

Application Instructions for
Research ND
Research ND BIO
FAST Track

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1.00 GENERAL PROVISIONS

1.01 PROGRAM PURPOSE

Research ND creates economic activity through the development of new technologies. Through Research ND, private partners have the opportunity to leverage their research, development and commercialization funds to gain access to the extensive research base of North Dakota's research universities - North Dakota State University and the University of North Dakota.

Through Research ND, firms have the opportunity to leverage their research, development and commercialization funds and gain access to the creative talents and extensive research base of North Dakota's Research Universities. Research ND matching funds are awarded on a competitive basis for projects based on proposals submitted jointly by researchers from one North Dakota's Research Universities and companies.

1.02 LEGISLATION

1.02a N.D.C.C. § 54-65-06 Research North Dakota Grants

"The department shall establish and administer a research North Dakota grant program to provide grants to a research university for research, development, and commercialization activities related to a private sector partner. The centers of excellence commission, established under chapter 15-69, shall make grant award determinations under this section. The department shall work with the centers of excellence commission in establishing guidelines to qualify for a grant under this section, including the requirement that an application must be accompanied by a partnership agreement between the private sector partner and a research university. The agreement must include details regarding the scope of the work, the budget, the location of the work to be completed, the intellectual property ownership rights, and the intellectual property income distribution. The commission may approve changes to the scope of the work or the budget only to the extent that the changes are agreed upon by the private sector partner and the research university. Before the commission directs the department to distribute funds awarded under this section, the research university shall provide the commission with detailed documentation of private sector participation and the availability of one dollar of matching funds for each dollar of state funds to be distributed. Matching funds must be in the form of cash and may not include in-kind assets."

1.02b Section 30 of Chapter 49 of the 2013 Session Laws

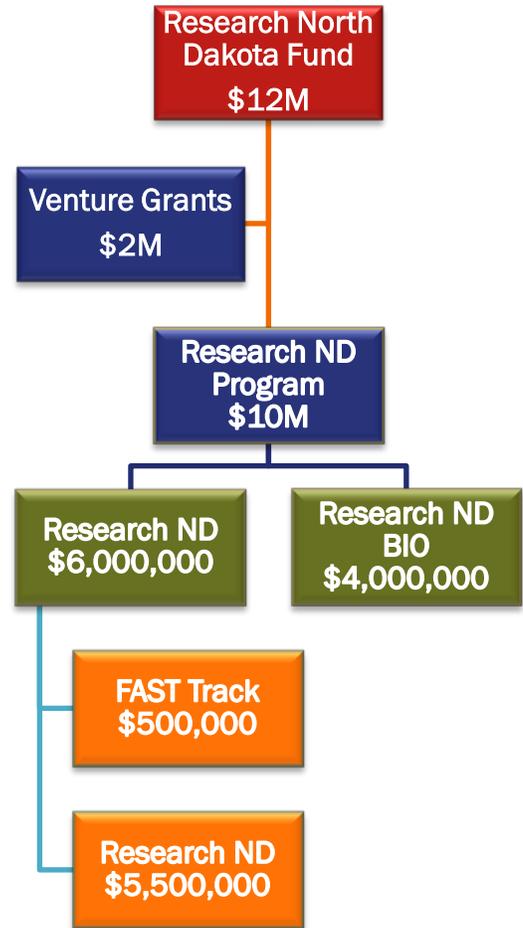
"The office of management and budget shall transfer the amount appropriated in the research North Dakota line item in section 1 of this Act to the research North Dakota fund for the purpose of implementing and administering the research North Dakota grant program and the research North Dakota venture grant program, for the biennium beginning July 1, 2013, and ending June 30, 2015. The department of commerce may use up to \$2,000,000 of the funds transferred to the research North Dakota fund for venture grants. The department of commerce shall use \$4,000,000 of the funds transferred to the research North Dakota fund for research North Dakota grants to conduct research on and develop and commercialize vaccines and antibodies for the prevention of, treatment of, or cure for cancer; virally infectious diseases; or other pathogens, including bacteria, mycobacteria, fungi, and parasites."

1.03 RESEARCH ND FUND

Twelve million dollars was designated for the Research ND fund by the 63rd Legislative Assembly. Two million dollars has been designated to support the commercialization of intellectual property developed at North Dakota Research Universities through Spinoffs or Startup companies locating in North Dakota.

The remaining \$10,000,000 of the Research ND fund will fund Research ND and Research ND BIO for the purpose helping to fund research, development and commercialization activities related to the private sector. Four million dollars of these funds (Research ND BIO) have been designated toward projects "...to conduct research on and develop and commercialize vaccines and antibodies for the prevention of, treatment of, or cure for cancer; virally infectious diseases; or other pathogens, including bacteria, mycobacteria, fungi, and parasites." The remaining \$6,000,000 (Research ND) may be used to fund research development and commercialization activities related to the private sector across all industry sectors. Initially, \$500,000 of the Research ND funds have been allocated to a sub-program entitled FAST Track. FAST Track has been developed to allow the Program to respond rapidly to industry needs by providing a mechanism of funding that can be approved administratively within the strictures of these policies.

The Commission may utilize up to 2.5% of the funds appropriated to the Research ND fund during the 2013-2015 biennium for administrative expenses. Administrative costs may include economic impact studies, printing expenses, audits, or attorney's fees. Commerce shall have the authority to pay program-related administrative expenses up to \$2,500 without prior direction from the Commission. Commerce shall notify the Commission of any such expenditure during a subsequent Commission meeting.



1.04 PROGRAM DESCRIPTIONS

1.04a Research ND

Research ND promotes the development and commercialization of products and processes through industry/university research partnerships. This program is open to all industry sectors with priority being granted to industry sectors that are targeted or identified within the Economic Development Foundations current strategic plan (www.commerce.nd.gov/resources).

