CELIAC DISEASE FOUNDATION
YOUNG INVESTIGATOR RESEARCH GRANT AWARD

INTRODUCTION AND SOURCE OF FUNDS

The Celiac Disease Foundation was established in 1990 to find the cause of and cure for celiac disease. Support for our research program is provided by concerned individuals, corporations, and philanthropic foundations.

The Foundation seeks to stimulate and encourage innovative research in the basic biomedical and clinical sciences, which is likely to increase our understanding of the etiology, pathogenesis, therapy, and prevention of celiac disease. Collaborative efforts between basic scientists and clinicians are encouraged.

OBJECTIVE

The Foundation offers the Young Investigator Research Grant Award to encourage the development of individuals with research potential to help them prepare for a career of independent basic and/or clinical investigation in celiac disease. Individuals who are already well established in the field of celiac disease research are not considered eligible for this award

APPLICANT ELIGIBILITY

Grants are not made to individuals, but only to institutions (each a "Grantee Institution") for the support of specific research projects. The application should identify an individual to lead the research project on behalf of a qualifying institution (such individual, the "Principal Investigator"). As the time of the application, the Principal Investigator must:

- Hold an M.D., Ph.D., or equivalent degree.
- Be employed by an institution (public non-profit, private non-profit, or government) engaged in health care and/or health related research within the United States. Research is not restricted by citizenship. However, proof of legal work status is required.
- Candidates holding M.D. degrees must have at least two years of post-doctoral experience, one of the two years must be documented research experience relevant to celiac disease prior to application. Candidates holding Ph.D. degrees must have at least one year of documented post-doctoral research relevant to celiac disease prior to application.
- Not have been alleged to have violated, or convicted of violating, the Federal Stark law, False Claims Act or Anti-Kickback Statute, Health Insurance Portability and Accountability Act as amended by the HITECH ACT ("HIPAA"); Federal Food, Drug and Cosmetic Act, including 21 CFR Part 54 relating to financial disclosures; federal Civil Monetary Penalty Statute; or similar state laws.
- Not be subject to debarment, exclusion, suspension or other ineligibility from participation in any federal or state health care program or other procurement or non-procurement programs, or to any investigation or proceedings regarding the same.
- Be in good standing with all applicable state professional licensing requirements.

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PROPOSAL ELIGIBILITY

- The submitted research proposal must be in the field of celiac disease.
- Only one proposal may be submitted per submission date.

TERMS OF AWARD

The total amount of the award is for up to $60,000 per year for a maximum of three years. Research grant applications will be judged on the originality, scientific merit and significance of the proposed study, and on the ability and research record of the investigator. Funds may be used to pay the salaries of technical assistants and the cost of equipment, supplies and materials necessary for carrying out the purpose of the grant. Funds may not be used to pay the salary and fringe benefits of the Principal Investigator, transportation to meetings, journal subscriptions, society dues, construction or renovation of buildings, or for the purchase of office equipment and furniture. No portion of the research grant may be used to pay institutional overhead or other indirect costs. A detailed budget indicating the planned use of the funds is required and subject to approval by the Foundation.

The Principal Investigator must submit letters of support from three references, one of whom will act as a scientific sponsor. The curriculum vitae of the sponsor must also be included. Letters should include a description of the environment in which the proposed research will be performed, and a brief description of the Principal Investigator's project and how it relates to the overall research goals of the sponsor's laboratory. A brief statement affirming protected research time must be included. Letters of reference must be submitted directly to the Celiac Disease Foundation, not to the Principal Investigator or Grantee Institution.

A progress report is required at the end of each six-month period in order to receive remaining funding. A detailed scientific report is required at the termination of the grant period. The Principal Investigator must attend the Celiac Disease Foundation's Annual National Conference and participate in donor-related activities, which may include being filmed and providing short presentations of scientific activities remotely or in person.

RULES GOVERNING RESEARCH GRANTS

1. Applications: Grant applications are evaluated by the Foundation's Research Committee, which makes recommendations to the Foundation's Board of Directors. The Celiac Disease Foundation reserves the right to consult qualified third parties in particular cases. All applications awaiting action will be held in confidence by the Foundation.

