AACR-Bayer Innovation and Discovery Grants

2017 Program Guidelines and Application Instructions

American Association for Cancer Research
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PROGRAM GUIDELINES

PROGRAM SUMMARY
Bayer and the AACR are proud to announce the 2017 AACR-Bayer Innovation and Discovery Grants. This grants partnership promotes the key tenets of the Bayer Grants4Targets™ Initiative, providing new treatment options for cancers with high unmet medical need, encouraging innovation and translation of ideas from basic research into novel drugs, and fostering collaborations between excellent academic groups and the pharmaceutical industry.

Applications are invited from researchers currently in the field as well as investigators with experience in other areas of cancer or biomedical research.

The grant provides $25,000 over one year for expenses related to the research project. Grant funds may be used for research expenses attributable to the project, which may include supplemental salary support, equipment, research/laboratory supplies, and other research expenses (indirect costs not permitted).

It is anticipated that ten grants will be funded.

APPLICATION DEADLINE
July 13, 2017, at 1:00 p.m. U.S. Eastern Time

NOTIFICATION OF AWARD
September 2017

ANNUAL GRANTS RECEPTION AND DINNER AT AACR ANNUAL MEETING 2018
April 17, 2018 - Grant recipient must attend the Grants Reception and Dinner to formally accept the grant. Funds for travel support to this Annual Meeting will be provided separate from the grant.

START OF GRANT TERM
October 1, 2017

APPLICANT ELIGIBILITY CRITERIA
Applicants must have a doctoral degree (including PhD, MD, DO, DC, ND, DDS, DVM, ScD, DNS, PharmD, or equivalent) in a related field and not currently be a candidate for a further doctoral degree.

Applications will be accepted from independent investigators at all levels who are affiliated with an academic, medical, or research institution within North America. (There are no citizenship requirements. However, by submitting an application for this grant, an applicant applying from an institution located in a country in which they are not a citizen or a permanent resident assures that the visa status will provide sufficient time to complete the project and grant term at the institution from which they applied.)

Employees or subcontractors of a U.S. government entity or for-profit private industry are not eligible. Employees or subcontractors of a U.S. government entity or for-profit private industry may serve as Collaborators, but no grant funds may be directed towards these individuals.

AACR membership is required. Nonmembers interested in this grant opportunity must submit a satisfactory application for AACR Active Membership by Thursday, July 13, 2017. The application will be applied to 2017 membership dues. Applications may be submitted using the Official Application for Membership online or downloaded as a PDF and submitted to the AACR office with the required documents.
Investigators may submit only one application for a 2017 AACR-Bayer Innovation and Discovery Grant but may concurrently apply for other AACR grants.

Postdoctoral or clinical research fellows or the equivalent who are working under the auspices of a scientific mentor are not eligible to apply. Qualified fellows are invited to apply for an AACR Fellowship. Members of the Scientific Review Committee are not eligible to apply for a 2017 AACR-Bayer Innovation and Discovery Grant.

All applicants with questions about eligibility should contact AACR’s Scientific Review and Grants Administration Department (AACR’s SRGA) at grants@aacr.org before submitting an application.

RESEARCH PROJECT CRITERIA
These grants will support basic, translational, and/or clinical research projects that examine important and druggable* novel targets and/or biomarkers. The proposed research must be focused in area(s) of oncogenetic signaling, immuno-oncology, and/or antibody drugs/thorium conjugates.

*For the purposes of this grant program, a "druggable" target is defined as a nucleic acid or a protein (e.g., an enzyme, a receptor) whose activity can be modified by a drug. The drug can be a small-molecular weight chemical compound or a biological, such as an antibody or a recombinant protein. The target should have been shown to be effective/mechanistically involved in cancer by relevant in vitro or in vivo models. A cancer-related biomarker might be a protein, a nucleic acid, or a metabolite that can be measured in biological fluids, tissue, or isolated cells for the diagnosis, monitoring, prognosis, or stratification of patients.

EVALUATION OF APPLICATIONS
Applications will be peer-reviewed by a Scientific Review Committee comprised of researchers and physician-scientists who are well-respected for their own accomplishments in cancer and drug discovery research and are viewed as leaders in the field.

In selecting the recipient(s), the Committee considers:

* **Investigator.** Is the applicant well suited to the project? Does the applicant have appropriate experience and training to successfully complete the proposed project? Has the applicant achieved, or have the potential of achieving, a track record of accomplishments to advance the field of cancer research?

* **Scientific Focus.** Does the project examine important and druggable novel targets and/or biomarkers? Is the proposed target disease-modifying and/or have a proven function in the pathophysiology of cancer? Is the target effective against or mechanistically involved in cancer? Is the research focused in the field(s) of oncogenetic signaling, immuno-oncology, and/or antibody drugs/thorium conjugates?