Research ND: Matching funds may be granted up to \$300,000 per project.

The Commission may review Applications for Research ND funding requesting up to \$500,000 in matching funds. Any projects requesting funding in excess of \$300,000 shall have to strongly justify the need for Matching Funds in excess of the \$300,000 award limit.

The Commission reserves the right to request that any proposal submitted for funding in excess of \$300,000 be broken down into Phases. The project may then be approved in its entirety but each Phase of the proposal will be funded as if it were a separate project according to the Programs disbursement policy. Funding for each subsequent Phase of the project is contingent upon the Commission's agreement that the milestones, objectives and goals of the previous Phase have been completed and there is sufficient cause for the project to continue.

1.04b Research ND BIO

A sub-program of Research ND specifically to provide matching grants to a Research University “to conduct research on and develop and commercialize vaccines and antibodies for the prevention of, treatment of, or cure for cancer; virally infectious disease; or other pathogens, including bacteria, mycobacteria, fungi and parasites” (Section 30 of Chapter 49 of the 2013 Session Laws) in conjunction with a Private Sector Partner.

Research ND BIO: Matching funds may be granted up to \$1,000,000 per project.

Applications for Research ND BIO funding in excess of \$500,000 shall submit a single proposal encompassing the entire project that is broken down into Phases where the Research ND BIO portion of the budget is limited to no more than \$500,000. The project may be approved in its entirety but each Phase of the proposal will be funded as if it were a separate project according to the Programs disbursement policy. Funding for each subsequent Phase of the project is contingent upon the Commission’s agreement that the milestones, objectives and goals of the previous Phase have been completed and there is sufficient cause for the project to continue.

1.04c FAST Track

The FAST Track program has been designed as a sub-program under Research ND for projects with a limited budget, short duration (no more than three (3) months) and a compelling need to begin on short notice.

FAST Track Program: Matching funds may be granted up to \$50,000 per project.

1.05 RIGHTS TO INTELLECTUAL PROPERTY

Matters with regard to Intellectual Property (e.g. intellectual property ownership, distribution of royalty payments, licensing fees) shall be defined in a binding agreement between the Research University and the PSP before the application is submitted. The Research University shall abide by State Board of Higher Education policy 611.2. The Commission and the North Department of Commerce do not reserve the right to any of the Intellectual Property that may be generated as part of funding through Research ND or any of its subprograms.

1.06 DEFINITIONS

Applicant: A Research University in partnership with the private sector which is applying for a matching grant from the Research ND Fund.

Application: The written document that is submitted to the Commission for consideration under the Research ND program.

Authorized Representative: An individual from either the Research University or the Private Sector Partner authorized by their representative organization to sign agreements.

Award: Funds distributed after a grant application has been approved and an agreement signed.

Award Agreement: A document describing the rights and duties of the Commission, Research University and Private Sector Partner. This document must be signed by all parties after a grant application has been approved and prior to award funds being distributed.

Cash: Funds from the Private Sector Partner provided to the Research University for use on the project’s scope of work.

Cash reserved: Cash to be spent by the Private Sector Partner on expenses directly related to the approved project.

Commission: The Centers of Excellence Commission or its representatives.

Fund: Means the Research North Dakota Fund available to the Commission to provide funding for the Program as authorized in N.D.C.C. § 54-65-06.

Grant: The monetary award made by the Commission to a Research University under the Program.

Grantee: The Research University which has been awarded a Grant from the Fund.

Errors: Significant inaccuracies, inconsistencies, omissions, or incorrect formatting identified in the application.

Matching Funds: Funds provided to the Research University from the Fund for work on an approved project.

Partnership Agreement: An agreement between the Private Sector Partner and a Research University that must include details regarding the scope of the work, the budget, the location of the work to be completed, the intellectual property ownership rights, and the intellectual property income distribution. (As defined in N.D.C.C. § 54-65-06.)

Principal Investigator: The Research University's lead scientific contact.

Private Sector: Businesses and industries that are not owned or controlled by the government.

Private Sector Funds: Any combination of Cash or Cash Reserved invested in a project by the Private Sector Partner in an amount of at least \$1 for every \$1 of matching funds requested by the Application in accordance with N.D.C.C. § 54-65-06.

Private Sector Partner: Any private sector entity that has entered into a Partnership Agreement with a Research University and submitted an application under one of the Research ND programs.

Project Budget: Total of Private Sector Funds and Research ND Funds to be applied to a project.

Project Director: The lead scientific contact from the Private Sector Partner.

Program: Any of the programs under the authority of the Commission utilizing Research ND funds.

Program Manager: The person designated by the Commerce Commissioner to provide the Commission with technical, administrative and economic development support.

Research University: An institution under the control of the North Dakota State Board of Higher Education which has a full-time student enrollment in excess of nine thousand students.

Research University Budget: The total of Cash from the Private Sector Partner and Matching Funds provided by Research ND.

Significance: The importance of the problem or critical barrier to progress that the proposed project addresses.

Spinoff business: The creation of an independent company through the sale or distribution of new shares of an existing business/division of a parent company. A spinoff is a type of divestiture.

Startup business: A company that is in the first stage of its operations. These companies are often initially bank rolled by their entrepreneurial founders as they attempt to capitalize on developing a product or service for which they believe there is a demand.

Subcontract: The term subcontract will be used to represent subcontracts, sub-awards, and consortium for the purposes of these policies.

Substantial Presence: The business must have its principal office in North Dakota and have the majority of its business activity performed in this state, except sales activity, or have a significant operation in North Dakota that has or is projected to have more than ten employees or \$150,000 of sales annually.

Technical Reviewers: Independent technical reviewers contracted through a third party to review the merits of the application.