2. Terms of a Grant: Unless otherwise specified in writing, Research Grants are given for terms of up to three years. The Grantee Institution and Principal Investigator must agree that their selection to receive a grant was not conditioned in any way on any pre-existing or future business relationships between the parties or on any business or other decisions, including healthcare related decisions, that Grantee Institution and/or Principal Investigator made or may make in the future.

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3. Purpose of Funds: Funds from Research Grants are not intended to subsidize normal institutional budgets or staff, nor to pay institutional overhead charges. Grant funds may not be used to pay salaries of Principal Investigators, transportation to meetings, or journal subscriptions. Grant funds may be used, however, to pay the salaries of technical assistants and the cost of equipment, supplies and materials necessary for carrying out the purpose of the grant. Grant funds are not available for construction or renovation of buildings, or for the purchase of office equipment and furniture. Similarly, dues and membership in scientific societies will not be underwritten.

4. Expenditures: All charges must conform to the budget submitted by the Grantee Institution. The Foundation reserves the right to a refund on demand of all grant funds expended in an unauthorized manner.

5. Accounting: The Grantee Institution will keep systematic records of all expenditures relating to the grant. Documentation consisting of invoices, bills, receipts, cancelled checks, etc. will be retained by the Grantee Institution for five (5) years after the close of the grant period. These documents must be available for inspection by representatives of the Foundation at any time upon reasonable notice during the grant period. The Foundation may, at its own expense, examine, audit or have audited the records of the Grantee Institution insofar as they relate to activities supported by the grant.

   Financial commitments against all grants must be liquidated as soon as possible after the grant period has ended, and the Grantee Institution must submit a final accounting of all expenses ("Final Financial Report") and return all unexpended funds within ninety (90) days of the end of the grant period unless an extension has been requested in writing and granted by the Foundation. The Foundation will not be responsible for any financial commitment against the grant. The Grantee Institution shall be responsible for any unauthorized expenditure or overexpenditures made from the grant.

6. Materials: All equipment or instruments purchased, prepared, manufactured, and paid for with funds from the grant for specific items named in the application shall, unless otherwise specified, become the property of the Grantee Institution.

7. Salaries: Personnel compensated under a Foundation grant shall not be considered as employees of the Foundation, but as employees of the Grantee Institution.

8. Other Financial Support: The application must list all current and pending support of the Principal Investigator, and provide abstracts of such support. If the Principal Investigator is awarded additional support during the term of a grant from the Celiac Disease Foundation, the Foundation must be notified. Additional support must not duplicate grant support from the Celiac Disease Foundation for the same project.

9. Program Changes: Change of the purpose or personnel for which a current grant was made will automatically terminate the grant unless written approval is obtained in advance from the Foundation; return of funds on a pro-rated basis will be required.

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10. Reports: Progress of work conducted under grants must be reported to the Foundation within thirty (30) days of the end of each six-month period in order to receive remaining grant funding. Failure to submit a report will result in termination of the grant. A detailed scientific report ("Final Scientific Report") is required at the termination of the grant period.

    Annual financial reports are due within ninety (90) days of the end of each grant year. Annual financial reports must contain all expenditures from the previous year. The Final Financial Report must contain all expenditures for the entire length of the grant.

11. Grant payments: Grant payments are paid to institutions on an annual basis. 80% of Year 1 will be paid at the beginning of the award when all assurances and terms of the award have been submitted. Year 2 funding will include the remainder of Year 1 as well as 80% of Year 2 and will be sent at the start of year 2. Year 3 funding (if applicable) will include the remainder of Year 2 as well as 80% of Year 3. The final payment of the remaining balance will be sent once the Final Financial Report and the Final Scientific Report have been received and approved.

    Personnel compensated in whole or in part with funds from the Celiac Disease Foundation are not considered employees of the Foundation. Institutions are responsible for issuing the appropriate IRS tax filings for all individuals receiving compensation from Celiac Disease Foundation grants and are responsible for withholding and paying all federal, state and local taxes with regards to such compensation. Thus, these and any other tax consequences are the responsibility of the Principal Investigator and Grantee Institution.

    The Foundation is not responsible for expenditures made prior to the start date of the grant, or if the complete budget is expended prior to quarterly payments or any expenditures that exceed the total amount of the award. The Celiac Disease Foundation will follow the payment schedule outlined in the award letter. Please refrain from sending invoices to the Celiac Disease Foundation from the institution as these will not be paid in the manner they are received.

