2020 AACR-THE MARK FOUNDATION FOR CANCER RESEARCH "SCIENCE OF THE PATIENT" (SOP) GRANTS

TERMS AND CONDITIONS

- I. <u>Definitions</u>. The following definitions shall apply in this Agreement:
- A. "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.
- B. "Budget" shall outline the details of how the Grantee and Institution will spend the Grant Funds.
- C. "Deliverables" are the progress reports, milestones reports, financial reports, and other materials to be produced or submitted on behalf of the Project that AACR and the Grantee have agreed upon for the Project.
- D. "Funder" is any third-party organization that may have provided support to AACR to sponsor this research.
- E. "Grant Funds" are the amount of funds that AACR is awarding to the Institution as further described in Section II.
- F. "Grant Term" shall mean the period of performance for this Agreement, which begins on the Effective Date and ends on November 30, 2023.
- G. "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.
- H. "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.
- I. "Proposal" is the final version, approved by AACR, of the proposal for the Project, which is the final version as of the Effective Date.
- J. "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, any interim, any annual, or 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 \$750,000. 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 the Funder. Additional materials will be provided to the Funder as detailed in Section VII.E.
- B. Grantee's attendance at the AACR Annual Meeting 2021 to formally accept the Grant during the annual Grants Reception and Dinner is a condition of acceptance of this Grant. Up to \$2500 may be allocated from the Grant to support the Grantee's attendance at this Annual Meeting.
- 1. In the event of unforeseen scheduling changes for the Grants Reception and Dinner, the Grantee will be contacted regarding alternative arrangements.

III. Term.

- A. The Grant Term of this Agreement will be three years 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 for each successive year of the Grant Term will be contingent on receipt by AACR of funding for this Project for such year from the Funder. If AACR fails to receive such funding with respect to any year, AACR may terminate this Agreement by written notice to Grantee and the Institution given as soon as reasonably possible prior to the start of such year.

IV. Payments. The Grant Funds shall be paid in the following installments: (i) \$225,000 within 30 days of the Effective Date; (ii) \$225,000 within 30 days after AACR's approval of timely submitted first annual progress, milestones, and financial reports described in Section VII; (iii) \$225,000 within 30 days after AACR's approval of timely submitted second annual progress, milestones, and financial reports described in Section VII; (iv) \$75,000 within 30 days after AACR's approval of timely submitted final progress, milestones, and financial reports described in Section VII. If the approved final financial report indicates that an amount less than \$75,000 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 each 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 and Budget 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. Salary and benefits expenses of the Grantee, postdoctoral or clinical research fellows, graduate students (including tuition), and/or research assistants, collaborator salaries and benefits are permitted, provided that no Grant Funds may be directed to collaborators or consultants working within U.S. government institutions or for-profit industry.
- 2. Research/laboratory supplies, equipment, publication charges for manuscripts that pertain directly to the funded Project and other research expenses. Budget requests for equipment that exceed 10% of the total budget must be accompanied by a detailed justification and approved in advance by AACR.
- 3. Registration, housing, travel, poster preparation fees, and subsistence expenses related to attendance at any scientific meetings or conferences applicable to the research Project. The Grantee **must** attend the AACR Annual Meeting 2021 and formally accept the grant during the annual Grants Reception and Dinner. Travel funds are for the grantee **ONLY**.
- C. Indirect costs must be kept to a minimum, and shall not exceed 10% (\$68,182) of the total direct costs of the Grant. Indirect costs include:
- 1. Facilities costs, such as depreciation and use allowances, interest on debt associated with certain buildings, equipment and capital improvements, operation and maintenance expenses, and library expenses; and

- 2. Administrative costs, such as general administration and general expenses, departmental administration, sponsored projects administration, and student administration and services.
- D. General office supplies, individual institutional administrative charges in addition to indirect costs (e.g., telephone, other electronic communication, IT network, etc.), professional membership dues, pre-award charges, and any other research-related expenses not directly related to the Project are **not** allowable expenses. 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.
- E. 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.
- F. 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.
- G. The Institution shall ensure that all Project staff use Grant Funds solely and expressly for the Project.
- H. 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.
- I. Partial funding of the Project from other sources is acceptable and encouraged to leverage the impact of 2020 AACR-The Mark Foundation for Cancer Research "Science of the Patient" (SOP) Grants. 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 it or Grantee may receive from other sources. Institution must require Grantee to document any additional funding supporting this Project, or other research that may significantly affect the Project, in the annual progress reports described in Section VII. Institution and Grantee are required to respond to requests from AACR for additional information about other funding, such as budgets and Project aims, for an evaluation of potential overlap.
- J. The Institution shall return to AACR any unexpended Grant Funds upon the expiration or earlier termination of this Agreement.

