

	PREPARED BY: IRB Staff	APPROVED BY: Heather Clark
DOCUMENT TITLE: HRP 503 B Bioscience Protocol	DEPARTMENT: Office of Research Integrity and Assurance (ORIA)	EFFECTIVE DATE: 09.20.2023

INSTRUCTIONS

- Complete each section of the application. Based on the nature of the research being proposed some sections may not apply. Those sections can be marked as N/A. Remember that the IRB is concerned with risks and benefits to the research participant and your responses should clearly reflect these issues. You (the PI) need to retain the most recent protocol document for future revisions. Questions can be addressed to research.integrity@asu.edu.
- **PIs are reminded that not all people considering this application will be specialized in the PI's area of expertise. Language used should reflect this fact.**
- When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.

IRB: 1. Protocol Title

Unraveling the Nexus of Glioblastoma Multiforme and Type 2 Diabetes in a Long-term Survivor - A Unique Case Study

IRB: 2. Background and Objectives

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

2.1 List the specific aims or research questions in 300 words or less.

2.2 Refer to findings relevant to the risks and benefits to participants in the proposed research.

2.3 Identify any past studies by ID number that are related to this study. If the work was done elsewhere, indicate the location.

TIPS for streamlining the review time:

- ✓ Two paragraphs or less is recommended.
- ✓ Do not cut and paste of entire scope sections for grant proposal, thesis or dissertation. The IRB will request additional information if needed.

Response:

The overarching question driving this research project is to explore the intricate connections between evolutionary oncology, neurology, and diabetes in a unique case study. With a focus on a patient who is surviving beyond the typical one-year mark, we aim to investigate the effects of an aggressive cancer (Glioblastoma Multiforme) and its potential impact on the neurological system and interaction with type 2 diabetes. This project's compelling question is rooted in the need for a better understanding of a patient's case for the family. This motivation is also rooted with the intriguing aspect of uncovering potential links between glioblastoma multiforme, which has high glucose demands, and diabetes. Research will be conducted through an in-depth analysis of the patient's chart and medical records, sourced from Kaiser Permanente and Dr. Peter Lee Kim, supplemented by direct communication with the attending physician. The resources needed include access to the patient's medical records.

IRB: 3. Data Use - What are the intended uses of the data generated from this project?

Examples include: Dissertation, thesis, undergraduate project, publication/journal article, conferences/presentations, results released to agency, organization, employer, or school. If other, then describe.

Response: This is a Barrett Honors Thesis which will result in a case study manuscript that we plan to submit to the journal Evolution Medicine and Public Health

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IRB: 4. Inclusion and Exclusion Criteria

4.1 List criteria that define who will be included or excluded in your final sample.

Indicate if each of the following special (vulnerable/protected) populations is included or excluded:

- Minors (under 18)
- Adults who are unable to consent (impaired decision-making capacity)
- Prisoners
- Economically or educationally disadvantaged individuals
- Pregnant Women

4.2 Describe how individuals will be screened for eligibility.

4.3 If not obvious, what is the rationale for the exclusion of special populations?

4.3 What procedures will be used to determine inclusion/exclusion of special populations?

TIPS for streamlining the review time.

- ✓ Research involving only data analysis should only describe what is included in the dataset proposed for use.
- ✓ Course evaluation data: if there is any intent to use the course evaluation data for research, submit to the IRB to get approval.
- ✓ For any research which includes or may likely include children/minors or adults unable to consent guidance is available at: <https://researchintegrity.asu.edu/human-subjects/special-considerations>
- ✓ For research targeting Native Americans or populations with a high Native American demographic, or on or near tribal lands additional guidance is available at <https://public.azregents.edu/Policy%20Manual/1-118-Tribal%20Consultation.pdf>
- ✓ Additional information for research involving minors on campus is available at: <https://cfo.asu.edu/minors-campus>
- ✓ Research involving broader ASU student community where students are recruited outside IRB Principal Investigator's unit requires Provost Committee Approval. Please reach out to shelly.potts@asu.edu for questions regarding this process.

