HSRB Human Studies Review Board

November 18, 2025

Monique E. Tadeo, MS, CIP
EPA Human Subjects Research Review Official and Director,
Program in Human Research Ethics and Oversight
United States Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: October 15, 2025, EPA Human Studies Review Board Meeting Report

Dear Ms. Tadeo:

The United States Environmental Protection Agency (EPA) requested that the Human Studies Review Board (HSRB) provide scientific and ethics review of a study protocol involving human subjects.

On October 15, 2025, the HSRB considered a study protocol for an evaluation of dermal and inhalation exposure of workers to mancozeb for on-farm treatment of potato seeds. Briefly, the goal of the proposed study is to collect occupational exposure measurements to represent potential exposures to mancozeb for three handler scenarios (i.e., treating, loading, and planting) related to “on-farm” liquid pesticide treatment of potato seed pieces (PSPs) and provide more representative exposure data for these on-farm activities.

The HSRB’s responses to the charge questions, along with detailed comments and recommendations for the EPA to consider are provided in the enclosed final meeting report.

Sincerely,

Philip Day

Philip Day, Ph.D.
Co-Chair, HSRB

Chad Cross

Chad Cross, Ph.D.
Co-Chair, HSRB

Report of the U.S. Environmental Protection Agency Human Subjects Review Board

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Contents

List of Acronyms

AaiH	Amount of active ingredient handled
AHETF	Agricultural Handler Exposure Task Force
CFR	Code of Federal Regulations
CI	Confidence interval
EPA	Environmental Protection Agency
HSRB	Human Studies Review Board
MU	Monitoring Unit
OT	Dioctyl Sulfosuccinate
PHED	Pesticide Handlers Exposure Database
PPE	Personal protective equipment
PSP	Potato Seed Piece
SOP	Standard operating procedure
WBD	Whole-body Dosimeter

HSRB Meeting Report

Russell R. (2025) Mancozeb: Liquid Spray On-Farm Potato Seed Treatment Study to Determine Dermal and Inhalation Exposure of Workers to Mancozeb during the On-Farm Treating, Loading, and Planting of Treated Potato Seed Pieces, unpublished protocol dated May 13, 2025, prepared for UPL NA, Inc., 73 p.

Introduction

On October 15, 2025, the Human Studies Review Board (HSRB) considered the scientific and ethical charge questions related to a study protocol titled "Mancozeb: Liquid Spray On-Farm Potato Seed Treatment Study to Determine Dermal and Inhalation Exposure of Workers to Mancozeb during the On-Farm Treating, Loading, and Planting of Treated Potato Seed Pieces." The Environmental Protection Agency (EPA) sought HSRB review of the study protocol in accordance with the applicable requirements of 40 Code of Federal Regulations (CFR) part 26.

Review Process

The Board conducted a public meeting on October 15, 2025. Advance notice of the meeting was published in the *Federal Register* as "Human Studies Review Board; Notification of a Public Meeting" (EPA, FRL-10408-01-ORD). This Final Report of the meeting describes the HSRB's discussion, recommendations, rationale, and consensus in response to the charge questions on ethical and scientific aspects of the research.

For each agenda item, the Agency staff presented their review of the scientific and ethical aspects of the research. Each presentation was followed by clarifying questions from the HSRB. The Board solicited public comments and then proceeded to address the charge questions under consideration. The HSRB discussed the science and ethics charge questions and developed a consensus response to each question. For each of the charge questions, the Chair called for the Board to vote to confirm concurrence on a summary statement reflecting the Board's response.

For their evaluation and discussion, the Board considered materials presented at the meeting, research articles, and related materials, the Agency's science and ethics reviews of the research studies, the Agency's statistical analysis of the research data, comments from the Public, and oral comments from Agency staff during the HSRB meeting discussions. A comprehensive list of background documents is available at https://www.epa.gov/scientific-leadership/hsrb-october-15-2025.

Charge Questions and Context

Charge to the Board – Science

Is the protocol "Mancozeb: Liquid Spray On-Farm Potato Seed Treatment Study to Determine Dermal and Inhalation Exposure of Workers to Mancozeb during the On-Farm Treating, Loading, and Planting of Treated Potato Seed Pieces" likely to generate scientifically reliable data, useful for estimating and assessing the exposure of those who conduct on-farm potato seed treatment, loading, and planting?