    Celiac Disease Foundation research grants are not designed to cover the total cost of the research proposed nor the investigator's compensation. The Grantee Institution is expected to provide the required physical facilities and administrative services normally available in an institution.

12. Discoveries: Any discovery made under a program supported by the Foundation must be reported promptly to the Foundation at the earliest possible time, normally upon discovery, and application for patent may not be made without the prior written consent of the Foundation. (See Patent and Intellectual Property Policy attached herewith.)

13. Publicity: The Grantee Institution must advise the Foundation in writing prior to publicizing, in any manner, discoveries made or developed under a grant. The communication should explain fully the nature of the information to be divulged, the time, the place, and the manner of its presentation.

14. Publication and Exhibits: Grant recipients are expected to publish their results in peer-reviewed scientific journals and to present their findings at scientific conferences and at the Foundation's National Conference. Any article, manuscript, poster presentation, exhibit, news release, institutional publication or other public communication prepared by anyone associated with the work covered by a grant and dealing with the project should bear the credit line: "Supported in part/in entirety by a grant from the Celiac Disease Foundation®." The Foundation shall receive timely and prior notice and an electronic copy of any public communication of work resulting from this grant, including scientific abstracts, posters, press releases or other media communications, and Internet-based communications.

15. Transfer of Grant: Grants may not be transferred from one individual or institution to another individual or institution without the prior written approval of the Foundation. Payments to the new institution will not be sent until a final accounting and a repayment of any unexpended funds have been received from the original institution and the transfer has been approved by the Foundation.

16. Deviation From Rules: The Foundation reserves the right immediately to discontinue the grant or to refuse to consider any application upon determination by the Foundation in its sole discretion that the Principal Investigator or the Grantee Institution are not adhering to the terms set forth in these Rules Governing Research Grants and in any award letter executed among the Foundation, the Grantee Institution and the Principal Investigator.

17. Change of Rules: The Foundation reserves the right to change or amend its Rules Governing Research Grants at any time. Unless implementation of the project for which the grant was given has already commenced, the Grantee Institution agrees to abide by such changes or terminate the grant at the time it goes into effect.

18. Human Subjects: If human subjects are to be used in the research, written, informed consent in compliance with 21 CFR Part 50 and related FDA guidance, all applicable state informed consent requirements, and all state and federal privacy laws, including but not limited to the HIPAA, must be obtained, and the research protocol must be approved by an appropriate institutional review board (IRB) or equivalent, prior to the start date of the award, in compliance with 21 CFR Part 56. The investigator bears full responsibility for obtaining such approval and, further, certifies by agreeing to these rules that the investigator and/or the institution will be fully responsible for any financial liability and legal expenses resulting from all direct and indirect damages of any kind resulting from research supported by the Foundation. This requirement will also pertain to animal research and the use of radioisotopes and biohazardous materials. A copy of the IRB approval must be provided to the Celiac Disease Foundation prior to the start date of the grant award, and to the extent that the IRB approval is amended thereafter, copies of any amendments must be provided promptly upon approval of the IRB.

19. Cancellation: The Foundation reserves the right immediately to cancel the grant with respect to any project that fails to make satisfactory scientific progress as determined by members of the Foundation's Research Committee.

The Foundation also reserves the right immediately to cancel the grant in the event that the Grantee Institution, Principal Investigator or anyone else participating in the project becomes debarred, excluded, suspended or otherwise ineligible from participation in any federal or state health care program or other procurement or non-procurement programs or becomes subject to an investigation or proceedings regarding the same.

The Board of Directors, in consultation with the Research Committee of the Foundation, otherwise may, for cause, cancel a grant at any time upon 90 days' notice, and require the return of any unused funds.

In the event of a cancellation of the grant for any reason, the Grantee Institution shall submit to the Foundation a Final Financial Report and return any unused funds within ninety (90) days of written notice by the Foundation of such cancellation.

20. Governing Rules: By the act of applying for a grant, the Principal Investigator certifies that he/she has read and will abide by these Rules Governing Research Grants.

