potential benefits of the research to the subjects and others; and (4) importance of the knowledge gained or to be gained.

If the research involves human subjects, it will be reviewed at one of three levels: (1) full board review, (2) expedited review, and (3) exempt review. Federal regulations describe categories of research on human subjects that may be exempt from regulatory requirements, including IRB oversight. However, the authority to determine if research is exempt should rest with the IRB or another entity officially designated by the institution (i.e., a researcher may not "self-exempt" their study from IRB review). That is, all research involving human subjects should be reviewed by an IRB or officially designated entity to determine if it is approved, disapproved, needs modification, or is exempt. The level of oversight for a project should be matched to the level of risk to human subjects.

For CRP, all projects involving human subjects must be submitted to an IRB for review and either receive IRB approval or be granted exemption from human subjects regulations before an award can be made. Applicants should file their proposal with their IRB<sup>A3</sup> at the same time the proposal is submitted to the CRP so that any approval procedure determined as necessary will not delay the award process. A proposal may be submitted to CRP prior to receiving IRB approval or being granted exemption; however, if the proposal is selected for funding, the award will be made conditional upon IRB granting approval or exemption from human subjects regulations within 60 days of the notice of conditional award. If the project involves research on human subjects, the contractor shall comply with the U.S.

Institutes of Health) Written consent can be waived and oral or implicit consent given under some circumstances (e.g., an online or mail survey, in which the respondent is free to respond or not and response can be taken to indicate consent).

A3 This may be the IRB of the applicant's institution or another IRB that has agreed to be the IRB of record for the applicant's project (see "What happens if my institution does not have an Institutional Review Board" section).

Department of Health and Human Services (HHS) Regulations (Title 45 Code of Federal Regulations Part 46) regarding the protection of human research subjects, unless that research is exempt as specified in the regulation.

If a proposed project involving human subjects is granted exemption from human subjects regulations [see 45 CFR 46.104], the applicant must provide documentation that an IRB (or the appropriate authority other than the project director or key personnel) has declared the project exempt from the human subjects regulations. Documentation should include the specific category justifying the exemption. Organizations without internal access to an IRB must seek approval or exemption from an independent review board or other appropriate authority (see "What happens if my institution does not have an IRB" section below).

## What happens if my institution does not have an Institutional Review Board?

According to federal regulations, all research on human subjects must be reviewed and/or overseen by an IRB or ethics committee, regardless of where the research is conducted. Investigators at institutions without IRBs can: (1) not conduct human subjects research, (2) limit research studies to those that can be classified as "non-research" or "non-human subject," or (3) find and work with an IRB or ethics committee to review and approve their research.

Investigators lacking an IRB can either undertake the process of starting one at their institution, use an external/commercial IRB (sometimes referred to as an Independent Review Board), or partner with an institution that has an IRB that is willing to serve as the IRB of record for the study. (Rice 2008) If an organization cannot use or partner with an external IRB or if TRB staff believe the project merits extra attention, then TRB staff may ask the National Academies' IRB to conduct a review following its normal procedures. The National Academies' IRB can be contacted by email at IRB@NAS.EDU.

## What happens if/when IRB regulations are not followed?

During CRP's conditional awarding of a contract, proof of IRB approval or exemption is a requirement. Funding may be withheld if IRB approval or exemption is not provided.

If CRP awards a contract to a project director/institution who indicated they were not carrying out research on human subjects but is found to be conducting research on human subjects, CRP could consider that a material failure to comply with the terms and conditions of the contract. In such a case, CRP could terminate the contract for cause and require repayment. In addition, since contractors are solely responsible for any liabilities that may arise in connection with the performance of a project if the impermissible research on human subjects resulted in a claim against CRP, the contractor could potentially be obligated to indemnify CRP for costs related to that claim.

Furthermore, the HHS Office for Human Research Protections is responsible for enforcing compliance with the regulations. If IRB regulations are not followed, consequences could include suspension of the research project or of all of a primary investigator's research projects; inability to use or publish research results; notification of noncompliance to sponsors, regulatory agencies, and funding agencies; inability to receive federal funding; additional monitoring and oversight by the IRB; termination of employment;

loss of licenses; and/or immediate shutdown of all research at an organization/institution (45 CFR 46; Rutgers).

## References, Additional Web Links, and Resources

Additional resources about IRB policies and procedures (including sources used to assemble this document) are available on the following websites:

- Health and Human Services Office for Human Research Protections
  - Human Subject Regulations Decision Charts
  - IRBs and Assurances
- National Institutes of Health
- National Science Foundation
  - Frequently Asked Questions & Vignettes
- Oregon State University Office of Research Integrity
- Rutgers University Office of Research Regulatory Affairs eIRB

Federal Committee on Statistical Methodology, Confidentiality and Data Access Committee (CDAC). 2018. CDAC: Resources for Confidentiality and Data Access Information.

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National Research Council. 2000. *Improving Access to and Confidentiality of Research Data: Report of a Workshop.* Washington, DC: The National Academies Press. <a href="https://doi.org/10.17226/9958">https://doi.org/10.17226/9958</a>.

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Rice, TW. 2008. How to Do Human-Subjects Research If You Do Not Have an Institutional Review Board. Respiratory Care. 53 (10) 1362-1367.