HSRB Response

The study proposed in the protocol "Mancozeb: Liquid Spray On-Farm Potato Seed Treatment Study to Determine Dermal and Inhalation Exposure of Workers to Mancozeb during the On-Farm Treating, Loading, and Planting of Treated Potato Seed Pieces" is likely to generate scientifically reliable data, useful for deriving unit dermal and inhalation exposure values for handlers that conduct on-farm potato

seed piece (PSP) treatment, loading, and planting given the study is conducted following the protocol and incorporating comments and recommendations from both the HSRB and U.S. EPA.

Science Review

The HSRB scientific experts reviewed the protocol and provided comments and recommendations based on their review. Each comment and recommendation are provided in the table below for consideration.

	Comment	Recommendation
1	Page 9, Section 2, Study Overview: The Study Overview states, "*Worker clothing and personal protective equipment (PPE) will comply with product labeling requirements*." Further, on Page 11, Section 3, the Study Rationale states, "*This study is being conducted to support the continued registration of an on-farm liquid mancozeb-based product for use on potato seed pieces. In addition to quantifying exposure to mancozeb, study data may ultimately be used to generically estimate chemical exposure to agricultural workers who treat, load, and plant potatoes treated with similar seed treatment formulations*." However, Page 10, Section 2 and elsewhere describe wearing of a second layer of clothing. It is unclear why the participating workers will be required to wear a second layer of clothing (in addition to the working garments required by the product label) during certain activities. Requirements of this second layer of clothing are not found in the PPE section of the product label (Appendix A), and wearing this second layer of clothing would result in an underestimate of worker dermal exposures under normal working conditions (e.g., work conducted according to label PPE requirements). But, it is noted that Document 1b, Overview and Justification For New Mancozeb Handler Exposure Study Scenarios, Page 5, states that "*These data will provide a better definition of exposure potential for on-farm*	The HSRB recommends that the protocol be clarified with regard to the objective for collecting data from workers who are wearing an additional layer of PPE, since this exceeds the minimum PPEs as required on the product label of the tested pesticide. In addition, it is the HSRB's understanding that the study data may also be used generically for other pesticides. If this understanding is correct and the primary objective of the protocol is to monitor worker exposures under minimum PPEs, the HSRB recommends also considering PPE label requirements for products with similar exposure scenarios (e.g., application of pesticides in liquid concentrate formulation and for PSP treatment) in order to expand use of the data collected.

	Comment	Recommendation
	uses of mancozeb with PSPs and will also include additional engineering controls, clothing, and PPE that will reduce the exposure potential for workers that handle liquid formulations of mancozeb on-farm for PSPs. These new exposure data will be fundamentally different from the existing PSP exposure data mentioned above because they reflect separate exposure estimates for three specific tasks using potato seed pieces performed by dedicated workers on the farm." Thus it appears that the primary objective of this protocol is to collect data on exposures while wearing PPE, to address this data gap. This objective should be stated clearly in the main protocol as part of the study rationale. If an additional objective of the study is to gather information that could be extrapolated to other pesticides, the protocol should state that any extrapolation would only be applicable under similar PPE scenarios. <u>Page 34, Section K – Second outer layer of clothing:</u> Section K, states "*for the treater, a second outer layer of clothing (cloth coveralls) to be worn when handling (mixing, loading, pouring or transferring) the formulated product or actively working with, on, or around, or when cleaning the potato seed treater. Loaders will also wear a second layer of clothing if they get inside the planter hopper (e.g., to clear remaining PSPs).*" This requirement of wearing additional PPE cannot be found in the product label (Attachment A). As mentioned in the comment above, HSRB is concerned that wearing additional layer of clothing may cause underestimation of dermal exposures and suggests that if a primary objective of	