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INSTRUCTIONS FOR RESEARCH GRANT APPLICATIONS

PLEASE NOTE: THE DEADLINE FOR ALL APPLICATIONS IS JUNE 1, 2020.

Applications should adhere to NIH-form SF 424 (R&R) formatting guidelines and an electronic copy sent to julia.mcbeth@celiac.org. Each section must be completed. If not applicable, please indicate this. Incomplete applications will not be reviewed. Review of applications is facilitated if the outline given below is followed as closely as possible. **Supplementary material will not be accepted after the submission deadline**.

1. Name and address of institution, including department, phone number, email address, division, if any, and location of the laboratory where research is to be conducted.

2. Names and titles of principal and co-investigators. Curricula vitae and a selective bibliography of each should be appended to the application. CV should, at a minimum, include: date of birth, citizenship, degrees held (with dates and schools), home address, daytime telephone number, awards and honors, membership in professional organizations, board eligibility or certification and positions held, including, in addition, any relevant research experience not otherwise listed.

3. Brief title of proposed research project.

4. Amount requested – Research Grants are limited to a total annual cost of $60,000 for up to three years.

5. Proposed period of award (beginning and termination dates).

6. Brief/Abstract summary of the proposed research and its potential significance for celiac disease in lay language geared to a twelfth grade reading level, 50-100 words, suitable for use in publications. The summary should include:

    a. What question will this research attempt to answer?
    b. Why is this question important to celiac disease?
    c. What is the study design?
    d. How do the hypothesis and specific aims fit with the Celiac Disease Foundation's scientific priorities?
    e. Will this research, if successful, further the Celiac Disease Foundation's mission to find the causes and cures of celiac disease and/or to improve the quality of life for celiac disease patients? If so, how will this project do so?

7. Proposed budget: Proposed budget and sources of funding for each year, listed as follows:

	Requested from Foundation	Paid from other funds	TOTAL
Technical personnel			
Recruitment & honoraria			
Equipment			
Consumable supplies			
Publications & presentations	_____		
Total	$_____	$_____	$_____

Each item of equipment costing more than $1000.00 should be listed separately. Supplies should be listed by major types, such as glassware, chemicals, animals, etc. Please note that Foundation policy does not provide funds for institutional overhead, or for major pieces of laboratory equipment.

a. Identify source of "other funds" in item #7 above. Indicate all current funding of all investigators named in the grant application. This should include funds from government, foundations and industry. The abstract of each grant application should be included as well as the title of the grant and the amount of support and support period. In addition, list other support, committed or pending, for this and for related projects during the period indicated in item #5.

b. Indicate other pending grant applications, amounts and extent of overlap, if any. If overlap does exist, a statement regarding intended disposition of funds in the event of dual granting is required, signed by an official of the Grantee Institution. Ordinarily this will result in the return of funds to all but one granting agency; however, monies granted could be modified appropriately.

8. Research Plan: A description of the proposed research should include the following (maximum of six pages):

   a. Background and specific goals of proposal being submitted.

   b. Methods of procedure.

   c. Significance of the proposed work and its relevance to the celiac disease.

   d. Indicate as accurately as possible the estimated time required for the proposed studies, giving the approximate sequence of experiments. If the time required is likely to exceed the grant period, indicate your present plans for completion of the project, whether by you or others. Specifically

what funding sources are committed or will be sought, and what personnel changes, if any, will occur?

e. Facilities available for this project, including laboratory space and major equipment. Include a statement of the time allotted for protected research.

f. An Appendix section of the application may contain only two (2) additional pages of references, tables, charts, and/or figures. One completed manuscript (either submitted or in press) may also be included.

9. Please have letters submitted from three references, one of whom will act as a scientific sponsor, as well as curriculum vitae of the sponsor. If the program director of the academic department is not included in the other two letters, then a brief statement from him/her affirming the percentage of protected research time that is required. Letters of reference should be submitted directly to the Celiac Disease Foundation or via email to julia.mcbeth @celiac.org, not to the Principal Investigator or the Grantee Institution.

10. Please indicate to whom checks should be drawn and where they should be sent if grant is approved. Note: **ALL** checks are made out to the Institution and must be sent to the appropriate finance office.