1.07 ABBREVIATIONS

PI – Principal Investigator

PD – Project Director

PSP – Private Sector Partner

1.08 PRIVATE SECTOR MATCH

For the Research ND and Research ND BIO awards, the grant from the State may not exceed fifty percent of the total project cost. Commission funding must be matched with private sector funds.

For Research ND and Research ND BIO awards the matching funds may include the following:

1. Cash given to the university for use on the approved project;
2. Cash reserved by the private sector to be spent on expenses directly related to the approved project (salaries, benefits, travel, direct expenses); or
3. A combination of the above to meet the match requirements in statute.

For the FAST Track Program all matching funds MUST be as cash given to the Research University.

Matching funds are limited to those expenses directly related to the project. If an application includes private sector salaries/benefits as match for a project only the portion of the individual(s) salary spent for time working directly on the outlined project may be counted as match.

Funds spent prior to the application date will not count toward the project match.

Funds received from other state programs (e.g. North Dakota Development Fund, Renewable Energy Council, Oil and Gas Research) by the private sector may not be used as match for this program.

2.00. INSTRUCTIONS FOR PREPARING AND SUBMITTING AN APPLICATION

2.01 OVERVIEW

An application must be direct, concise, and informative. The application form (SFN 60452) is available at www.researchnd.com or may be obtained by contacting the North Dakota Department of Commerce at the address listed below. It must be prepared according to the instructions.

For Research ND, Research ND BIO, and FAST Track applications this is a joint application between a ND Research University and a PSP. The application needs to present a cohesive picture of the work to be done, the impact to the private sector, and clearly delineate the responsibilities of the Research University and the PSP. The completed application should be reviewed through both the Research University and PSP's organizational review process prior to submission through the Research University's normal grant submission process.

The completed application should be reviewed through both the Research University and PSP's organizational review process.

Coordinate with an Authorized Organization Representative (AOR) at the Research University to submit the application by the date specified in the Research ND Solicitation.

2.02 SOFTWARE REQUIREMENTS

The Application is supplied is a fillable pdf. The application may be filled out using Adobe Acrobat or Adobe Acrobat Reader. A free version of Adobe Acrobat Reader may downloaded from <http://get.adobe.com/reader/>.

2.03 DOCUMENTS FOR SUBMISSION

The Application may be submitted as multiple files (the main pdf and Appendices). Scanning paper documents except those pages requiring signatures is to be avoided.

2.04 FORMATTING SPECIFICATIONS

2.04a Page Limits

Section of Application		Page Limits
I.	Abstract	Must fit in box provided
II.	Project Description Justification Project Description	1 page 11 pages
III.	Technological and Economic Impact	1 pages
IV.	Confidential Information	2 pages
V.	Budget (Research University)	2 pages per year of project
VI.	Budget Justification (Research University)	2 pages per year of project
VII.	Budget (Private Sector Match)	2 pages per year of project
VIII.	Budget Justification (Private Sector Match)	2 pages per year of project
IX.	Biographical Sketch PI PD Other key personnel	4 pages 4 pages 2 pages
X.	Facilities and Equipment	2 pages
XI.	Subcontract Budget and Justification	2 pages

2.04b Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes: Figures, charts, diagrams and tables may be included with the application either in the main body of the application or included in a separate Appendix. All information provided in a separate Appendix will be counted toward the page limitations identified above. Figure Legends may use a smaller type size but it must be in a black font color and readily legible. Color may be used in figures, graphs, diagrams, and charts.

2.04c Grantsmanship: Use English and avoid jargon. If terms are not universally known, spell out the term the first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

2.05 SIMILAR, ESSENTIALLY IDENTICAL, OR IDENTICAL APPLICATIONS:

Research ND will not accept similar grant applications with essentially the same research focus from the same primary sector organizations. This includes derivative or multiple applications that propose to develop a single product, process or service that, with non-substantive modifications, can be applied to a variety of purposes. Applicant organizations should ascertain and assure that the

materials they are submitting on behalf of the PI are the original work of the PI and have not been used elsewhere in the preparation and submission of a similar grant application.

Individual applications from a single Research University with different PSPs may have similar research focus as long as the work on the projects is being done independently.

2.06 SUBMITTING YOUR APPLICATION

The Authorized Organization Representative (AOR) from the Research University is the only official with the authority to actually submit applications to the Research ND program. Therefore the PI and PD will need to work closely with the Research University AOR to determine that all the necessary steps have been accomplished prior to submitting an application. This includes any internal review process required by the applicant organization.

AORs from each Research University may contact the Program Manager to be given login and password information to submit completed applications to the Research ND program via an FTP site.

2.07 APPLICATION SUBMISSION DATES

Applications will be accepted on a quarterly basis for Research ND Program and its subprogram Research ND BIO depending on the availability of funds.

Grant Cycle	Submission Deadline
1	November 22, 2013
2	February 21, 2014
3	May 23, 2014
4	August 22, 2014
5	November 21, 2014
6	February 20, 2015
7	May 22, 2015

Applications submitted for the dates listed above considered on time if they are time stamped by FTP server on or before 5:00 PM local time for the submitting Research University.

FAST Track applications will be accepted throughout the biennium depending on the availability of funds. Please contact the Program Manager if considering a FAST Track application so arrangements can be made to insure the Program Manager or designee is available to review the Application.

The applications will initially be reviewed after submission to insure that the applications are complete and meet the eligibility requirements of the program. If errors are found in the application, the applicants can either return the amended application within 48 hours of receiving notification of the errors or resubmit the application for a later funding round assuming funds are still available.

3.00 COMPLETING RESEARCH ND APPLICATION

3.01 OVERVIEW

This section contains all of the instructions you will need to complete the Research ND application. Please note that conformance to all instructions is required and strictly enforced.