Comment		Recommendation
	this protocol is to assess the effectiveness of additional PPE in reducing active ingredient exposures, this should be stated clearly in the protocol objectives.	
2	Page 10. Planter incidental exposure is uncertain because in the description of duties, planters may clear machines.	The HSRB recommends stating what incidental exposure may be and if the clearing of machines involves hands or tools.
3	Page 11. Incentives are inadequately described.	The HSRB recommends addressing the following point. What are the incentives for a farm to allow participation? Are there prior relationships? How many researchers are on a farm site at any one time?
4	Page 13. Page 13 states, "female workers will be required to self-administer a urine pregnancy test in a private location on the morning they participate in the study to ensure they are not able to become pregnant."	The HSRB recommends correcting this statement, as a pregnancy test examines presence/absence of pregnancy.
5	Page 13. Heat stress may be problematic.	The HSRB recommends clarifying the likely months of field work.
6	Pages 19 and 20 – Degradation of mancozeb on PSPs: To assess mancozeb degradation on PSPs during storage (after treatments and before planting), this protocol proposes to conduct a separate degradation study and derive a degradation curve for mancozeb residues on PSPs over time. This degradation curve will then be used to estimate the amount of active ingredient handled (AaiH) for loaders and planters. The HSRB is concerned about the uncertainties associated with this method, because 1) the degradation rate can be different under different storage conditions, and 2) the degradation regression depends on equation to be selected and number of equation parameters.	The HSRB recommends directly collecting PSPs on the days of loading/planting and analyzing for mancozeb for residues on PSPs and the AaiHs. This alternative method uses the same analytical procedures as the degradation curve method but provides direct and more accurate measurements of mancozeb on PSPs after storage.

Comment		Recommendation
7	Page 20 – Similarity restrictions: It is unclear whether this study allows the same worker to be enrolled multiple times but in different exposure scenarios (e.g., first time as a treater and second time as a loader). It is also unclear whether more than one worker (e.g., one loader and one planter) is monitored on the same workday and on the same farm.	The HSRB recommends providing clarifications to avoid potential misunderstanding.
8	Page 22, Section C - Different definitions of loaders: The definition of loader in this study is workers transferring treated PSPs to planter vehicles. This is different from the general definition of loader, which is termed as a worker transferring pesticides into pesticide application equipment (such as tanks of an aerial applicator or a ground boom tractor). Similarly, a treater in this study is comparable to a mixer/loader/applicator scenario as generally defined for pesticide handlers.	The HSRB recommends providing clarifications to avoid potential misunderstanding.
9	Page 22. Sample collection is mentioned as occurring part-way through the workday or at a convenient time for the workers. The parentheses indicate after completion of treating, loading, planting and before workers return to other work.	The HSRB recommends explaining how this variation and flexibility affects exposure and exposure measurements (e.g., use rates or time spent). Is it convenient to restrict workers to what is mentioned in the parentheses?
10	Page 23. It mentions the potential use of photographs in the study. Does this include video as well?	The HSRB recommends clarifying this point and indicating if separate acknowledgements may be needed for photography and video.
11	Page 26, Section H – Worker withdrawal: If a worker withdraws from the study during a monitoring period, it is unclear whether an additional worker of the same exposure scenario (e.g., treater) is recruited to assure exposures of 63 workers are monitored to fulfill the study goal.	The HSRB recommends providing clarifications to avoid potential misunderstanding.

	Comment	Recommendation
12	Page 26. Page 26 mentions that participants do not need to enroll in the study to receive incentive payments.	The HSRB recommends clarifying the process of incentive payments for those enrolling, those not enrolling, and those choosing to withdraw from the study.
13	Page 28, Section 9 – Field Materials and Methods: Section 9 states, "*Exposure matrices will be collected from experienced workers treating, loading, and planting treated seed using typical procedures. This provides the best estimate of potential dermal and inhalation exposure to mancozeb for workers involved in activities associated with treating, loading, and planting*." It is unclear what is meant by "exposure matrices," for example who is responsible for collecting the information, what information is gathered, and how it is collated and used to support exposure estimates.	The HSRB recommends clarification on what is meant by "exposure matrices," including describing who collects these data and how these data are used to characterize and quantify exposure measurements, and consider providing an example matrix.
14	Page 31. This statement makes it seem that data may be impacted by procedure: "In order to minimize the potential for operator exposure, the study will only involve liquid spraying systems with internal and/or shield spray nozzles."	The HSRB recommends stating whether this procedure is typical in the field and how it may impact normal exposures.
15	Page 32, Section I – Pouring of pesticides: It is unclear whether open-pouring is separated from use of a closed loading system. It is unclear whether the treater exposure data will be divided to two sub-scenarios based on whether a closed loading system is used. Both the current (Agricultural Handler Exposure Task Force (AHETF)) and previous (Pesticide Handler Exposure Database (PHED)) U.S. EPA data (https://www.epa.gov/sites/default/files/2021-05/documents/occupational-pesticide-handler-unit-exposure-surrogate-reference-table-may-2021.pdf) consider them as two	The HSRB recommends providing clarifications to avoid potential misunderstanding.