11. Include at the end of the application the following statement:

"I have read and accept the current Rules Governing Research Grants of the Celiac Disease Foundation."

followed by the signature of the Principal Investigator, co-investigator, collaborator or consultant, along with name, title and date. For **ALL** applications, the name and signature of the Institutional Officer is required on this statement.

SPECIAL INSTRUCTIONS FOR CLINICAL TRIALS

The Research Plan will need to include everything required in the Application Preparation section above, plus the following information:

Specific Aims:
These should include a delineation of the primary and secondary end points to be measured with an appropriate explanation of the relative importance of the various end points.

Significance:
The application should clearly state the need for the study and how the results would impact the prevailing practice in this area.

Experimental Design and Method:
The inclusion and exclusion criteria should be listed, and the procedure(s) to be utilized for assignment of patients to experimental groups should be described. The study design for the interventions to be used should be presented in detail including the rationale for the particular design chosen and procedures to assure

compliance with and implementation of the proposed protocol. Potential biases in the proposed protocol and how they will be addressed should be presented.

Clinical, laboratory and physiological tests should be described including methods of randomization. Finally, assumptions and calculations to arrive at the proposed sample size should be included.

The availability of patients for the proposed study, including the specific characteristics that are required for the group should be presented. Approaches should be outlined that will be used for the recruitment, retention and follow-up of the required number of patients. Data should be presented supporting recruitment and retention estimates. Plans should be described for patient protection, including informed consent, monitoring of data for safety and early termination as required. Appropriate informed consent forms from all participating groups (centers) should be included. Certification of approval from the Human Studies Committee (or its equivalent) for each participating institution should also be included. Projected rates of patient enrollment should be included. If enrollment falls behind projected levels, funding may be delayed or terminated.

The organization of the study and how the trial will be managed should be described, including the function of any internal or external advisory committees and any data and safety monitoring groups. In multicenter trials, you should provide a description of the responsibility and role of a data coordinating center as well as policies and methods concerning blinding of study results. Accordingly, a plan should be submitted describing the procedure for the coordination of all participating centers. The Celiac Disease Foundation does not assume responsibility for the conduct of the activities that the grant supports or the acts of the grant recipient as both are under the direction and control of the Grantee Institution and subject to the institution's medical and scientific policies. The Grantee Institution must safeguard the rights and welfare of individuals who participate as subjects in research activities by using and having approved appropriate informed consent documents in compliance with 21 CFR Part 50 and HIPAA and applicable state privacy laws, reviewing proposed activities through an Institutional Review Board (IRB), as specified by the Food and Drug Administration and the National Institutes of Health Office for Human Research Protections, US Department of Health and Human Services (DHHS). Furthermore, the Grantee Institution must adhere to DHHS, including FDA, guidelines regarding financial conflicts of interest, recombinant DNA, research misconduct and vertebrate animals. These policies apply to the Principal Investigator as well. Finally, a timetable for completion of the various phases of the trial should be presented.

A procedure or plan for data management should be described, including data collection forms, if available. Data analysis methodology linking the analyses to the hypotheses to be tested should also be included. Primary and secondary end points should be clearly defined, justified and related to the power calculations.

Evidential Enclosures:
All activities involving human subjects or vertebrate animals must be approved by an appropriate institutional review board (IRB) or equivalent prior to the start date of award. A copy of the actual signed or stamped approval is required. Enclose letters of commitment from each participating center, signed by the cooperating investigator and business official. In addition, informed consent forms from all participating centers should be included in this section.

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Curriculum Vitae:
NIH-style biosketches of all key investigators, center directors, and multidisciplinary team members should be included (5 PAGE MAXIMUM).

Facilities:
Clinical, data management, and laboratory facilities should be described in detail for all participating institutions, where applicable.

Budget:
A total overall budget and a complete justified budget for each year of support should be presented. If the trial is designed for more than the three-year period, complete justified budgets for post-Celiac Disease Foundation years and a plan for securing funding for additional year(s) must be included. If the study involves multiple centers, a composite matrix should be submitted, where applicable. If part of the costs of the total trial are to be provided by sources other than the Celiac Disease Foundation, these contributions should be presented in detail along with supporting letters from appropriate and responsible individuals.