3.02 APPLICATION

1. Type of Submission: Check one of the Type of Submission boxes.

Instructions for Research ND, Research ND BIO and FAST Track

Research ND: The Research ND program was established by law during the 63rd Legislative Session of ND (N.D.C.C § 54-65-06). It is intended to stimulate partnerships between ND research universities and business concerns. This program is designed to assist these partnerships in several areas including; but not limited to:

1. Commercialization of new technologies
2. Help with research and development of new products
3. Improve existing products or processes

Research ND BIO: Four (4) million dollars of the Research ND program funds were legislatively mandated to be used specifically “to conduct research on and develop and commercialize vaccines and antibodies for the prevention of, treatment of, or cure for cancer; virally infectious disease; or other pathogens, including bacteria, mycobacteria, fungi and parasites” (Section 30 of Chapter 49 of the 2013 Session Laws).

Joint projects between the private sector and a Research University proposing projects that meet the above criteria would check Box 1b. If a project meets the above criteria and checks Box 1a the Department of Commerce may administratively designate the project to the correct program.

FAST Track: The FAST Track program has been designed as a sub-program under Research ND which can be approved of administratively. To be funded under this program, a project needs to meet the following criteria

- a) Have an expected project duration of less than three (3) months;
- b) Involve only PSP(s) registered with the ND Secretary of State’s office with significant operations in ND that has or is projected to have by the end of the project period more than ten employees or \$150,000 of sales annually;
- c) The states portion of project costs is \$50,000 or less; and
- d) The cost sharing/matching funds will be provided as a cash payment to the Research University.

Title of Application: Enter a brief descriptive title of the project. This field is required. Each new application must have a different title from any other Research ND, Research ND BIO or FAST Track project by the same PI.

Date Submitted: Enter the date the application is submitted to the Department of Commerce Office of Innovation and Entrepreneurship.

Proposed Project Starting Date: Enter the anticipated start date of the project

Proposed Project Ending Date: Enter the anticipated ending date of the project

2. Funding: Enter information into these boxes based on the projects budget page

Requested State Funds: Enter the amount of state funds that are being requested for the project. Funds requested in this section must conform to the restrictions on project size as stated in the Research ND Policies and in Section 1.04 of these instructions.

Private Sector Cash to Center: Enter the amount of Private Sector Funds for the project that will be given directly to the Research University for work on the project.

Private Sector Cash Reserved: Enter the amount of Private Sector Funds that will be expended by the PSP for their role in the project. Included in this box are funds expended by the PSP for salaries, fringe benefits, subcontracts, materials, and supplies directly related to the project.

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Total Project Cost: This field will automatically calculate the total project cost based on the figures entered into the previous three fields.

3. Research University: This box contains information related to the Research University.

Name: Enter the name of the Research University.

DUNS: Enter the DUNS number of the Research University if available.

EIN: Enter the Research University's EIN or TIN as assigned by the Internal Revenue Service.

Mailing Address: Enter the Research University's main mailing address including street, city and ZIP code.

4. Principal Investigator (Research University)

Name: Enter the last, first, and middle names of the PI for the Research University in this box delineated by commas. First and last names are required, the middle name is optional.

Degree(s): Enter the degrees held by the Research University's PI.

Position/Title: Enter the Position/Title of the PI.

Department/Service/Laboratory/Equivalent: Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization to which the PI is assigned or that will undertake the proposed activity.

Mailing Address: Enter the complete mailing address of the Research University's PI.

Major Subdivision: Enter the name of the primary organizational division, office, or major submission, to which the Research University PI is assigned or that will undertake the proposed activity.

Email Address: Enter the primary email address of the PI.

Telephone Number: Enter the daytime phone number of the PI.

Fax Number: Enter the fax number for the PI.

5. Administrative Official to be Notified if Award is Made:

This information is for the Administrative or Business Official, not the PI. This person is the individual to be notified if additional information is needed and/or if an award is made.

Name: Enter the name of the Research University's Administrative Official in this box. First and last names are required, the middle name is optional.

Title: Enter the Position/Title of the Research University's Administrative Official

Mailing Address: Enter the complete mailing address of the Research University's Administrative Official.

Telephone Number: Enter the daytime phone number for the Research University's Administrative Official.

Fax Number: Enter the fax number for the Research University's Administrative Official.

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Email Address: Enter the primary email address for the Research University's Administrative Official..

6. Official Signing for Research University:

This information is for the individual with signing authority for the Research University, not the PI.

Name: Enter the name of the Official Signing for the Research University in this box. First and last names are required, the middle name is optional.

Title: Enter the Position/Title of the Official Signing for the Research University.

Mailing Address: Enter the complete mailing address of the Official Signing for the Research University.

Telephone Number: Enter the daytime phone number for the Official Signing for the Research University. and fax numbers for the PI.

Fax Number: Enter the fax number for the Official Signing for the Research University.

Email Address: Enter the primary email address of the Official Signing for the Research University.

Signature: Space for the signature of the Official Signing for the Research University.

Date: Date that the form was signed by the Official Signing for the Research University.

7. Private Sector Partner: This box contains information related to the projects PSP.

Company Name: Enter the name of the PSP.

DUNS: Enter the DUNS number of the PSP if available.

EIN: Enter the PSP's EIN or TIN as assigned by the Internal Revenue Service.

Mailing Address: Enter the PSP's main mailing address including street, city and ZIP code.

Registered with the ND Secretary of State's Office?: Indicate if the PSP is registered to do business in North Dakota with ND Secretary of State's office.

Substantial Presence in ND: Indicate if the PSP meets the definition of a "substantial presence" in ND or plans to meet this requirement by the end of the project. If this box is checked Yes, how the company meets or will meet this requirement needs to be clearly stated in section 14.

Technologic and Economic Impacts of the Application.