- VI. <u>Change in Project or Use of Funds</u>. Any changes from the Proposal that may substantially alter the goal, methodology, or specific aims 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) an interim progress report, (iii) an updated milestones report, (iv) a financial report of expenditures to date and the amount remaining to be transferred, (v) a written confirmation from the current Institution that it is aware of the transfer, (vi) a written confirmation from the new institution of its willingness to accept responsibility for the Grant, (vii) an updated budget and budget justification outlining how remaining funds will be spent at the new institution, and (viii) 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. <u>Prior approval</u> from the AACR is required to significantly rebudget. Significant rebudgeting is defined as when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established by the <u>approved</u> budget by more than 20% of the <u>annual</u> Grant amount. To obtain prior approval, the Grantee must submit a formal request in writing, along with a revised budget and budget justification, sent electronically to AACR's SRGA. All other budget revisions may be made at the Grantee's discretion as long as they do not exceed the threshold established by AACR and are for eligible expenses as outlined in Section V. Notwithstanding the foregoing, budget limits on travel will be strictly followed and cannot be adjusted.
- D. 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. Progress, milestones, and financial reports are due in AACR's SRGA according to the due dates listed below. Progress, milestones, and financial reports must be submitted using the templates 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 reports corresponding to the status of the Project have been submitted and approved. If any scheduled 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 reports.
- B. Required Reports. The Institution is responsible for the Grantee's compliance with the following reporting requirements:
- 1. First Annual Report. The Grantee shall submit a detailed annual report corresponding to the first year of the Grant Term summarizing research progress, including a lay summary and a summary of research completed for each specific aim. The Grantee shall also submit an updated version of the milestones report noting progress towards the milestones for that reporting period and a financial report showing the amount of Grant Funds expended, how the Grant Funds were used, and how expenditures compared to the Budget for that reporting period. The annual and milestones reports will be due within 30 days from the end of the reporting period and the financial report will be due within 60 days from the end of the reporting period. Unexpended funds remaining in the Grantee budget may be carried over to the next funded year. However, a detailed explanation must be provided for unexpended funds in excess of 20% of the yearly budgeted amount and approval must be granted in advance by AACR's SRGA. The annual progress report should be substantive and include relevant and sufficient details.
- 2. Second Annual Report. The Grantee shall submit a detailed annual report corresponding to the second year of the Grant Term summarizing research progress, including a lay summary and a summary of research completed for each specific aim. The Grantee shall also submit an updated version of the milestones report noting progress towards the milestones for that reporting period and a financial report showing the amount of Grant Funds expended, how the Grant Funds were used, and how expenditures compared to the Budget for that reporting period. The annual and milestones reports will be due within 30 days from the end of the reporting period and the financial report will be due within 60 days from the end of the reporting period. Unexpended funds remaining in the Grantee budget may be carried over to the next funded year. However, a detailed explanation must be provided for unexpended funds in excess of 20% of the yearly budgeted amount and approval must be granted in advance by AACR's SRGA. The annual progress report should be substantive and include relevant and sufficient details.

- 3. <u>Final Report.</u> A final progress report, a final updated version of the milestones report, and a final financial 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". Grantees may not apply for other AACR Grants until the final reports are received and considered acceptable by AACR's SRGA. The final progress report should be substantive and comprehensive.
 - C. The submission dates for reports are as follows.