U.S. Department of Justice, Office of Justice Programs. Sieber, J. 2001. <u>Summary of Human Subjects Protection Issues Related to Large Sample Surveys.</u>

# Appendix B. Transportation Research Board (TRB) Cooperative Research Program (CRP) Conflict of Interest Disclosure Policy

To meet institutional obligations and commitments and pursuant to Section 2-1 of the National Academy of Sciences (NAS) Procurement Supplement entitled "Identifying Conflicts of Interest," it is essential that any contractor, supplier, vendor, or subawardee, which shall include any individual or entity who participates at any stage in a CRP procurement or subaward activity not be compromised by any conflict of interest, or by the direct and substantial appearance of a conflict of interest ("Conflict of Interest"), with respect to such activities.

Each named member of the proposed CRP research team, including the prime contractor and all subcontractors, must disclose all of his or her Conflicts of Interest, including those related to his or her employer or other Entity described below, and those of the team member's spouse, domestic partner, and dependent children that are related to the Research, as described in more detail below. The team members are not charged with deciding whether a specific interest or relationship constitutes a conflict of interest or could affect the design, conduct, or reporting of the Research. NAS has the sole responsibility for determining whether a conflict of interest exists with respect to a specific Research Project.

Conflict of interest Section of Each Proposal to the CRP. Each Proposal shall include a section on Conflict of Interest that presents information relevant to possible sources of financial or organizational conflict of interest that could be perceived as jeopardizing an objective approach to the research effort, and proposers must disclose any such circumstances. If there are none, each Proposal shall contain a certification that no conflict of interest exists. Proposals with a Research plan that includes a conflict of interest for any Investigator or related parties will not be considered for award. If a conflict of interest develops or becomes known during the conduct of research, the contract is subject to termination.

Definition of Conflict of Interest: It is a conflict of interest for organizations, investigators, or investigation team members, as defined below ("Investigator"), who have a <u>current</u> financial conflict of interest with respect to issues that are the subject of the Research. There is a conflict of interest if any Investigator has a *financial interest* that could be affected directly and predictably by the outcome of the Research, as described in more detail below. For example, a conflict of interest includes any Research where an Investigator on a CRP research project team will review or develop standards or guidelines affecting products, including manufactured goods, materials, models, software, or processes, in which they have any financial interest as described below.

#### Disqualifying Financial Conflicts of Interest

An Investigator may not be retained for a Research project if the Investigator has a financial conflict of interest with respect to the issues to be addressed by the Research. The Investigator's employer, or other entity described in item 3 below, shall also have a disqualifying conflict of interest.

An Investigator has a conflict with respect to a Research project in any of the following circumstances:

- 1. The Investigator has a financial interest that could be affected directly and predictably by the outcome of the Research.
- 2. The Investigator's spouse, domestic partner, or dependent child has a financial interest that could be affected directly and predictably by the outcome of the Research; or
- 3. The Investigator has a current relationship with an Entity that has a financial interest that could be directly and predictably affected by the outcome of the committee's work if the relationship involves
  - i. a business partnership or employment;
  - ii. the provision of **compensated** advisory or consulting services, including compensated service on a scientific or technical advisory board;
  - iii. the provision of representation services or service as an expert witness, whether compensated or not:
  - iv. service as an officer, director, trustee, or other fiduciary of the entity, whether compensated or not: or
  - v. research support for the Investigator, except for research support that is awarded based on merit without restrictions on the conduct of the research or the publication of the results.

Financial interests include stocks, bonds, and other financial instruments and investments; patents, copyrights, and other intellectual property interests; and ownership interests in for-profit business enterprises. Financial interests do **not** include any financial asset with a value of less than \$15,000 or diversified mutual funds and similarly diversified investments. There is no minimum threshold for income or compensation.

The term "conflict of interest" applies not only to the personal interests of each Investigator but also to the *interests of others* with whom the Investigator has substantial common financial interests. Thus, in assessing an Investigator's potential conflicts of interest, consideration will be given not only to the interests of the Investigator, but also to the interests of the Investigator's spouse, domestic partner, and dependent children, and any Entity with whom the Investigator has substantial common financial interests. Consideration will also be given to the interests of those for whom the Investigator is acting in a fiduciary or similar capacity (e.g., serving as an officer or director of a corporation, whether profit or nonprofit, or serving as a trustee).

"Investigator" means the Principal Investigator, and all other named members of the proposed research team if they are employed by the prime contractor or any of the subcontractors.

"Research" means an investigation, study, or experiment designed to contribute to generalizable knowledge relating broadly to transportation, including **any** project under the CRP Program. This term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a test or product).

The conclusion that an actual or apparent conflict of interest exists is not intended to be an assessment of any Investigator's actual behavior or character. The exclusion of an Investigator with a conflict of interest from a Research project is intended to avoid a potentially compromising situation, thereby protecting the Investigator; NAS, TRB, and CRP; and the public interest.

The institutional response to a potential conflict of interest, or the direct and substantial appearance of a conflict of interest, is to avoid contracting with the Investigator or their employer to the extent necessary to eliminate the conflict. When requested by NAS, Investigators will be required to submit an Investigator Conflict of Interest and Disclosure Form before any subaward process will be initiated. Anyone added to the team during the course of the subaward must also submit a form. Failure of the Investigator to disclose a relevant Financial Interest, or to update their Investigator Conflict of Interest and Disclosure Form, may result in termination of a subaward, at the sole discretion of NAS, and may result in a suspension or prohibition of receiving future CRP funding by the Investigator and the entity. Any false statement, misrepresentation, or material omission may also subject the Investigator and entity to liability for damages, and to prosecution to the fullest extent permitted under applicable laws.

The Director, Office of Contract and Grants, has the primary responsibility for the administration of this policy, in consultation with the Executive Director, TRB, and the NRC Executive Office.