8. Project Director (Private Sector)

Name: Enter the last, first, and middle names of the PD for the PSP in this box delineated by commas. First and last names are required, the middle name is optional.

Degree(s): Enter the degrees held by the PD.

Position/Title: Enter the Position/Title of the PD.

Department/Service/Laboratory/Equivalent: Enter the name of the primary organizational department, service, laboratory, or equivalent level within the organization to which the PD is assigned or that will undertake the proposed activity.

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Mailing Address: Enter the complete mailing address of the PD.

Major Subdivision: Enter the name of the primary organizational division, office, or major submission, to which the PD is assigned or that will undertake the proposed activity.

Email Address: Enter the primary email address of the PD.

Telephone Number: Enter the daytime phone number of the PD.

Fax Number: Enter the fax number for the PD.

9. Official Signing for Private Sector:

This information is for the individual with signing authority for the private sector, not the PD. This person should have the appropriate authority to obligate funds for the PSP and be able to fulfill the financial reporting requirements of Research ND, Research ND BIO and/or FAST Track.

Name: Enter the last, first, and middle names of the Official with signing authority for the Private Sector in this box delineated by commas. First and last names are required, the middle name is optional.

Title: Enter the position/Title of the Official Signing for the Private Sector

Mailing Address: Enter the complete mailing address of the Official Signing for the Private Sector.

Telephone Number: Enter the daytime phone and fax numbers for the Official Signing for the Private Sector.

Fax Number: Enter the daytime phone and fax numbers for the Official Signing for the Private Sector.

Email Address: Enter the primary email address for the Official Signing for the Private Sector.

Signature: Signature of the Official Signing for the Private Sector.

Date: Date that the form was signed by the Official Signing for the Private Sector.

10. Abstract:

The Abstract must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Abstract must not include any proprietary/confidential information.

11. Checklist (Research University)

This section should be completed by the PI. Instructions are in the following section *12. Checklist (Private Sector Partner)*.

12. Checklist (Private Sector Partner)

This section should be completed by the PD.

Are Human Subjects Involved?: If activities involving human subjects are planned at any time during the proposed project at any performance site, check yes. Check yes even if the proposed project is exempt from Regulations for the Protection of Human Subjects. If activities involving

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human subjects are not planned at any time during the proposed project at any performance site, select no and skip the rest of block 1. This field is required.

If YES to Human Subjects: Is the Project Exempt from Federal Regulations?

If the project is exempt from Federal regulations, check Yes.

If the project is not exempt from Federal regulations, check No.

If EXEMPT, check appropriate exemption number:

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph **2**) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If not EXEMPT, is the IRB review Pending?

If IRB approval has been granted or is pending, check Yes.

If IRB review has not been sought, check No.

IRB Approval is not required at the time of submission.

Human Subject Assurance Number: Enter the approved Federal Wide Assurance (FWA) that the applicant has on file with the Office for Human Research Protections, if available. If the applicant has a FWA number, enter the 8-digit number.

Insert "None" if the applicant organization does not have an approved assurance on file with OHRP. In this case, the applicant organization, by the signature in item 19 on the SF424 (R&R) Cover component, is declaring that it will comply with 45 CFR part 46 and proceed to obtain a human subjects assurances (see <http://www.hhs.gov/ohrp>).

Is this a biomedical or behavioral research study involving drugs, treatments, devices, or new ways of using known drugs, treatments, or devices?: Check YES or NO

If yes, will the requested funds be used for a clinical trial?: Check YES or NO

If yes, which Phase?: Check the box corresponding to the Clinical Trial Phases defined below.

Instructions for Research ND, Research ND BIO and FAST Track

Phase I Clinical Trial: Phase I clinical trials are done to test a new biomedical or behavioral intervention in a small group of people (e.g. 20-80) for the first time to evaluate safety (e.g. determine a safe dosage range, and identify side effects).

Phase II Clinical Trial: Phase II clinical trials are done to study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

Phase III Clinical Trial: Phase III studies are done to study the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

Phase IV Clinical Trial: Phase IV studies are done after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Proposals must aim to generate data that inform a decision whether to continue further clinical development of the proposed intervention.

Are Vertebrate Animals Used?: If activities involving vertebrate animals are planned at any time during the proposed project at any performance site, check Yes. If No, skip the rest of block 2.

Note that the generation of custom antibodies constitutes an activity involving vertebrate animals.

If YES to Vertebrate Animals: Is the IACUC review Pending?

If IACUC approval has been granted or is pending, check Yes.

If IACUC review has not been sought, check No.

IACUC Approval is not required at the time of submission.

Animal Welfare Assurance Number: Enter the Federally approved assurance number, if available.

To determine if your organization holds an Animal Welfare Assurance, see <http://grants.nih.gov/grants/olaw/olaw.htm#assur>. If the applicant organization does not have an approved Animal Welfare Assurance on file with the [Office of Laboratory Animal Welfare \(OLAW\), NIH](#), enter "None" in the Animal Welfare Assurance Number field. By inserting "None" at the time of submission, the applicant organization is essentially declaring that it will comply with the [PHS Policy on Humane Care and Use of Laboratory Animals](#).

Is approval pending for all other required compliance activities?: Indicate if approval has been sought from all compliance committees that have oversight over the proposed project. These committees may include but are not limited to: select agents, export control, radiation safety, institutional biosafety, UAS privacy.

If approval has been granted or is pending, check Yes.

If review has not been sought, check No.

Approval is not required at the time of submission.

Is proprietary/privileged information included in the application?: Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, it is necessary to include this information **only** in *15. Confidential Information*. This field is required.