	Financial Report	Financial Report	Progress Report	Progress Report
	Through:	Due Date:	Through:	Due Date:
Report 1:	October 31 2021	December 31, 2021	November 30, 2021	December 31, 2021
Report 2:	October 31, 2022	December 31, 2022	November 30, 2022	December 31, 2022
Report 3:	November 30, 2023	January 31, 2024	November 30, 2023	January 31, 2024

- D. All AACR grant-supported research projects are subject to final performance evaluations. Annual performance evaluations may also be conducted at AACR's discretion. The performance evaluation will be conducted using the Grantee's Proposal and all progress reports and an overall performance evaluation rating will be issued. AACR will provide copies of anonymized performance evaluation reports to the Grantee. If the AACR, after review of the progress reports and performance evaluation results, believes that the accomplishments did not meet the goals and specific aims established for the Project, detailed information on specific areas of deficiency will also be provided to the Grantee (and Institution at AACR's discretion). Grantees will be asked to respond to any deficiencies in the progress identified by any performance evaluation. A Grantee that receives an unfavorable final performance evaluation may become ineligible for AACR funding in the future.
- E. If applicable, the Grantee and Institution agree to provide to AACR all information requested that is necessary for the Funder and AACR to fulfill its reporting obligations under Section 6002 of the Affordable Care Act, which added Section 1128G to the Social Security Act, and its implementing regulations codified at 42 CFR 402 and 403 (collectively the "Sunshine Act"), in a form and/or manner reasonably requested to satisfy these reporting obligations.

- F. By accepting this Grant, the Institution and Grantee give AACR and the Funder permission to include Grant information (e.g., name, degrees, institution, project title, grant amount, abstract) in publicly accessible databases. AACR will provide copies of annual and final progress reports to the Funder 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 the Funder 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 annual and final reports clearly marked as confidential should be treated as such and will inform the Funder 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.
- G. After the Grant Term has expired, the Grantee will continue to respond to AACR and the Funder's reasonable requests for information on their career progress and may be requested to provide their current Curriculum Vitae, update their contact information, or provide other relevant information. The Grantee understands that this obligation survives the Grant Term and that they have an ongoing reasonable obligation to provide this information.
- H. 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 during Institution's normal business hours and at such times and locations as reasonably agreed to by the Institution and AACR but in any event shall occur in each instance within 10 business days of AACR's request and at AACR's sole expense.

VIII. <u>Publications and Acknowledgment of Support.</u>

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 2020 AACR-The Mark Foundation for Cancer Research "Science of the Patient" (SOP) Grant, Grant Number TBD" Electronic copies of all such publications must be forwarded to the AACR's SRGA after acceptance but before publication. 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 to any AACR journal are entitled to a full waiver of the flat publication fee. Color fees will still apply, but the author may benefit from the AACR member discount for the color figure charges if a first or last author is an active AACR Member and their membership information is included with the manuscript submission. (Author Choice fees the AACR's free-upon-publication option, is not waived.) In order to receive the publication fee waiver, the Grantee must be a bylined author and must include the AACR grant number in the Grant Support section of the manuscript. The Grantee must submit the manuscript after the start of the Grant Term but no later than twelve months after the termination of the Grant, which includes approved no-cost time extensions to the Grant Term
- C. Any reference to the 2020 AACR-The Mark Foundation for Cancer Research "Science of the Patient" (SOP) Grant shall include the grant name in its entirety.
- D. The Grantee, Institution, the AACR, and the Funder 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. <u>Ownership</u>. As between the parties, Grantee shall own all right, title, and interest in and to all inventions (whether patentable or not), compositions of matter, discoveries, materials, methods, improvements, formulas, processes, products, data, software and other copyrightable works created, made, developed, conceived or reduced to practice by or on behalf of Grantee in the performance of the Project, including without limitation all associated patents, copyrights, trade secrets and know-how (collectively the "<u>Project IP</u>"), subject to the rights granted to the Foundation as provided herein.
- B. <u>Patent Prosecution and Maintenance</u>. Grantee shall have the right, at its sole cost, to file for and obtain any patents or other legal protection for any Project IP and the Foundation

shall not have any obligations with respect thereto. Grantee shall provide the Foundation with a written disclosure of any Project IP that is or may be patentable or otherwise protectable, and shall notify the Foundation of the filing of any patent application or other legal protection claiming or covering any Project IP, the granting of any patent claiming Project IP, and the licensing or other transfer of rights to any third party to practice any Project IP (whether on an exclusive or non-exclusive basis, and whether for commercial or non-commercial purposes).

