MEMORANDUM

To: Hengameh Raissy, PharmD, Vice President for Research at UNM Health Sciences
Thomas Byrd, MD, Executive Chair, Human Research Review Committees

From: Michael Richards, MD, MPA, Executive Vice President of UNM Health Sciences, Chief Executive Officer of the UNM Health System, and Institutional Official

CC: Scot Sauder, Esq., Deputy University Counsel for Health Sciences

Date: February 11, 2025

RE: Human Subjects Research Protection Program-Updated and Revised Delegations of Authority

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Under Regents Policies 3.4 and 3.7, the Regents designated me as the "Institutional Official" with respect to the University of New Mexico's Institutional Compliance Programs including, without limitation, its human subjects protection program. In this capacity, I am the individual charged with signing the assurance documents on file with the Office of Human Research Protections ("OHRP") of the U.S. Department of Health & Human Services ("DHHS"), which is the UNM Health Sciences Center's assurance to the Federal Government that it will comply with all applicable federal laws, rules and regulations with respect to the protection of human subjects in our human subjects research efforts at the UNM Health Sciences Center and the University as a whole. These regulations impose certain obligations upon me as the Institutional Official.

The purpose of this Memorandum is to:

- clarify and confirm the delegation of authority to the Human Research Review Committees at the UNM Health Sciences (each, an "HRRC", and, all collectively, the "HRRCs"),
- reaffirm the autonomy of the HRRCs relating to its review of research,
- clarify and confirm the role of the Vice President for Research for Health Sciences as the Institutional Official's designee and her relationship with and to the Human Research Protections Office ("HRPO") and the authorities and responsibilities delegated to her, and
- clarify and confirm those authorities and responsibilities I am retaining as the "Institutional Official."

Delegation to the HRRCs and Commitment to Autonomy

All Human Research at the UNM Health Sciences Center must undergo review by an organizationally-designated HRRC. Activities that do not meet the definition of Human Research (i.e., some classroom or training activities or certain quality improvement activities that do not meet the definition of Human Research) do not require HRRC review and approval and do not need to be submitted to the HRRC unless there is a question regarding whether the activity is Human Research.

The HRRCs are hereby delegated and shall have the authority to:

- Approve, require modifications to secure approval, defer, and disapprove all Human Research overseen and conducted by the organization, with the exception of approved external IRBs as provided in the *Investigator's Manual*. All Human Research must be approved by an HRRC designated by the Institutional Official.
- Suspend or terminate approval of Human Research not being conducted in accordance with the HRRC's requirement or that has been associated with unexpected serious harm to subjects.
- Observe the informed consent process and the Human Research process.
- Determine whether an activity is Human Research.
- Evaluate financial interests of investigators and research staff and have the final authority to decide whether the financial interest and management plan as written allow the Human Research to be approved.
- Place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research, related to non-compliance with approved protocols.

HRRC members and the employees within the HSC Office of Research, including the HRPO, have the responsibility to follow and apply Human Research Protection Program policies and procedures that apply to HRRC members and staff.

The University of New Mexico is fully committed to ensuring the autonomy of the HRRCs in exercising their decision-making and other responsibilities for the review of research. Affiliate or community reviewers have both the obligation and right to report any attempts at undue influence upon them to make decisions with respect to matters, actions, or decisions within the delegated authority of the HRRCs (as described above). "Undue influence" refers to interference with the normal functioning and decision-making of an HRRC in order to secure a particular determination or outcome.

The following example may help illustrate "undue influence." A Departmental Chair requests a visit with an HRRC member who is a senior faculty member in their Department. The Chair expresses concern that the HRRC committees have been making too many unfavorable decisions regarding protocols from that Department. The HRRC member is asked to divulge information concerning how the convened HRRC Committee makes decisions and how the process could be made more favorable to the Department's applications. Specific protocols are not discussed but it appears that by the requests made by the Chair, he/she is seeking to improperly influence research review decisions made by the HRRC. The IRB member, knowing that all HRRC proceedings are confidential, should refer the Chair to the Vice President for Research for more information about IRB operations.