Response: This is a case study of a single subject who has given informal consent, and will be formally consented after IRB approval.

IRB: 5. Number of Participants

5.1 Indicate the total number of individuals you expect to recruit and enroll.

5.2 For secondary data analyses, the response should reflect the number of cases in the dataset.

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Response:

One individual will be recruited and enrolled.

IRB: 6. Recruitment Methods

- 6.1 Identify who will be doing the recruitment and consenting of participants.
- 6.2 Identify when, where, and how potential participants will be identified, recruited, and consented.
- 6.3 Name materials that will be used (e.g., recruitment materials such as emails, flyers, advertisements, etc.) Upload each recruitment material as a separate document. Name the document with the current date: name of the recruitment_material_dd-mm-yyyy
- Describe the procedures relevant to using materials (e.g., consent form).

Response:

The researchers will recruit and obtain consent of the participant. This is a case-study of one person. No recruitment materials will be used.

IRB: 7. Study Timelines

Describe

- 7.1 The duration of an individual participant's participation in the study (including any follow up).
- 7.2 The duration anticipated to enroll all study participants.
- 7.3 The estimated date for the investigators to complete this study (up to and including primary analyses).

Response:

The study will be completed by April 2024. The patient does not need to participate, their medical records will be analyzed. The estimated date of completion is April 2024.

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IRB: 8. Procedures Involved

- 8.1 Describe and explain the study design. Describe procedures including:
- 8.2 The documents/ measures / devices/ records /sampling that will be used to collect data about participants. (Attach all surveys, scripts, and data collection forms.)
- 8.3 What data will be collected including long-term follow-up?
- 8.4 All drugs and medical devices used in the research and the purpose of their use, and their regulatory approval status.
- 8.5 Describe any costs that participants may be responsible for because of participation in the research. (travel or parking costs for example, and explain any reimbursement procedures.)
- 8.6 For each procedure listed, describe **who** will be conducting it, **where** it will be performed, **how long** is participation in each procedure, and **what data** will be collected in each procedure.
- 8.7 For **secondary data analyses**, identify if it is a public dataset (please include a weblink where the data will be accessed from, if applicable). If not, describe the contents of the dataset, how it will be accessed, and attach data use agreement(s) if relevant.

TIPS for streamlining the review time.

- ✓ For studies with multiple procedures the IRB recommends including a table enumerating the name of the measures, corresponding citation (if any), number of items, sources of data, time/wave if a repeated measures design.
- ✓ Provide intervention materials, session outlines, or any other supplemental material that will be involved in the research process.
- ✓ **Upload all the materials relevant to this section. Name the document: supporting documents dd-mm-yyyy**

Response:

Data will be obtained from pre-recorded data present in the patient's medical records. This will be accessed from the Kaiser Permanente patient portal. These medical records include all pertinent medical information for the patient. However, no identifying information will be included in the publication or on the researchers' computers. The study team will not interact with the participant to collect data. All data is collected from access to the patient's medical records. Study team members are given access to the Electronic Medical Records at Kaiser through their own portal. Consent to do so was exchanged between the participant and the study team through Kaiser. Data that will be analyzed will be the patient's past conditions, medication dosages, and MRI scans obtained. Dr. Kristin Swanson and Dr. Peter Lee Kim aid in this study as a point of reference for confusion for researchers when interpreting data. Dr. Swanson does not know the identity of the patient. Dr. Lee Kim is the participant's oncologist. Dr. Swanson and Dr. Lee do not interact with the data required in this study, nor do they analyze the data.

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IRB: 9. Compensation

- 9.1 Report the amount and timing of any compensation or credit to participants.
- 9.2 Identify the source of the funds to compensate participants.
- 9.3 Justify that the compensation to participants is reasonable and/or how the compensation amount was determined.
- 9.4 Describe the procedures for distributing the compensation or assigning the credit to participants.