* **Innovation and Significance.** Does the research have the potential to provide a new treatment option for cancers with high unmet medical need? Does the research demonstrate innovation and translation of ideas from basic research into novel drugs?

TOBACCO INDUSTRY FUNDING AND CONFLICTS OF INTEREST STATEMENT
Scientific investigators or health professionals who are funded by the tobacco industry for any research project are not eligible for any AACR grant. Grantees who accept funding from the tobacco industry for any research project during the term of an AACR grant must inform the AACR of such funding, whereupon the AACR grant will immediately be terminated.
Tobacco industry funding is defined for purposes of AACR grant applicants and recipients as money provided or used for all or any of the costs of any research project, including personnel, consumables, equipment, buildings, travel, meetings and conferences, and operating costs for laboratories and offices. It is not defined as money provided or used for meetings or conferences that don’t relate to any particular research projects.

Tobacco industry funding includes: funds from a company that is engaged in or has affiliates engaged in the manufacture of tobacco produced for human use; funds in the name of a tobacco brand, whether or not the brand name is used solely for tobacco products; funds from a body set up by the tobacco industry or by one or more companies engaged in the manufacture of tobacco products.

The following do not constitute tobacco industry funding for the purposes of this policy:

- Legacies from tobacco industry investments (unless the names of a tobacco company or cigarette brand are associated with them)
- Funding from a trust or foundation established with assets related to the tobacco industry but no longer having any connection with the tobacco industry even though it may bear a name that (for historical reasons) is associated with the tobacco industry.
APPLICATION INSTRUCTIONS
AACR requires applicants to submit a completed application by 1:00 p.m. U.S. Eastern Time on Thursday, July 13, 2017 to grants@aacr.org, under the subject line “2017 AACR-Bayer Innovation and Discovery Grants Application Submission”.

In order to submit a complete application, applicants need to complete the application template provided by AACR. The following instructions provide details about how to access the application template and successfully submit an application for consideration.

DOWNLOAD TEMPLATE & INSTRUCTIONS. The Program Guidelines and Application Instructions document (which includes the Terms and Conditions of the Grant) and Experimental Plan template can be downloaded from the AACR website: www.aacr.org/funding. The application also requires additional attachments for which templates are not provided (applicant's biographical sketch and appendices [if applicable]).

APPLICATION FORMAT. The following information is required to submit a complete application.

1. APPLICANT INFORMATION. List applicant’s name, title, institution, email address, phone number, and mailing address.

2. PROPOSAL TITLE. Enter the title of the research project. The title is limited to no more than 75 words. Do not use abbreviations.

3. SCIENTIFIC ABSTRACT. The abstract is limited to 250 words and should provide a brief summary of the proposed experimental plan. If funded, this Abstract will become public information; therefore, do not include proprietary/confidential information.

4. BUDGET DESCRIPTION. The budget is limited to one page. Applicants must submit a budget in the amount of $25,000. Please state the requested amount of funds and briefly explain how these funds will be used.

Indirect costs, tuition, travel, professional membership dues, and any other research-related expenses not directly related to the project are not allowable expenses. For the purposes of this grant, any general office supplies or individual institutional administrative charges (e.g., telephone, other electronic communication, utilities, IT network, etc.) are considered to be part of indirect and are not allowable budget line items. In addition, no grant funds may be directed towards salary or benefits of any individuals from a U.S. government entity or for-profit industry, nor for any research expenses related to the project that are incurred by these individuals.

5. EXPERIMENTAL PLAN. The experimental plan is limited to one page. Please provide a clear, concise, and comprehensive overview of the proposed work. Include information regarding background, rationale, methods, and any existing tools at your disposal. Identify the target or biomarker to be evaluated (e.g., gene ID, gene symbol) and comment on its druggability (i.e., is the target or biomarker most effectively modified by a small-molecule approach, biologic, or other? If “other”, please specify.)

6. REFERENCES. References are not required, but if references are included, they must be limited to one page. AACR reference style follows that of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals.
7. **REQUIRED SIGNATURES.** Signatures from the institutional signing official and the applicant are required. Please review the statements, as well as the Grant Agreement for this funding opportunity, and provide the necessary signatures.

8. **BIOGRAPHICAL SKETCH.** Please provide applicant’s biographical sketch. Only the NIH Biographical Sketch Form [OMB No. 0925-0001/0002 (Rev. 10/2015)] is acceptable and must be written in English.