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PATENT AND INTELLECTUAL PROPERTY POLICY

1. All inventions or intellectual property ("Property") that results from research supported, in whole or in part, by grant awards from the Celiac Disease Foundation ("the Foundation") must be reported in writing at the earliest possible time to the Foundation, normally upon discovery and in any event prior to disclosure to any person or entity other than the Grantee Institution. The Grantee Institution shall notify the Foundation within a reasonable time, preferably within 30 days, of receiving an invention disclosure or other notice indicating existence of a Property and to notify the Foundation immediately of the decision to apply for letters of patent or other legal protection for the Property. The Foundation agrees to keep all information confidential and not to release any information relating to such inventions, intellectual property or applications for protection to any third party, except as specifically set forth below or upon written agreement with the Grantee Institution, which consent cannot be unreasonably withheld. All patenting expenses or intellectual property application expenses shall be borne by the Grantee Institution.

2. Title to all Property shall reside with the Grantee Institution to the extent that such title is rightfully claimed by the institution under its institutional patent policy or procedure. If a Grantee Institution has no established institutional patent policy or procedure for administering inventions or intellectual property, or if the institutional patent policy or procedure does not claim rights for the institution or individual inventor, then the Foundation shall have the right to determine the disposition of the Property rights in accordance with the provisions set forth below.

3. Distribution of income derived from any Property, which might include equity disposition, shall be shared by the Grantee Institution and the Foundation on mutually agreeable terms, such terms to be determined as soon as practicable and negotiated in good faith by the parties, preferably prior to any licensing or commercial exploitation of the Property, and in any event no later than 6 months after first receipt of income. Such distribution shall be guided by the principle that the Foundation's proportion of the income shall be reasonably related to the Foundation's proportion of support for the research leading to the Property. The Grantee Institution agrees to notify the Foundation reasonably promptly after beginning negotiations with potential licensees and to notify the Foundation upon execution of any license or other agreement to commercialize the Property. The Grantee Institution will provide a copy of the license or other agreement, or excerpts that establish the financial terms relevant to the Foundation's right to income from the Property together with the name of the licensee, the subject matter, field, scope and term of the license and any other terms relevant to the Foundation, including without limitation whether such license is exclusive or nonexclusive.

4. If any Property is made with or results from the joint support of the Foundation and another organization, that organization, the Grantee Institution, and the Foundation will confer, in good faith, to arrive at a mutually satisfactory disposition of the Property rights guided by the principle that distributions of income be made in proportion to each party's contribution of support for the research leading to the Property.

5. No patent, patent application or other type of protection for a Property shall be abandoned without first notifying the Foundation and giving the Foundation a reasonable opportunity at its discretion either to file patent applications at its cost and/or to take title to the Property. If the Foundation elects to file patent applications, to the extent it is legally able to do so, the Grantee Institution shall negotiate with the Foundation in good faith to assign or license its rights in the Property to the Foundation.

6. If Grantee Institution does not effectuate a license to Property within one (1) year from the date that such Property is disclosed in writing to the Foundation by the Grantee Institution or the Principal Investigator, then the Foundation shall have the right to introduce to the Grantee Institution one or more bona fide potential licensees and the Grantee Institution shall enter into good faith negotiations for license of the Property with such potential licensee(s). Upon consummation of any such license, the Foundation's introduction of the licensee to the Grantee Institution shall be counted to the benefit of the Foundation in calculating its share of any income from the Property.

7. The Grantee Institution agrees that when it licenses a Property, it will use reasonable efforts to obligate the licensee to exert its best efforts to commercialize or cause to be commercialized the Property as rapidly as practical, consistent with sound and reasonable business practices and judgment and reserve the right to terminate the license upon a failure by licensee to do so. If the Grantee Institution relicenses any Property, the Foundation shall be entitled to a share of any relicensed Property income according to the principles set forth above.

8. The Foundation reserves the right to public acknowledgment for Property resulting from research supported by the Foundation, and to itself publicize its contribution to such Property and research. However, the Foundation's name and logo may not be used in association with any Property without the prior written approval of the Foundation.

9. The Foundation shall have the rights to use the Property without payment of royalties or license fees solely for the use by the Foundation for its own internal or public education purposes, but not for use by any of its other Grantee Institutions.

The Principal Investigator and Grantee Institution are responsible for ensuring that there are no provisions in their consulting or business agreements that conflict or are inconsistent with this policy.