TIPS for streamlining the review time.

- ✓ If partial compensation or credit will be given or if completion of all elements is required, explain the rationale or a plan to avoid coercion
- ✓ For extra or course credit guidance, see “Research on educational programs or in classrooms” on the following page: <https://researchintegrity.asu.edu/human-subjects/special-considerations>.
- ✓ For compensation over \$100.00 and other institutional financial policies, review “Research Subject Compensation” at: <https://researchintegrity.asu.edu/human-subjects/special-considerations> for more information.

Response:

No compensation will be provided.

IRB: 10. Withdrawal of Participants

- 10.1 List anticipated circumstances under which participants will be withdrawn from the research without their consent.
- 10.2 Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.

Response:

In the case of the participant withdrawing from the research, all personal information will be deleted and the study will not continue.

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IRB: 11. Risks to Participants

- 11.1 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related the participants' participation in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Reference this information when appropriate.
- 11.2 If applicable, indicate which procedures may have risks to an embryo or fetus should the participant be or become pregnant.
- 11.3 If applicable, describe risks to others who are not subjects.
- 11.4 If there are risks, clearly describe the plan for mitigating the identified risks.

Safety Monitoring

This is required when research involves more than Minimal Risk to participants. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor. Describe:

- 11.5 The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe.
- 11.6 What data are reviewed, including safety data, untoward events, and efficacy data?
- 11.7 How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
- 11.8 Who will review the data?

Response:

There may be risk of minimal psychological harm. Researchers are studying an aggressive cancer with a poor prognosis and continuous discussion of this subject may cause some distress to the subject. However, if the subject wants to withdraw from the study, we will stop at any time. There is a possible risk of a breach of privacy. However, all identifiable data is stored on a password-protected computer and all HIPAA data is stored in the patient portal and not on the computer. No identifiable data will be published in the case report.

IRB: 12. Potential Direct Benefits to Participants

- 12.1 List the potential direct benefits to research participants. If there are risks noted in 11 (above), articulated benefits should outweigh such risks. These benefits are not to society or others not considered participants in the proposed research. Indicate if there is no direct benefit.
- 12.2 A direct benefit comes as a direct result of the subject's participation in the research. An indirect benefit may be incidental to the subject's participation. Do not include compensation as a benefit.
- 12.3 Include the probability, magnitude, and duration of the potential benefits.

Response:

A direct benefit includes a better knowledge and understanding of the diagnosis. An additional benefit may include findings that can affect the care plan for the patient and, thus potentially prolong survival.

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IRB: 13. Site(s) or locations where research will be conducted

List the sites or locations where your research team will conduct the research.

13.1 Identify where research procedures will be performed. 13.2 For research conducted outside of the ASU describe:

- Site-specific regulations or customs affecting the research.
- Local scientific and ethical review structures in place.

13.2 For research conducted with secondary data (archived data):

- List what data will be collected and from where.
- Describe whether or not the data requires a Data Use Agreement or any other contracts/agreements to access it for research purposes.

13.3 If this is a **multi-site study** where you are the lead investigator, describe the processes you will use to ensure communication among sites, such as:

- Each site has the most current version of the protocol, consent document, and HIPAA authorization.
- Required approvals have been obtained at each site (including approval by the site's IRB of record).
- Describe processes you will use to communicate with participating sites.
- Participating sites will safeguard data as required by local information security policies.

Response:

Data will be collected from the patient's medical chart through the Kaiser Permanente patient portal.