9. **APPENDICES.** Appendices are not required and may ONLY be used for the following materials. Appendices are not to include figures, tables, or other data that otherwise should be contained within the Experimental Plan. The following materials are permitted:
   a. Clinical Trial Protocol
   b. Unpublished Manuscripts. (Manuscripts that have been published should not be attached as appendices. Instead, please list the citation on the References page.)
   c. Large size versions of figures and/or detailed legends presented in the Experimental Plan. The use of this appendix is in no way intended to increase the Experimental Plan page limit.
   d. Use of this appendix is restricted to no more than one page of figures and/or legends. This appendix is to be used when reducing the size of the figure or legend to fit within the Experimental Plan would significantly compromise the quality of the image. In no case should there be more than one page of text in this appendix. **Overuse or misuse of this appendix may result in your application being rejected or your appendix being removed from your application.**

**SUBMITTING A COMPLETE APPLICATION**

After completing the experimental plan template, combine this file into a portable document format (PDF) with the applicant’s biographical sketch and any appendices (if applicable). Save the file using the following format: “Applicant Last Name_2017 AACR-Bayer IND Grant Submission” and submit by sending the application as an e-mail attachment to grants@aacr.org. Please use the subject line: “2017 AACR-Bayer Innovation and Discovery Grants Application Submission”.

**CHANGES TO YOUR APPLICATION**

**Withdrawal of Application.** Please advise the AACR promptly, in writing, should you decide to withdraw your application for any reason. Your correspondence should include your name, the grant opportunity to which you applied, the project title, and the reason for withdrawal.

**Change of Address.** Notify the AACR in writing of any changes of address, e-mail, or phone number, following the submission of an application. The e-mail address provided with your application will be used for all official communication about your submission including the recipient selection results.

**Change of Institution or Position.** If you change your institution or professional position, contact the AACR to determine whether your application is still eligible for review.

**INQUIRIES**

Inquiries about the program guidelines, eligibility requirements, and application materials can be directed to Ms. Cory Prescott at AACR at 215-446-7280, or by e-mail at grants@aacr.org.
2017 AACR-BAYER INNOVATION AND DISCOVERY GRANTS

TERMS AND CONDITIONS

I. Definitions. The following definitions shall apply in this Agreement:

A. “Budget” shall be the budget description included with the Proposal that summarizes how the Grant Funds will be spent.

B. “Grantee” is identified as the key individual with the primary responsibility for the Project for the entire Grant Term at the level of involvement specified in the Proposal.

C. “Grant Funds” are the amount of funds that AACR is awarding to the Institution as further described in Section II.

D. “AACR’s Scientific Review and Grants Administration Department (AACR’s SRGA)” is the administrative division of AACR responsible for coordination of Projects among the Institution, Grantee, and AACR regarding any issues pertaining to the Project or the administration of the Grant.

E. “Grant Term” shall mean the period of performance for this Agreement, which begins on the Effective Date and ends on September 30, 2018.

F. “Medical Records” are any medical records of Project subjects reflecting treatment provided in connection with the Project, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs, and other diagnostic images.

G. “Deliverables” are the final progress report and other materials to be produced or submitted on behalf of the Project that AACR and the Grantee have agreed upon for the Project.

H. “Proposal” is the final version, approved by AACR, of the proposal for the Project, which is the final version as of the Effective Date.

I. “Study Data” are records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Project including, without limitation, reports (e.g., case report forms, any data summaries, and the final report) and all information regarding inventories and disposition of all drugs and devices used in or resulting from the Project to the extent housed or maintained at the Institution.

II. Award of Grant.

A. AACR shall provide the Grantee’s Institution with Grant Funds in the total amount of $25,000. Grant Funds will be paid to Institution as set forth in Section IV. The Grant is made contingent on the Grantee’s agreement to forego any other funding that would require relinquishment of the Grant.

1. Because of the importance of the Grantee to the Project, AACR will provide information about the Grantee (e.g., name, degrees, institution, project title) to Bayer. Additional materials will be provided to Bayer as detailed in Section VII.E.
B. Grantee’s attendance at the AACR Annual Meeting 2018 to formally accept the grant during the annual Grants Reception and Dinner is a condition of acceptance of this Grant. For the Grantee’s registration and attendance at this Annual Meeting, the Grantee will be reimbursed for eligible travel expenses of up to $1,000, which will be separate from the grant.

III. **Term.**

A. The Grant Term of this Agreement will be one year beginning on the Effective Date.

B. If the Grantee is unable to commence the Project by the Effective Date, AACR’s SRGA must be immediately notified. The AACR retains the right to terminate the Grant if the Project is not, or will not be, commenced within 30 days of the Effective Date, unless prior approval from AACR’s SRGA is obtained.

C. Notwithstanding anything in this Agreement to the contrary, the continuation of the term of this Agreement will be contingent on receipt by AACR of funding for this project from Bayer. If AACR fails to receive such funding, AACR may terminate this Agreement by written notice to Grantee and the Institution given as soon as reasonably possible.