If the answer to Question 5 is YES, the PI for the Research University and the PD for the Private Sector must indicate that they have read the instructions for *15: Confidential Information* of the application and are familiar with the information covered under N.D.C.C. § 44-04-18

(<http://www.legis.nd.gov/cencode/t44c04.pdf?20130911154104>). Information exempted by N.D.C.C. § 44-04-18 needs to be placed only in section 15. *Confidential Information* of the application and only proprietary/confidential may be placed in section 15. *Confidential Information* of the application.

13. Project Description

Notice of Proprietary Information: Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, when the application contains information that constitutes trade secrets, or information that is commercial or financial, or information that is confidential or privileged, make sure you have checked “Yes” to both “Is proprietary/privileged information included in this application?” and “If yes, indicate if you have read the instructions for section 15. Confidential Information and are clear as to the information that is covered under N.D.C.C. § 44-04-18.4 and have only included proprietary/privileged information in section 15 of the application.” in the checklist.

Justification: State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will have as it relates to research, development and commercialization of a product to the private sector.

List succinctly the specific objectives of the research proposed in this application including milestones. Specific objections may include but are not limited to: create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

The Justification section is limited to one page.

Project Description: A detailed description of the project including: objectives, expected results and techniques. Include in this section a project management plan, including a well-defined milestone chart, schedule, and plan for communications among investigators. Include information about how each objective relates to the project’s significance as outlined in the justification portion of the application.

Follow the page limits for the Project Description in the table of page limits (see Section 2.04c PAGE LIMITS in these instructions).

Specific Instructions for projects involving clinical trials.

The application must include a clear description of the outcome measures; subject eligibility criteria; recruitment and retention strategies; procedures to avoid bias in allocation of subjects to treatment and in assessment of outcomes; the treatment regimen; and subject follow-up procedures. Statistical methods should be proposed that are appropriately matched to the study design. Sample size, power calculations, and plans for analyses, data management, quality control, and data sharing must be included. Statisticians sometimes use computer simulations to investigate the operating characteristics of complex clinical trial designs (such as adaptive designs), to choose between alternative outcome measures, or to determine sample size, taking into account the impact of such factors as noncompliance, dropout, missing data, and subject eligibility criteria (risk profile). If simulations were performed to aid in the design of this clinical trial, sufficient details about the simulations should be provided (possibly in an appendix to the trial protocol) to assure that the simulations were performed and analyzed in a valid manner.

The Application should also include a proposed timeline for reaching important study milestones such as: (a) obtaining regulatory approval for the protocol; (b) establishing agreements with participating industry partners; (c) obtaining adequate supply of the investigational agent; (d) finalizing the study procedures and training participating clinical site staff; and (e) enrolling 25%, 50%, 75% and 100% of the sample size.

Instructions for Research ND, Research ND BIO and FAST Track

If the intervention is a drug, biologic, or device, the application must include the status of all regulatory approvals necessary to conduct the proposed trial (e.g., active IND/IDE, report on pre-IND/IDE meetings, exemption letter from FDA). IRB approval is not required at the time of application submission, but prior to funding. Documents showing the evaluation of the intervention by the FDA must be included with the application, e.g., an active IND/IDE, an exemption letter from the FDA, or a compelling explanation why FDA approval is not applicable. Prior to making an award, the Office of Innovation and Entrepreneurship will require documentation of the receipt of any other necessary regulatory approvals (e.g., Recombinant DNA Advisory Committee approval).

14. Technologic and Economic Impacts

Explain how the proposed project will benefit the PSP in the areas of technologic improvements to new or existing products or the expected economic impacts of the project. Section III of the Application is subject to open records requests so do not include proprietary or other confidential information. If necessary to fully explain the technologic or economic impacts of the proposed project confidential or proprietary information can be included in Section IV of the application but this is discouraged.

Include in this section, to the extent possible, the expected benefit to the State of North Dakota. For companies with a presence in North Dakota economic impact to the State would include increased private sector revenue, new job creation, and job retention which do not need to be discussed beyond their impact on the private sector. Any additional expected economic impact to the State should be addressed in this section. For PSP that do not currently have operations in the State discuss how the project will have an economic impact on North Dakota outside of the grant monies spent at the Research University, if any. Include in this discussion any plans to open facilities in North Dakota, contract with existing North Dakota manufacturers, or other plans that would have economic impact to the State.

This section of the application is subject to open records requests so do not include proprietary or other confidential information. If necessary to fully explain the technologic or economic impacts of the proposed project confidential or proprietary information can be included in "Section IV: Confidential Information" of the application but this is discouraged.

15. Confidential Information

Patentable ideas, trade secrets, privileged or confidential commercial or financial information, disclosure of which may harm the applicant, should be included in applications only when such information is necessary to convey an understanding of the proposed project. If the application includes such information, it is necessary to include this information only in this section of the application.

If confidential information is included in the application, it is the applicants responsibility to insure that such information conforms to the definitions of confidential/proprietary information in N.D.C.C. § 44-04-18.4. The inclusion of materials other than those protected by N.D.C.C. § 44-04-18.4 in this section of the application will negate any protection offered by N.D.C.C. § 44-04-18.4.

16. Budget (Research University)

If the proposed project has a proposed duration of one year or less, the entire budget can be placed on a single budget page. If the proposed project has a proposed duration of greater than one year include up to 2 budget pages for the first year and one page for each additional year. Lines can be added and deleted from each table as needed using the '+' and '-' buttons at the end of each row.

The Research ND, Research ND BIO and FAST Track programs do not pay indirect costs.

Funds requested in this section must conform to the restrictions on project size established in **1.04 Program Description**

Instructions for Research ND, Research ND BIO and FAST Track

Personnel: This section should include the names of all key persons at the Research University who are involved on the project. Details of collaborators at the PSP will be included in 18. **Budget (Private Sector).** Only include individuals in this section of the budget where there is an associated salary and/or fringe benefits.