IRB: 14. Resources Available

Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform your roles. When applicable describe knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research. Describe other resources available to conduct the research:

For example, as appropriate:

- 14.1 Describe your facilities.
- 14.2 Describe the availability of medical or psychological resources that participants might need as a result of any anticipated consequences of the human research. These should reflect the risks identified above.
- 14.3 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.
- 14.4 Describe the qualifications/credentials of the research team in terms of degrees earned, area of study, and how it relates to proposed study.**

Response:

The patient has access to psychological and medical resources, at no cost at his primary physician's office. No facilities will be used, but sufficient technology is available to conduct the analysis of the data. The undergraduate student at ASU has taken numerous neuroscience and science courses that will aid her in her research. Dr. Carlo Maley has extensive research experience in the field. Dr. Kristin Swanson conducts GBM research at Mayo Clinic and has completed extensive research in the field. Finally, Dr. Peter Lee Kim is a practicing, board-certified oncologist at Kaiser Permanente. Dr. Peter Lee Kim is the primary physician on the patient's case.

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IRB: 15. Prior Approvals

- 15.1 Describe any approvals that will be obtained prior to commencing the research. (E.g., school, external site, funding agency, laboratory, radiation safety, or biosafety approval.)
- 15.2 In some circumstances, the external organization may require ASU's IRB approval prior to granting approval to the research team. If this is the case, explain in the protocol, and include language that approval will be added via modification prior to research proceeding.

Response:

No other prior approvals are needed.

IRB: 16. Data Management and Confidentiality

- 16.1 Indicate steps that will be taken to protect participant's privacy
- 16.2 Describe the steps that will be taken to **secure** the data during storage, use, and transmission. (Training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data collected)
- 16.3 Describe how data and any specimens will be handled:
- What **personal identifiers** will be included in that data or associated with the specimens?
 - Describe how any data will be **de-identified**, linked or tracked (e.g. master-list, contact list, reproducible participant ID, randomized ID, etc.). Outline the specific procedures and processes that will be followed.
 - **Where and how** data or specimens will be **stored**?
 - **How long** the data or specimens will be stored?
 - Who will have **access** to the data or specimens?
 - Who is responsible for receipt or transmission of the data or specimens?
 - How will data and specimens be **transported**?
 - If data or specimens will be banked for **future use**, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens.
 - Describe the procedures to **release data or specimens**, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.
 - For studies accessing existing data sets, clearly describe whether or not the data requires a **Data Use Agreement/ Business Associate Agreement or any other contracts/agreements to access it for research purposes.**
- 16.4 If your study is sponsored by HHS: NIH, you will need to comply with the revised 2023 NIH Data Management and Sharing policy. Additional information and requirements are available at <https://libguides.asu.edu/NIH-2023>. Please be aware, per 2023 NIH DMS policy, DMS plan is required at the time of proposal submission.

Response:

No personal identifiers will be present in the data used by the researchers. All identifiable data will be password protected in the patient portal. Deidentified data will be maintained in the event of further clarification for the publication of the paper. No exact dates or other HIPAA protected data will be included. No data will be transferred or downloaded to ASU servers or computers.

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IRB: 17. Consent Process

Describe the process and procedures you will use to obtain consent. Include a description of:

- 17.1 Who will be responsible for consenting participants?
- 17.2 Where will the consent process take place?
- 17.3 How will the consent be obtained (e.g., verbal, digital signature)?
- 17.4 If your study is sponsored by HHS: NIH, you will need to comply with the revised 2023 NIH Data Management and Sharing policy. Additional information and requirements are available at <https://libguides.asu.edu/NIH-2023>. To comply with this policy, please state if the consent form will include verbiage to inform participants about where the data will be made available for future research

TIPS for streamlining the review time.

- ✓ If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in their preferred language. Indicate the language that will be used by those obtaining consent. For translation requirements, see Special Considerations: Translating documents and materials under <https://researchintegrity.asu.edu/human-subjects/protocol-submission>. Note that in addition to translated materials submitted as part of the modification, the research team will need to upload the completed back translation certificate form or documentation of professional translation.
- ✓ Translated consent forms should be submitted after the English is version of all relevant materials are approved.
- ✓ If a waiver for the informed consent process is requested, justify the waiver in terms of each of the following: (a) The research involves no more than minimal risk to the subjects; (b) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (c) The research could not practicably be carried out without the waiver or alteration; and (d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- ✓ ASU consent templates are [\[here\]](#).
- ✓ **Consents and related materials need to be congruent with the content of the application.**

Response:

Hannah Human will obtain consent from the subject (see attached consent form). She will provide the participant extensive information on the intentions and possible results of the study, with the use of a consent form. The consent will be obtained through a physical or digital signature.