IV. **Payments.** Grant Funds shall be paid in the following installments: (i) 90% of the total amount of the Grant within 30 days of the Effective Date; (ii) 10% of the total amount of the Grant within 30 days after AACR’s approval of timely submitted final progress report described in Section VII. If the approved final progress report indicates that an amount less than the total amount of the Grant is due to the Institution, only that amount required to reconcile the Grant budget will be provided by AACR to the institution. All payments together will equal the total amount of the Grant. In all instances, AACR will make every effort to complete report approval within 60 days of receipt of all reports due on the due date.

V. **Use of Grant Funds.**

A. Institution will permit the Grantee to use the Grant Funds for direct research expenses in accordance with the Proposal following the Effective Date. The Institution shall be responsible for administering the Grant in accordance with the Proposal. All disbursements shall be in strict accordance with this Agreement.

B. Grant Funds will be used for research expenses attributable to the Project, which may include:

1. Supplemental salary support, equipment, research/laboratory supplies, and other research expenses.

C. Indirect costs, tuition, travel, professional membership dues, and any other research-related expenses not directly related to this Project are not allowable expenses. For the purposes of this Grant, any general office supplies or individual institutional administrative charges (e.g., telephone, other electronic communication, utilities, IT network, etc.) are considered to be part of indirect and are not allowable budget line items. In addition, no Grant Funds may be directed towards salary or benefits of any individuals from a U.S. government entity or for-profit industry, nor for any research expenses related to the Project that are incurred by these individuals.

D. No Grant Funds provided may be used for any political campaign, or to support attempts to influence legislation by any governmental body, other than making available the results of nonpartisan analysis, study and research. Grant Funds may not become part of the Institution’s or any organization’s endowment fund, capital campaign, construction or renovation costs.
E. The Institution will be accountable for the appropriate use of the Grant Funds and for the performance of the Project. The Institution shall be liable for reimbursement to AACR of any Grant Funds associated with any inappropriate or unauthorized expenditures of Grant Funds or fraudulent or improper conduct involving the use of Grant Funds.

F. The Institution shall ensure that all Project staff use Grant Funds solely and expressly for the Project.

G. The Institution shall ensure that the Grantee exercises proper stewardship over Grant Funds and that costs charged to the Grant are allowable, allocable, reasonable, necessary, and consistently applied. AACR may disallow any cost if it determines, through audit or otherwise, that the cost does not meet the tests of allowability, allocability, reasonableness, necessity, and consistency.

H. Partial funding of the Project from other sources is acceptable and encouraged to leverage the impact of the 2017 AACR-Bayer Innovation and Discovery Grant. However, it is the responsibility of the Institution to ensure that the total amount charged for any given research expense across all funding sources does not exceed 100% of the actual cost of that research expense. Institution is responsible for determining whether acceptance of this Grant would jeopardize support for it or Grantee may receive from other sources.

I. The Institution shall return to AACR any unexpended Grant Funds upon the expiration or earlier termination of this Agreement.

VI. **Change in Project or Use of Funds.** Any changes from the Proposal that may substantially alter the goal and/or methodology of the Project must be submitted to AACR’s SRGA and approved by AACR prior to expenditure of Grant Funds on any such matters not described in the Proposal. AACR reserves the right to terminate the Grant if the Grantee’s position, Project, Institution, or funding support changes substantially from what was described in the Proposal.

A. If the Grantee is appointed to a new position at the Institution during the Grant Term, Institution is required to notify AACR in writing within 15 days of notice to the Grantee of such appointment so that AACR may determine if the continuation of the Grant is appropriate.

B. If the Grantee notifies the Institution of an intent to transfer to a new institution during the Grant Term, the Institution is required to notify AACR in writing within 15 days of receipt of such notice from Grantee. The Grant will be terminated unless a written request is made to AACR by Grantee to transfer the Grant and such request is approved by AACR.

1. In order to request such consent, the Grantee shall submit to AACR, in writing: (i) a request to transfer the Grant, (ii) a description of the current progress on the grant, (iii) the total amount of funds expected to be expended both at the current Institution and the new institution, (iv) a written confirmation from the current Institution that it is aware of the transfer, (v) a written confirmation from the new institution of its willingness to accept responsibility for the Grant, and (vi) a description of any Project modifications that may be required.

2. AACR may request additional information from the Grantee, Institution, or the new institution as needed.
3. AACR will determine, within a reasonable period of time following receipt of the aforementioned information, if the transfer of the Grant to the new institution is acceptable. If approved, AACR will execute a new Grant Agreement with the new institution.

C. The Institution shall notify AACR’s SRGA of any absence from professional duties by the Grantee during the Grant Term that extends 30 or more days and the reason for such absence.