Comment		Recommendation
	different exposure scenarios and present unit exposure values separately.	
16	Page 35, Section L – Air sampling: Based on descriptions in the last paragraph of Section L, ambient air outside the respirators is collected. However, according to the table on Page 10, respirators are required for treaters and loaders and during certain activities (not the whole workday). It is unclear how the monitored air concentrations are translated to inhalation exposures for workers.	The HSRB recommends providing clarification on how the collected air data is used to calculate worker inhalation exposures. The HSRB also recommends clarifying steps to confirm the air sampling will not breakthrough the capacity of the sampling tubes.
17	Page 35. The protocol states that a woman attest to pregnancy status.	The HSRB recommends that all women should take a pregnancy test.
18	Page 37, Section 7 – Air sample collection: Only one OVS tube is used to monitor worker inhalation exposure for a whole monitoring period. It is unclear whether additional testing is conducted ahead of time to ensure tube breakthrough is not expected for the sampling period (up to a whole workday).	The HSRB recommends providing clarification on how the collected air data is used to calculate worker inhalation exposures. The HSRB also recommends clarifying steps to confirm the air sampling will not breakthrough the capacity of the sampling tubes.
19	Page 37, Section O – Hand Wash Samples: The sample collection description is unclear about whether new collection bowls are used for each sample.	The HSRB recommends confirming and stating that a separate collection bowl is used for each hand wash sample.
20	Page 37. There seems to be a missing connection to a Standard Operating Procedure (SOP) for flow rate.	The HSRB recommends stating from what SOP the 2L/min flow rate is derived.
21	Page 38, Section O – Inner Dosimeter Samples. The Protocol states, "*The inner dosimeter will be cut into six sections per Testing Facility SOP736: lower arms, upper arms, front torso, rear torso, lower legs and upper legs*" for measurement of active ingredient on the inner dosimeter. It is unclear how measurements from separate dosimeter sections are used: e.g., will they be reported separately to capture differences in exposure to different body	The HSRB recommends providing clarification on how inner dosimeter sample results are reported, e.g., will they be reported per body surface area, total body surface area, or by dosimeter mass. In addition, if measurements are normalized to surface area of skin (either by body part or whole body), the HSRB recommends providing further clarification on how the inner dosimeter is cut and measured to ensure measurements accurately reflect

	Comment	Recommendation
	areas, or will total body exposure only be calculated and reported? In addition, it is unclear if active ingredient measurements will be normalized to body surface area (either by body part or total body surface area). The HSRB notes that if the inner dosimeter is cut, inaccuracy in how/where it is cut across researchers could affect reported per-body part measurements.	surface area exposed and can be extrapolated to applicators of different sizes.
22	Page 40, Section Q – Field Recovery Evaluation. The Protocol states, "*After fortification, the inner dosimeter sections and OVS tubes will be exposed to ambient conditions (i.e., weathered) for the longest expected exposure monitoring period in a location away from possible contamination. Inner dosimeter held fortifications will be weathered under one layer of cloth. Although in some scenarios two layers of outer clothing will be worn, the single layer covering the inner dosimeter fortifications will represent treater, loader, and planter monitoring units (MUs)*." The Protocol is unclear how the fortification samples are used—e.g., will sample results be adjusted in any way based on what is measured in these samples? Also, if these samples are intended to capture a measure of how ambient conditions could weather samples, the HSRB recommends that inner dosimeter fortifications be held under the same number of layers of cloth as worn by the test subjects.	The HSRB recommends clarifying how the fortification data are used and specifying that inner dosimeter fortifications be collected under the same number of layers of cloth as worn by the test subjects.
23	Page 40, Section Q – Field Recovery Evaluation. The Protocol states, "*Finally, two untreated control samples of each matrix will be processed in the same manner as the fortified samples (i.e., OVS tubes and inner dosimeter samples weathered, and hand wash and face/neck wipe samples*	The HSRB recommends clarifying how inner dosimeter controls are collected and handled.