- C. <u>Development and Commercialization of Project IP</u>. Grantee acknowledges and agrees that, in accordance with the Foundation's charitable purpose, Project IP supported with Foundation funds shall be made broadly available to patients in a reasonable time frame, at a reasonable price and on a non-discriminatory basis. Grantee shall inform the Foundation of any commercialization efforts with respect to any Project IP and shall offer the Foundation the first opportunity to fund or otherwise invest in such commercialization efforts, before offering any third party the right to fund or otherwise invest in such efforts.
- D. <u>Diligence</u>; Research License. If the Foundation determines in good faith, after consulting with Grantee, that Grantee has not itself or through one or more licensees diligently pursued the further development or commercialization of any Project IP that could improve outcomes for cancer patients within a reasonable time period (not to exceed twenty-four (24) months after the creation, making, conception or reduction to practice of such Project IP), then at the Foundation's request Grantee shall meet with the Foundation to discuss a development/commercialization plan for such Project IP. If Grantee is unable or unwilling to further develop the Project IP within the timeframe determined in the plan, then at the Foundation's request Grantee shall grant to the Foundation a non-exclusive, royalty-free, sublicensable (through multiple tiers), worldwide, perpetual right and license to use, practice and improve upon any and all Project IP for non-commercial research purposes.

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 <u>United States Department of Health and Human Services ("HHS")</u> and approved by HHS, or by the <u>Association for the Accreditation of Human Research Protection Programs ("AAHRP")</u>. 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-U.S. institutions must adhere to ethical standards for the protection of human subjects that are at least equivalent to U.S. 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 <u>Public Health Service Policy on Humane Care and Use of Laboratory Animals</u>, the <u>NIH Grants and Contracts Policy & Compliance guidelines</u>, 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-U.S. Institutions must adhere to ethical standards for the care and use of animals for research purposes that are at least equivalent to U.S. 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 <u>Association for Assessment and Accreditation of Laboratory Animal Care International's Guide for the Care and Use of Laboratory Animals</u>.
- 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. <u>Indemnification</u>. 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 final progress, milestones, and financial reports 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, Specific Aims and Deliverables, approval of the final progress, milestones, and final financial reports 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.
- 1. The Institution may request a no-cost extension (NCE) for either a sixmonth or 12-month period, with total NCEs not to exceed 12 months. NCE requests must be submitted by the Grantee on the no-cost extension application template which will be provided upon request by AACR, which requires a detailed justification for the extension and an update on the progress of the Project. This form needs to be submitted along with an updated milestones report and an updated financial report.
- 2. The NCE application and accompanying reports must be received electronically by AACR's SRGA at least 60 days prior to the end date of the Grant Term. NCE requests will not be considered if (i) the request is made less than 60 days prior to the termination date of the Grant, (ii) less than \$5,000 in Grant funds are remaining according to the most recently approved financial report, or (iii) all Project aims will be completed by the end of the Grant Term.
- 3. If the NCE is approved, an Addendum to the Grant Agreement will be provided to the Institution by the AACR. The Addendum, signed by the Institution, must be returned to the AACR's SRGA in order for the NCE to take effect. The Addendum will provide new reporting requirements. The final progress report, milestones, and final financial report will be due 60 days after the termination date of the NCE.

- 4. If upon receipt of the interim NCE progress, milestones, and financial reports, AACR's SRGA determines that all Grant Funds have been allocated and/or all Project aims have been completed, the AACR reserves the right to terminate the NCE early and request any additional reports necessary to close out the Grant.
- C. 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 financial report of expenditures must be submitted by the Institution with a check for the remaining balance of the Grant Funds, as well as final progress and milestones reports outlining the work accomplished to date. Progress, milestones, and financial reports must be submitted using the templates provided by AACR.
- D. 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.
- E. AACR may terminate this Agreement at any time, and cease further funding, if the Funder fails to provide sufficient funds to support the Project, as determined by AACR in its sole discretion, or if the Funder discontinues funding for the AACR-The Mark Foundation for Cancer Research "Science of the Patient" (SOP) Grant.

- F. 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.
- G. 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 each year of 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 the Funder 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. 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 "AACR-The Mark Foundation for Cancer Research "Science of the Patient" (SOP) 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.