VII. Reporting Requirements.
A. Initial funding and continued funding of the Project are contingent upon compliance by the Grantee and Institution with the reporting requirements set forth herein and approval of the reports by AACR as described in this Section. The final Progress Report is due in AACR’s SRGA according to the due date listed below. The final Progress Report must be submitted utilizing the template provided by AACR which will be available on the proposalCENTRAL Award Management System site no later than 60 days prior to the reports due date. Continuation of the Grant funding is dependent on the Grantee’s productivity and evidence of scholarship, and not on obtaining a particular result. AACR will withhold release of any future Grant Funds until the scheduled report corresponding to the status of the Project has been submitted and approved. If the Report is more than 90 days past due, and no explanation has been provided for such delay satisfactory to AACR, AACR may terminate the Grant, and upon such termination the procedures of Section XIII.F. shall apply. AACR will inform the Grantee and Institution of approval or deficiencies in the report.

B. Required Report. The Institution is responsible for the Grantee’s compliance with the following reporting requirement:

1. Final Report. A final Progress Report shall be submitted to AACR no later than 60 days after the ending date of the Grant Term. Unexpended funds should be returned via check made payable to “AACR.” The final Progress Report should summarize all progress made over the course of the grant term as well as how the Grant Funds were used.

C. The submission dates for reports are as follows.

1. Final Progress Report: November 30, 2018

D. By accepting this Grant, the Grantee gives AACR and Bayer permission to include Grant information (e.g., name, degrees, institution, project title, grant amount, abstract) in publicly accessible databases. AACR will provide copies of the Final Progress Report to Bayer or its designees, including copies submitted by the Grantee of any publications and/or press releases and/or other publicity materials generated by the Institution. AACR and/or Bayer or its designees may use publicly non-confidential and/or previously published information from the reports for public dissemination, such as within their newsletters, on websites, or in other similar public resources; provided, however, that AACR shall not make any disclosure of research results that may affect the validity of the study or influence its results. To facilitate such public dissemination, the Grantee and Institution shall fully cooperate with AACR in responding to AACR’s reasonable requests for information with respect to the Project. AACR recognizes that information contained within final reports clearly marked as confidential should be treated as such and will inform Bayer that prior approval from AACR would be necessary before disclosing confidential information publicly. AACR will take into consideration the comments of the Grantee prior to publicly disseminating such reports.
E. After the Grant Term has expired, the Grantee will continue to respond to AACR and Bayer’s reasonable requests for information on his/her career progress and may be requested to provide his/her current Curriculum Vitae, update his/her contact information, or provide other relevant information. The Grantee understands that this obligation survives the Grant Term and that he/she has an ongoing reasonable obligation to provide this information.

F. The Institution will provide access for AACR’s auditors to Institution’s books and records directly related to the Project for a financial audit of the receipt and use of the Grant Funds. Such audits will be at such times and locations as reasonably agreed to by the Institution and AACR but in any event shall occur in each instance within five business days of AACR’s request and at AACR’s sole expense.

VIII. Publications and Acknowledgment of Support.
A. The Institution and Grantee are encouraged to publish and present the results of the Grantee’s research conducted under this Agreement. Any publications resulting from research funded in whole or in part by the Grant must be cited as follows: “Research supported by the 2017 AACR-Bayer Innovation and Discovery Grant” In addition, whether during the term of the Grant or afterwards, the Grantee and the Institution shall include this citation on any publicity or communications (external or internal) resulting from the Grant, including but not limited to press releases, media reports, interviews, conference talks, and poster presentations of Study Data. Copies of all such publications must be forwarded to AACR’s SRGA.

B. Active grantees who submit manuscripts for publication to any AACR journal are entitled to a waiver of publication fees for submission and page charges. In order to receive the waiver, the Grantee must mention the AACR grant in the cover letter accompanying the manuscript and in the support section of the manuscript. The Grantee must submit the manuscript after the start of the grant term but no later than three months after the termination of the Grant.

C. Any reference to the 2017 AACR-Bayer Innovation and Discovery Grant shall include the grant name in its entirety.

D. The Grantee, Institution, the AACR, and Bayer may state factually on any of their websites and other materials their involvement with this Project and may reference on such websites any materials published in accordance with this Section VIII hereof without seeking prior approval from the AACR. No external announcement, press release, or other public statement shall be made by the Grantee, Institution, or any of its affiliated members, agents, or subcontractors to publicize their involvement with this Project, regardless of the medium used, without prior written approval of the AACR, unless required by law or regulation, or to respond to an urgent situation in which it is unreasonable to secure prior approval. The AACR will use its best efforts to review the language as promptly as possible and its approval will not be unreasonably withheld or delayed. AACR will provide Grantee and Institution with reasonable advance notice and an opportunity to comment prior to issuing any public statement regarding the Project.

E. Except as provided in this Agreement regarding acknowledgment in publications, prior approval must be obtained from AACR’s SRGA for any use of the logos, trademarks, or service marks of AACR.

F. AACR requires that the Institution list the annual support provided to the Institution by this grant whenever Institution lists grantor-supported research during the term of this Agreement.
IX. **Research Intellectual Property.**

A. The Institution or the Grantee, as prescribed by Institution policy, shall be responsible for obtaining patent or any other legal protection for each invention or discovery, as they deem appropriate, made during the course of the Project. Neither AACR nor Bayer will have any responsibility therefor.