	Comment	Recommendation
	immediately frozen). For these control samples, just one set of two inner dosimeters will be collected under one layer of cloth to serve as controls." It is unclear how the inner dosimeter controls are collected and handled—e.g., will they be exposed to air or kept in their original packaging, and how will they be handled prior to shipment to the analytical laboratory?	
24	Page 41. The protocol states that samples are shipped frozen.	The HSRB recommends clarifying where and how samples are frozen – is that at another facility away from the field?
25	Based on the HSRB's experience with PHED and AHETF and the objective of the proposed study, it is expected that the collected data is converted to generic unit exposure values (exposure per unit amount of pesticide handled), similar to what are currently summarized in the U.S. EPA's Occupational Pesticide Handler Unit Exposure Surrogate Reference Table (https://www.epa.gov/sites/default/files/2021-05/documents/occupational-pesticide-handler-unit-exposure-surrogate-reference-table-may-2021.pdf). One key assumption of deriving unit exposure values is that exposures are directly proportional to the AaiH. Therefore, it is necessary to test whether the data collected in this study follows this assumption.	The HSRB recommends testing the proportionality, as highlighted in Comment 5 of the Statistics Review below.
26	Field logistics are inadequately described.	The HSRB recommends clarifying the following points. What facilities are used to set up equipment or more importantly to disrobe the participants and ensure privacy? Every farm is set up very differently. How do we ensure no cross-contamination of the dosimeters or anything else, and whether there is a field table and materials set up appropriately in the field to cut up the samples? How is a sink set up for

Comment		Recommendation
		washing hands and getting consistency across farms?
27	The dosimeter material is not fully described.	The HSRB recommends clarifying the following points. Describe in more detail the material of the dosimeter and from which standard this is taken. There was a mention that it is airy, does that imply holes and perforations. This will allow pesticide through the material and onto the skin. The skin beneath is not wiped for possibility of the chemical getting to and onto the skin surface, so will this be taken into consideration?
28	Subjects should be provided instructions to wear appropriate undergarments to avoid embarrassment.	The HSRB recommends ensuring that participants receive adequate instructions.
29	Observed behavior changes are not mentioned as a limitation.	The HSRB recommends mentioning the limitation that participants being observed may change their normal behaviors and engage in safer practices than they otherwise normally would.
30	The EPA exposure calculations need to be examined closely. Because jobs are restricted from overlapping in the study (e.g., treaters, loaders, and planters), the MUs are calculated separately; however, it seems on a working farm that jobs do, in fact, overlap.	The HSRB recommends clarification about how overall real-world exposures are calculated.
31	There seems to be a mismatch between what may happen in the study versus typical worker conditions.	The HSRB recommends clarifying the following point. If a worker's clothes have holes, it is suggested that they be replaced; however, this would likely not be done by a typical worker. Also, it is mentioned that workers standing downwind would be asked to move; however, where the worker normally stands seems to be important in how they typically do their work when not part of the study.

Statistics Review

The HSRB statistical experts reviewed the protocol and provided comments and recommendations based on their review. Each comment and recommendation are provided in the table below for consideration.

Comment		Recommendation
1	Mixed model approaches to data analysis appear appropriate and desirable.	As recommended by the EPA, the HSRB agrees that mixed models should be used to analyze the data. In addition to characterizing exposure distributions, these models can also be used to evaluate the relationship between AaiH and exposure.
2	There is inadequate description of the analytical approach for dosimeter samples.	The HSRB recommends clarifying whether the inner dosimeter samples from the six sections are statistically analyzed separately or combined into a single dosimeter outcome variable.
3	Obtaining observational data from each strata should be addressed to strengthen the study design.	The HSRB recommends that, if feasible, require, instead of attempt, to obtain observations from each of the three proposed AaiH strata. Ensuring representation across all strata will strengthen the study's ability to model the relationship between AaiH and exposure.
4	The analysis of the relationship between AaiH and exposure will use 95% CIs to evaluate consistency with either proportionality or independence. These are two competing hypotheses that do not encompass the entire range of slope values, and neither may be confirmed.	The HSRB recommends that also calculating a Bayes factor would assist in determining which relationship is better supported.

Charge to the Board – Ethics

If amended to address the EPA's and the HSRB's recommendations, is the research likely to meet the applicable requirements of 40 CFR part 26, subparts K and L?

HSRB Response

If amended to address the EPA's and HSRB's recommendations, the latter summarized below, the proposed research is likely to meet the applicable requirements of 40 CFR part 26, subparts K and L.

Ethics Review

Participant Selection and Recruitment

Experienced adult workers (18 years or older), excluding children and pregnant or nursing women. Female participants must have a negative pregnancy test or affirm non-pregnancy per protocol/consent. Recruitment via employer letters, workplace flyers, and telephone screening scripts (English/Spanish available). The consent describes compensation including $20 for the consent meeting and up to $200 for participation; amounts are commensurate with time/effort and not unusual for employed adult populations.