Role	Identify the project role of each senior/key person in this section. This section could also include such roles as Co-PD/PI, Postdoctoral Associates, and Other Professionals.
Base Salary (\$)	Enter the <u>monthly</u> compensation paid by the Research University for each person working on the project. This includes all activities such as research, teaching, patient care, or other. You may choose to leave this column blank.
Cal. Months	Identify the number of months devoted to the project for each person being paid through this project application
Requested Salary (\$)	This field will be automatically calculated based on the information in the previous two table cells.
Fringe Benefit Rate	Enter applicable fringe benefits rate for each position. Enter the fringe benefit as a percentage of Base Salary (in decimal form)
Fringe Benefits	This field will be automatically calculated based on the Base Salary and Fringe Benefit Rate provided
Funds Requested (\$)	This field will be automatically calculated based on the Requested Salary and Fringe Benefits.
Total (\$)	This field will be automatically calculated.

Equipment:

Equipment Item	Equipment is defined as an item of property that has an acquisition cost of \$5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year. List each item of equipment separately and justify each in the budget justification section. Allowable items ordinarily will be limited to research equipment and apparatus not already available for the conduct of the work. General-purpose equipment, such as a personal computer, is not eligible for support unless primarily or exclusively used in the actual conduct of scientific research.
Funds Requested	List the estimated cost of each item of equipment including shipping and any maintenance costs and agreements. This is required information.
Total	This field will be automatically calculated based on the information placed into the Funds Requested column.

Travel: Limited to \$2000 of travel directly related to the proposed project.

Destination	Identify the total funds requested for travel In the budget justification section, include the purpose, destination, dates of travel (if known), and the number of individuals participating for each trip. If the dates of travel are not known, specify estimated length of trip (e.g., 3 days).
Total	This field will be automatically calculated based on the information placed into the Funds Requested column.

Other Direct Costs

Description	List total funds requested for materials, supplies, publication costs, and other direct costs in this section. In the budget justification, indicate general categories such as glassware, chemicals, animal costs, including an amount for each category. Categories less than \$1,000 are not required to be itemized.
Other	Include in this section all other direct costs associated with the project along with a description. Add lines as necessary.
Total Other Direct Costs	This field will be automatically calculated based on the information placed into the Funds Requested column.

Subcontracts: Separate budgets and budget justifications for each subcontract may be included with the application depending on the policies of the Research University. However, if the total of all subcontracts is greater than or equal to 30% of the Research University’s budget separate budget and budget justification pages are required for each subcontract. The forms for the subcontract budgets and budget justification can be found in sections 20 and 21 of the application. These sections may be duplicated as necessary for each subcontract or sections 20 and 21 of the application or a file containing only these two sections may be downloaded from www.ResearchND.com.

Subcontracts/Subawards/ Consortium/ Contractual Costs	List total funds requested for 1) all subaward/consortium organization(s) proposed for the project, 2) any other contractual costs proposed for the project, and 3) any payments for consultants associated with the project. This line item should include both direct and indirect costs for all subaward/consortium organizations. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a categorical breakdown of costs. When this is the case, provide detailed information as part of the budget justification.
Equipment or Facility Rental/User Fees	List total funds requested for equipment or facility rental/user fees. In the budget justification, identify each rental user fee and justify.
Total	Total Funds requested for all subcontracts.

17. Budget Justification (Research University)

Use the budget justification to provide the additional information requested in each budget category identified above and any other information the applicant wishes to submit to support the budget request. The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support and other direct cost categories.

18. Budget (Private Sector)

If the proposed project has a proposed duration of one year or less, the entire budget can be placed on a single budget page. If the proposed project has a proposed duration of greater than one year include up to 2 budget pages for each year of the proposal. Lines can be added and deleted from each table as needed using the ‘+’ and ‘-’ buttons at the end of each row.

The Research ND, Research ND BIO and FAST Track programs do not pay indirect costs.

Funds requested in this section must conform to the restrictions on project size established in **1.04 Program Description**

Cash to the Research University: Include direct cash payments to the Research University including anticipated dates and amounts.

Instructions for Research ND, Research ND BIO and FAST Track

Personnel: This section should include the names of all key persons at the PSP who are involved on the project. Details of collaborators at the PSP will be included in 18. *Budget (Private Sector)*. Only include individuals in this section of the budget where there is an associated salary and/or fringe benefits.

Role	Identify the project role of each senior/key person in this section. This section could also include such roles as Co-PD/PI, Postdoctoral Associates, and Other Professionals.
Base Salary (\$)	Enter the <u>monthly</u> compensation paid by the Research University for each person working on the project. This includes all activities such as research, teaching, patient care, or other. You may choose to leave this column blank.
Cal. Months	Identify the number of months devoted to the project for each person being paid through this project application
Requested Salary (\$)	This field will be automatically calculated based on the information in the previous two table cells.
Fringe Benefit Rate	Enter applicable fringe benefits rate for each position. Enter the fringe benefit as a percentage of Base Salary (in decimal form)
Fringe Benefits	This field will be automatically calculated based on the Base Salary and Fringe Benefit Rate provided
Funds Requested (\$)	This field will be automatically calculated based on the Requested Salary and Fringe Benefits.
Total (\$)	This field will be automatically calculated.

Equipment:

Equipment Item	Equipment is defined as an item of property that has an acquisition cost of \$5,000 or more (unless the organization has established lower levels) and an expected service life of more than one year. List each item of equipment separately and justify each in the budget justification section. Allowable items ordinarily will be limited to research equipment and apparatus not already available for the conduct of the work. General-purpose equipment, such as a personal computer, is not eligible for support unless primarily or exclusively used in the actual conduct of scientific research.
Funds Requested	List the estimated cost of each item of equipment including shipping and any maintenance costs and agreements. This is required information.
Total	This field will be automatically calculated based on the information placed into the Funds Requested column.