B. The Institution shall notify AACR’s SRGA of any discovery that is or may be patentable or otherwise protectable under applicable law and that is discovered in the course of the research funded through the Grant. The Institution shall also notify AACR’s SRGA of the granting of each patent or other legal protection and of all commercial exploitation of any invention, even if it occurs after the Ending Date.

X. **Research Ethics Requirements.**

A. For research involving **human subjects**, the Institution shall certify, and require the Grantee to certify, that the proposed research project has been reviewed and approved in writing by an accredited university or medical school Institutional Review Board (“IRB”) constituted in accordance with current regulations promulgated by the **United States Department of Health and Human Services (“HHS”)** and approved by HHS, or by the **Association for the Accreditation of Human Research Protection Programs (“AAHRP”)**. More specifically:

1. Certification by the IRB must be documented by submitting a copy of the institutional letter of approval, which identifies the Principal Investigator (PI) of the Project, the Grantee as an individual authorized to work on the Project, the Project title, the date of approval, and is signed by the IRB Chair or equivalent responsible institutional official. Prior IRB certification for another project cannot be substituted, but can be officially amended to include the Project. If the IRB has deemed the Project to be “Exempt,” a copy of the institutional letter signed by the IRB Chair or equivalent responsible institutional official confirming exempt status must be submitted.

2. The Institution bears ultimate responsibility for protecting human subjects under the Grant, including human subjects at all participating and consortium sites, and for ensuring that an Assurance approved by the Office for Human Research Protections (“OHRP”) and certification of IRB approval have been obtained before human subjects research can be conducted at each collaborating site.

3. Grantee shall secure a legally acceptable informed consent from any human subjects taking part in any research supervised by such Grantee funded in whole or in part by Grant Funds in accordance with and to the extent required by current regulations promulgated by HHS.

4. Grantees at non-US institutions must adhere to ethical standards for the protection of human subjects that are at least equivalent to US standards, and to the legal requirements of the country where the research will be conducted. Certification of ethical standards approval must be documented by submitting a letter, which cites all relevant approval and license numbers and dates required by the country where the research will be conducted. In the absence of an official ethical review board (or equivalent) or legal requirements, the Grantee must agree in writing to adhere at minimum to the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.

B. For research involving **laboratory animals**, the Institution shall ensure compliance with applicable chapters of the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the NIH Manual for Grants and Contracts, and any and all requirements of the institution where such research shall occur concerning animal welfare. More specifically:
1. Certification by the Institution Animal Care and Use Committee ("IACUC") or equivalent must be documented by submitting a copy of the institutional letter of approval, which identifies the Principal Investigator (PI) of the Project, the Grantee as an individual authorized to work on the Project, the Project title, the date of approval, and is signed by the IACUC Chair or equivalent responsible institutional official. Prior IACUC certification for another project cannot be substituted, but can be officially amended to include the Project.

2. Grantees at non-US Institutions must adhere to ethical standards for the care and use of animals for research purposes that are at least equivalent to US standards and to the legal requirements of the country where the research will be conducted. In the absence of an official ethical review board (or equivalent) or legal requirements, the Grantee must agree in writing to adhere at minimum to the Association for Assessment and Accreditation of Laboratory Animal Care International’s Guide for the Care and Use of Laboratory Animals.

C. AACR will not support this Project if the Institution and Grantee do not provide the requested certification documentation and certification is required to continue the Project. AACR will withhold subsequent grant payments until such documentation has been submitted and accepted by AACR. Failure to provide the necessary IRB and/or IACUC certification or the equivalent could constitute a material breach of this Agreement and provide a basis for AACR to terminate this Agreement.

XI. Study Data.
   A. The Institution shall ensure the prompt, complete, and accurate collection, recording, and classification of the Study Data and Medical Records under the Grantee’s supervision. The Institution shall:
      
      1. Maintain and store Study Data and Medical Records in a secure manner with physical and electronic access restrictions, and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations, and industry standards.
      
      2. Protect the Study Data and Medical Records from unauthorized use, access, duplication, disclosure, loss, and damage.
      
      B. The Institution shall maintain all Study Data and Medical Records for the longer of a period of 10 years after the end of the Project, or as long as required by applicable laws and regulations.
      
      C. The Institution shall afford AACR or its designee reasonable access to the Grantee’s facilities and shall, at AACR’s expense, provide copies of Study Data to AACR. Reports referenced in Section VII shall be prepared as part of the Project and not at any additional expense to AACR. The Institution and the Grantee shall, upon request, afford regulatory authorities reasonable access to its facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data, subject to appropriate confidentiality and HIPAA protections. AACR shall comply with all applicable laws and regulations regarding subject data privacy as they relate to the use and disclosure of individually identifiable health information contained in any patient records.
      