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IRB: 18. Investigational New Drug or Devices

If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:

9 19.1 Identify the holder of the IND/IDE/Abbreviated IDE.

10 19.2 Explain procedures followed to comply with FDA sponsor requirements for the following:

FDA Regulation	Applicable to:		
	IND Studies	IDE studies	Abbreviated IDE studies
21 CFR 11	X	X	
21 CFR 54	X	X	
21 CFR 210	X		
21 CFR 211	X		
21 CFR 312	X		
21 CFR 812		X	X
21 CFR 820		X	

Resource: <https://oprs.usc.edu/files/2017/05/IND-IDE-4-1-13.pdf>

Response:
N/A

IRB: 19. Human Subjects Certification from Training.

19.1 Provide the names of the members of the research team.

Note: ASU affiliated individuals do not need attach Certificates. Non-ASU investigators and research team members anticipated to manage data and/or interact with participants, need to provide the most recent CITI training for human participants available at www.citiprogram.org. Certificates are valid for 4 years.

TIPS for streamlining the review time.

- ✓ If any of the study team members have not completed training through ASU's CITI training (i.e. they completed training at another university), copies of their completion reports will need to be uploaded when you submit.
- ✓ For any team members who are affiliated with another institution, please see "Collaborating with other institutions" [\[here\]](#)
- ✓ The IRB will verify that team members have completed IRB training. Details on how to complete IRB CITI training through ASU are [\[here\]](#)

Response:
Hannah Human, Carlo Maley, Kristin Swanson. Kristin Swanson will not engage in human subject research, but would, instead, act as a point of reference.

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20. Conflicts of Interest

20.1 Do any of the team members have a conflict of interest related to this research?

COI definition -

Financial interest: The receipt or expectation of anything of pecuniary (money) or proprietary (ownership) value from a non-ASU entity (domestic or foreign, private or public). Examples of possible interests (not limited to):

- Compensation of any amount including (not limited to) consultant fees, payments for services, honoraria, royalties, or other income.
- Ownership interest of any value including (not limited to) stocks and stock options, private equity, or other ownership interests.
- Venture capital financing.
- Intellectual property interests of any value including (not limited to) patents, trademarks, copyrights, and licensing agreements.
- Board or executive relationship, regardless of compensation.
- Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher-education institution or affiliated research institute, academic teaching hospital, or medical center.

20.2 Who holds the interest? The individual involved in the research, or relative of this individual. Disclose financial interests in ERA MyDisclosures module. For questions related to financial interests, email COI@asu.edu.

Response:

The investigators have no conflicts of interest.

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General Tips:

- Have all members of the research team complete IRB training before submitting.
- Keep things simple and clear. A submission shouldn't require any guesswork or require outside information by the reviewers.
- Ensure that all your instruments, recruitment materials, study instruments, and consent forms are submitted via ERA when you submit your protocol document. For recommended templates, see <https://researchintegrity.asu.edu/human-subjects/forms>
- Submit a complete protocol. Don't ask questions in the protocol – submit with your best option and, if not appropriate, revisions will be requested.
- If your study has undeveloped phases, clearly indicate in the protocol document that the details and materials for those phases will be submitted via a modification when ready.
- Review all materials for consistency. Ensure that the procedures, lengths of participation, dates, etc., are consistent across all the materials you submit for review.
- Only ASU faculty, full time staff may serve as the PI. Students may prepare the submission by listing the faculty member as the PI. The submit button will only be visible to the PI.
- For information on how and what to submit with your study in ERA, see <https://researchintegrity.asu.edu/human-subjects/protocol-submission>. Note that if you are a student, you will need to have your Principal Investigator submit.