Informed Consent Process
In-person consent process using Advarra-approved form; Spanish available upon request. Privacy protections include private disrobing and confidential handling of sensitive information.

Risks and Benefits
Potential risks include pesticide contact (mancozeb), physical/heat stress, irritation from sampling solutions (Aerosol Dioctyl Sulfosuccinate (OT)), and embarrassment during disrobing. Risk-minimization measures include label-compliant PPE, experienced participants, medical monitoring/first-aid availability, and post-sampling hygiene steps.

Participants will follow label-required PPE; protocol discusses layered clothing and respirator use where applicable. EPA recommends capturing a "single-layer clothing" scenario or providing rationale for its omission.

Basis for 40 CFR part 26, Subparts K and L determination:

- Subpart K (protection of pregnant or nursing women and of children in intentional exposure research): The protocol excludes children and pregnant or nursing women; includes pregnancy testing/affirmation; and provides IRB approval with modifications. Consent materials disclose the pesticide to which subjects may be exposed and associated risks.
- Subpart L (EPA reliance): Because prohibited populations are excluded and consent/ethical safeguards are in place, reliance on data developed under this protocol would not be barred by §26.1703, provided the protocol is amended as recommended and implemented accordingly.

Comment		Recommendation
1	The informed consent process needs to be clarified.	The HSRB recommends specifying a concrete process to confirm that all participants are adults (e.g., government-issued photo identification), so enrollment is restricted to 18 years or older.
2	The protocol and informed consent form to be updated to include additional information about the use of a respirator by participants.	The HSRB recommends revising the protocol and consent to require documented respirator medical clearance and fit testing before any subject performs a respirator-required task; employer attestations alone aren't sufficient. If a participant lacks these, arrange the clearance/fit test in advance and retain proof.
3	The process for consenting a participant who prefers the consent process in Spanish is insufficient.	When Spanish consent/materials are requested, the HSRB recommends ensuring a fluent Spanish-speaking researcher is on site for the study day to conduct consent and handle questions/instructions.
4	The protocol needs to include more information on the process for monitoring and evaluating participants' skin for inclusion or exclusion.	The HSRB recommends adding pre- and post-monitoring skin checks (hands, neck, face) for irritation or exclusionary conditions; name the responsible staff and their qualifications.

5	The study should include a decontamination process for participants at the end of their participation or the end of a study day, whichever comes first.	The HSRB recommends including an end-of-day/end-of-participation decontamination step instructing participants to wash hands and face before leaving, to reduce irritation from sampling solutions.
6	Study withdrawal procedures need to be further clarified.	The HSRB recommends clarifying procedures in the following way: if a participant stops early and declines sample collection, research staff will remove dosimeters safely, have the participants wash hands/face, provide the appropriate payment, and allow them to depart; state how any partial data/samples are handled.
7	Information in the protocol and consent form detailing participant compensation are insufficient.	The HSRB recommends clarifying the payment structure (e.g., whether the info session/consent time is compensated separately) and consider reasonable additional compensation if participants must complete medical clearance/fit testing to be eligible—while avoiding undue influence.
8	The criteria in which the Study Director can withdraw participants needs to be clarified and amended.	The HSRB recommends defining objective, limited criteria for Study Director removals; avoid open-ended discretion to withdraw subjects.
9	The process for assessing and triaging in-study incidents and illnesses needs to be further clarified.	The HSRB recommends describing how in-study incidents or illnesses is triaged: who assesses severity and relatedness, and which criteria/thresholds trigger treatment, pausing monitoring, or withdrawal.
10	The protocol does not contain a sufficient process detailing the assessment of adverse effects at the 14-day follow-up.	The HSRB recommends stating what happens if participants report adverse effects at the 14-day follow-up— including evaluation, documentation, any medical referral, and reporting obligations.
11	The informed consent form needs to be updated with more information for potential participants.	The HSRB recommends the following: ● Start with a concise “key information” section that clearly explains reasons to participate or not; ● Include the required statement about future use of identifiable data/biospecimens (either permitted after removing identifiers or not permitted);

		● Say whether individual/clinically relevant results will be returned, and under what conditions; ● Mirror all protocol edits so consent and protocol remain consistent.

Recommendations for Future Studies

There are no additional recommendations for future studies.