      D. This Section XI shall survive termination or expiration of this Agreement.

XII. Indemnification. The Institution hereby indemnifies and holds harmless AACR for any and all claims, liabilities, losses, and expenses (including attorneys’ fees) to the extent arising from or caused by any of Institution’s negligent, reckless or intentionally wrongful act or omission, including without limitation research misconduct, undisclosed conflict of interest or professional malpractice, or fraud or other misconduct in applying for or expending Grant Funds or in carrying out, or reporting on, the Project.
XIII. **Term and Termination.**

A. Grantee may not terminate the Project prior to the end date without good cause and prior written approval from AACR. Failure to obtain such approval may constitute a breach of this Agreement. Institution shall require Grantee to comply with this provision and provide AACR with prompt notice of any intent to terminate the Project. If approved, the termination shall be effective on the date upon which the Grantee is notified by AACR of approval of Grantee’s request to terminate. Any unspent funds shall be returned to the AACR, and the final Progress Report submitted to the AACR within 60 days of termination.

B. Unless extended by written agreement between AACR and the Institution, the Grant Agreement will terminate upon the completion of the Project in accordance with the Goals and Deliverables, approval of the final Progress Report by AACR, and final payment in accordance with the Payment Schedule set forth in Section IV. AACR will provide the Institution with notice in writing that the Agreement has been terminated in accordance with these terms. AACR may terminate this Agreement at any time, and cease further funding, if AACR determines, in its sole discretion, that the Grantee, or Institution (i) has materially breached this Agreement and such breach has not been cured within 30 days after notice is provided of said breach; or (ii) has significantly deviated from the stated aims of the Proposal without prior approval of AACR; or (iii) is not using Grant Funds for work as set forth in the Proposal; or (iv) has taken action inconsistent with the stated objectives of the Proposal; or (v) has committed scientific fraud including fabrication, falsification, or plagiarism in proposing, conducting, or reporting the results of the Project; (vi) if the Institution ceases to be qualified as a non-profit entity that is tax-exempt under federal and state laws; or (vii) if any scheduled Report is more than 90 days past due without an explanation having been provided satisfactory to AACR. AACR retains the right to terminate the Grant if the Project is not commenced or pursued in a timely manner as set forth in Section III and in accordance with the Goals, Specific Aims, and Deliverables.

1. AACR will allow the Grantee or Institution to take corrective measures should the possibility of termination arise from financial, ethical, administrative, or programmatic insufficiencies. In such cases, the Grant will be suspended until corrective actions are taken as outlined by AACR. AACR will notify the Grantee and Institution as to the nature of such insufficiencies and give the Grantee and Institution a reasonable opportunity (not more than 30 days) to resolve the insufficiencies to the reasonable satisfaction of AACR. If the insufficiencies are not resolved within a reasonable time of not more than 30 days or are not otherwise resolved to the reasonable satisfaction of AACR, AACR may upon written notice to the Institution terminate this Grant. Upon notification by AACR of termination, a final Progress Report the work accomplished to date as well as a summary of expenditures must be submitted by the Institution with a check for the remaining balance of the Grant Funds. The Progress Report must be submitted utilizing the templates provided by AACR.

C. Any violation of a provision of this Agreement relating to Research Ethics as set forth in Section X, and other related requirements referred to and incorporated therein, shall be considered a material breach of this Agreement and may be grounds for immediate termination.

D. AACR may terminate this Agreement at any time, and cease further funding, if Bayer fails to provide sufficient funds to support the Project, as determined by AACR in its sole discretion, or if Bayer discontinues funding for the 2017 AACR-Bayer Innovation and Discovery Grant program.
E. In the event of a termination of this Agreement pursuant to Section XIII(C) or XIII(D), AACR shall be entitled to return of all unexpended Grant Funds and reimbursement of expended Grant Funds if AACR determines that such Grant Funds were improperly expended or if the benefit of the expenditure is substantially eliminated by the conduct giving rise to the termination. In addition, termination of this Agreement pursuant to Section XIII(C) or XIII(D) may jeopardize any future Grants by AACR to the Grantee and/or the Grantee’s Institution. In the event of a termination pursuant to Section XIII(E), AACR shall be entitled to a return of all unexpended Grant Funds. In addition to the provisions of Section XII above, if AACR is required to engage in litigation against the Institution to obtain any of the remedies set forth herein in the event of a termination, and is successful in obtaining any such remedy, the Institution shall pay AACR’s reasonable attorneys’ fees and costs as part of such remedy.

F. The Institution may terminate this Agreement at any time based on a material breach of the Agreement by AACR, provided that such breach has not been cured by AACR within 30 days after notice is provided of said breach.