Travel: Limited to \$2000 of travel directly related to the proposed project.

Destination	Identify the total funds requested for travel In the budget justification section, include the purpose, destination, dates of travel (if known), and the number of individuals participating for each trip. If the dates of travel are not known, specify estimated length of trip (e.g., 3 days).
Total	This field will be automatically calculated based on the information placed into the Funds Requested column.

Other Direct Costs

Description	List total funds requested for materials, supplies, publication costs, and other direct costs in this section. In the budget justification, indicate general categories such as glassware, chemicals, animal costs, including an amount for each category. Categories less than \$1,000 are not required to be itemized.
Other	Include in this section all other direct costs associated with the project along with a description. Add lines as necessary.
Total Other Direct Costs	This field will be automatically calculated based on the information placed into the Funds Requested column.

Subcontracts: Separate budgets and budget justifications for each subcontract may be included with the application depending on the policies of the PSP. The forms for the subcontract budgets and budget justification can be found in sections 20 and 21 of the application. These sections may be duplicated as necessary for each subcontract or sections 20 and 21 of the application or a file containing only these two sections may be downloaded from www.ResearchND.com.

Subcontracts/Subawards/ Consortium/ Contractual Costs	List total funds requested for 1) all subaward/consortium organization(s) proposed for the project, 2) any other contractual costs proposed for the project, and 3) any payments for consultants associated with the project. This line item should include both direct and indirect costs for all subaward/consortium organizations. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a categorical breakdown of costs. When this is the case, provide detailed information as part of the budget justification.
Equipment or Facility Rental/User Fees	List total funds requested for equipment or facility rental/user fees. In the budget justification, identify each rental user fee and justify.
Total	Total Funds requested for all subcontracts.

19. Budget Justification (Private Sector)

Use the budget justification to provide the additional information requested in each budget category identified above and any other information the applicant wishes to submit to support the budget request. The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support and other direct cost categories.

20. Budget (Subcontract)

Use the instructions for section 18. *Budget (Private Sector)* to fill out this section of the application.

21. Budget Justification (Subcontract)

Use the instructions for section 19. *Budget Justification (Private Sector)* to fill out this section of the application.

22-24. Biographical Sketch

Include biographical sketches for all senior/key personnel and Other Significant Contributors. The Biographical Sketch may not exceed four pages per person for the PI and PD. All other key personnel are limited to two pages. These page limits includes the table at the top of the first page.

Education and Training: Complete the educational block at the top of the format page beginning with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training, separately referencing residency training when applicable. For each entry provide the name and location of the institution; the degree received (if applicable); the month and year the degree was received, and the field of study. For residency entries, the field of study section should reflect the area of residency. Lines may be added to the table as needed using the '+' and '-' buttons at the end of each table row.

Employment: List in chronological order previous positions, concluding with your present position.

Selected Peer-reviewed Publications: Limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recency, importance to the field, and/or relevance to the proposed research.

Research Support: List both selected ongoing and completed (during the last three years) research projects (Federal or non-Federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and responsibilities of the senior/key person identified on the Biographical Sketch. *Do not include number of person months or direct costs.*

This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team.

25. Facilities and Equipment

This information is used to assess the capability of the organizational resources available to perform the effort proposed.

Facilities: Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.

Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

For Early Stage Investigators, describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI's project, and availability of organized peer groups; logistical support such as administrative management and oversight and best practices training; and financial support such as protected time for research with salary support.

If there are multiple performance sites, describe the resources available at each site.

Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about select agents must be described in the Project Description.

Equipment: List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities

26. References Cited

Include references in this section that may be beneficial to the technical reviewers. No specific format is required but be consistent.

Appendix I

An affidavit stating that the PSP does not have an outstanding tax liability owed to the State of North Dakota or any of its political divisions. In addition, the affidavit should state that the PSP does not have any outstanding match requirements to any state funded matching grant programs.

Appendix II

N.D.C.C. § 54-65-06 includes the following language:

“The department shall work with the centers of excellence commission in establishing guidelines to qualify for a grant under this section, including the requirement that an application must be accompanied by a partnership agreement between the private sector partner and a research university. The agreement must include details regarding the scope of the work, the budget, the location of the work to be completed, the intellectual property ownership rights, and the intellectual property income distribution.”

Failure to include the fully executed partnership agreement at the time of submission will result in the application being returned un-reviewed and the application will not be accepted for submission until the next submission deadline.

4.00 INFORMATION AVAILABLE TO THE GENERAL PUBLIC

The Office of Innovation and Entrepreneurship makes information about awarded grants available to the public, including the title of the project, the grantee institution, the PI, PM, and the amount of the award. The Project Abstract of a funded research grant application will be placed on the Office of Innovation and Entrepreneurship website in the Funded Awards section.

4.01 OPEN RECORDS LAWS

ND Open Records Law (N.D.C.C. § 44-04-18) requires the release of certain information about grants upon request, regardless of the intended use of the information. Generally available for release, upon request are: all funded grant applications and progress reports; progress reports of grantees; and final reports of any review or evaluation of grantee performance conducted or caused to be conducted by the Office of Innovation and Entrepreneurship.

Generally not available for release to the public are: grant applications for which awards have not been made; and summary statements of findings and recommendations of review groups.

Trade secrets and commercial, financial, or otherwise proprietary information may be withheld from disclosure. Information, which, if disclosed, would be a clearly unwarranted invasion of personal privacy, may also be withheld from disclosure. Although the grantee institutions and the PI and the PD will be consulted about any such release, the Office of Innovation and Entrepreneurship will make the final determination subject to consultation with the Attorney General’s office. If a requested document contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the balance of the document will be released.