XIV. Miscellaneous.
A. The Institution shall maintain insurance for the Project for medical professional liability and comprehensive general liability, on a “claims made” basis, against claims for personal injury, including bodily injury or death, and property damage and shall provide “tail” coverage for additional years after the termination of the Project sufficient to insure against any claims that may be asserted within the applicable statute of limitations. Such insurance shall be primary and noncontributory with any other insurance carried by the AACR or Bayer and shall provide appropriate waivers. The Institution shall ensure that Grantee maintains insurance meeting the same criteria or that Grantee is provided with the same coverage under Institution insurance. Proof of such insurance shall be provided to AACR upon request.

B. The Institution represents that it is, and will continue to be during the Grant Term of this Agreement, recognized by the Internal Revenue Service (IRS) as a non-profit entity that is tax-exempt under federal and state laws. The Institution shall notify AACR immediately of any change in its tax-exempt status.

C. Headings and titles are inserted in this Agreement for convenience, are descriptive only, and shall not be deemed to add to or detract from or otherwise modify the meaning of the paragraphs.

D. Nothing in this Agreement shall be construed to make the parties agents of each other or partners, or to permit either party to incur any expense or bind the other to any obligation not specifically set forth herein.

E. This Agreement may not be modified or amended except by an instrument in writing signed by both parties to this Agreement.

F. Neither Party may assign or otherwise delegate any of its rights or obligations hereunder without the prior written consent of the other Party. Any attempted assignment in violation of this paragraph shall be null and void, without legal force or effect.

G. Any representations that are deemed to be false will constitute a breach of the Agreement.
H. Any notice(s) required or permitted to be given by this Agreement relating to the terms and conditions of this Agreement shall be in writing and shall be delivered by e-mail, postal mail, facsimile (provided the sender has evidence of successful transmission), courier or shipping company, or personal delivery to the receiving party at its address. Any notice so delivered shall be deemed to be given, delivered and received, if delivered by personal delivery, on the day of delivery and if delivered by e-mail, postal mail, facsimile or courier or shipping company, on the day following dispatch.

I. This Agreement and all attachments hereto constitute and contain the entire agreement and understanding between the parties, and supersedes and replaces all prior negotiations and all agreements, proposed or otherwise, whether written or oral, concerning the subject matter hereof. No course of dealing, usage of trade or course of performance shall be relevant to explain, supplement or modify any express provision of this Agreement. Unless otherwise stipulated in writing, this Agreement is made with the understanding that AACR has no obligation to provide other or additional support to the Institution, any Grantee or any other person.

J. All payments by AACR to the Institution hereunder will reference the “2017 AACR-Bayer Innovation and Discovery Grant,” and will be made in U.S. dollars.

K. Neither party shall be liable for any failure to perform as required by this Agreement to the extent such failure to perform is due to circumstances reasonably beyond such party's control, including, without limitation, labor disturbances or labor disputes of any kind, accident, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures imposed by law or regulation, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, or other such occurrence.
MORE ABOUT THE PARTNERS

Synonymous with discovery and innovation, Bayer HealthCare is recognized the world over as a leader in the healthcare and pharmaceutical industry. With a legacy of therapeutic advances that have benefited people across the globe, Bayer HealthCare understands the critical importance of investing in scientific research and discovery to treat and combat disease. With this in mind, the American Association for Cancer Research (AACR), a leader in facilitating and advancing discovery and innovation in cancer research, welcomes Bayer HealthCare’s partnership in a cutting-edge research initiative modeled after, and building on, the exciting Bayer HealthCare Grants4Targets Initiative. As such, leveraging an AACR- Bayer HealthCare collaboration, the AACR will bring a new research opportunity to its base of over 35,000 members, composed of cancer scientists both within the United States and abroad.

Founded in 1907, the American Association for Cancer Research (AACR) is the world’s first and largest professional organization dedicated to advancing cancer research and its mission to prevent and cure cancer. AACR membership includes more than 37,000 laboratory, translational, and clinical researchers; population scientists; other health care professionals; and patient advocates residing in 108 countries. The AACR marshals the full spectrum of expertise of the cancer community to accelerate progress in the prevention, biology, diagnosis, and treatment of cancer by annually convening more than 30 conferences and educational workshops, the largest of which is the AACR Annual Meeting with nearly 19,500 attendees. In addition, the AACR publishes eight prestigious, peer-reviewed scientific journals and a magazine for cancer survivors, patients, and their caregivers. The AACR funds meritorious research directly as well as in cooperation with numerous cancer organizations. As the Scientific Partner of Stand Up To Cancer, the AACR provides expert peer review, grants administration, and scientific oversight of team science and individual investigator grants in cancer research that have the potential for near-term patient benefit. The AACR actively communicates with legislators and other policymakers about the value of cancer research and related biomedical science in saving lives from cancer. For more information about the AACR, visit www.AACR.org.