In contrast, developing and implementing productivity measures and standards for HRPO staff or prioritizing work within the HRPO, to ensure effective and efficient operations of the HRPO, would not be considered "undue influence."

Concerns relating to possible attempts at undue influence may be reported, in person or in writing, to the HRRC Executive Chair, the Executive Research Operations Officer, the HRPP Director, the Vice President for Research for Health Sciences, or the Office of University Counsel.

Concerns relative to undue influence may also be reported anonymously to the HSC's Compliance Hotline at (888) 899-6092.

Role of the Institutional Official and Delegation of Certain Authorities and Responsibilities to the Vice President for Research for Health Sciences

As stated previously, the Regents designated me to serve in the role of the "Institutional Official." In this connection, this means that, consistent with Federal Regulations and Guidance, I have the authority to take the following actions or delegate these authorities to a designee:

- Create the Human Research Protection Program budget.
- Allocate resources within the Human Research Protection Program budget.
- Appoint and remove HRRC members and HRRC chairs.
- Hire and fire HRPO staff, consistent with UNM Human Resources policies and procedures.
- Determine what HRRCs the organization will rely upon. In this regard, as the Institutional Official, I have the authority to determine whether the University may rely on any one or more external IRBs or central IRBs.
- Approve and rescind IRB authorization agreements.
- Place limitations or conditions on an investigator's or research staff's privilege to conduct Human Research.
- Create policies and procedures related to the Human Research Protection Program and the HRPO that are binding on the organization.
- Suspend or terminate HRRC approval of research.
- Disapprove research approved by the HRRC, as set forth in the *Investigator's Manual.*

In addition, I, as the Institutional Official, have the responsibility to:

- Oversee the review and conduct of Human Research under the jurisdiction of the Human Research Protection Program.
- Periodically review the University's Human Research Protection plan to assess whether it is providing the desired results and implement amendments or changes as needed.
- Establish policies and procedures designed to ensure that Human Research will be conducted in accordance with ethical and legal requirements.
- Ensure that the research review process is independent and free of coercion or undue influence, and ensure that the official of the organization cannot approve research that has not been approved by an HRRC designated by the organization.
- Implement a process to receive and act on complaints and allegations regarding the conduct of our Human Research Protection Program.
- Investigate and remediate identified systemic problem areas, and where necessary, remove individuals from involvement in our Human Research Protection Program.
- Ensure that the Human Research Protection Program has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner.
- Review and sign Federalwide Assurances (FWA) and addenda.
- Fulfill educational requirements mandated by OHRP.

In this connection, with this Memorandum, I am delegating the Vice President for Research for Health Sciences the following authorities:

- Appointing HRRC members. If the Vice President for Research for Health Sciences determines to not renew, or to suspend or to terminate, the HRRC membership of any individual for whom it has been determined that he/she is not fulfilling membership responsibilities and/or obligations, the Vice President for Research for Health Sciences shall first consult with the HRRC Executive Chair, and shall inform me in writing of the decision to include a written justification for the decision;
- Appointing the IRB Chair or Alternate Chair. If the Vice President for Research for Health Sciences determines not to renew, or to suspend or terminate, one or more HRRC Chairs for whom it has been determined that he/she is not fulfilling such Chair's responsibilities and or obligations, the Vice President for Research for Health Sciences shall first consult with the HRRC Chair, and shall inform me in writing of the decision to include a written justification for the decision;
- Performing periodic evaluation of the performance of the HRRC Executive Chair and the individual HRRC Chairs and administrative staff. In this connection, the HRPO and its staff shall report administratively to the HSC Office of Research under the auspices of the Vice President for Research for Health Sciences. The attached organizational chart is hereby approved as the organizational chart for our Human Research Protection Program;
- Managing and administering funds and ensuring that adequate personnel, space and other resources are allocated to the Human Research Protections Program. To prepare the annual budget for the HRPO and the HRRC, the Vice President for Research for Health Sciences will consult with the Executive Director of the Office of Research for Health Sciences, the Office of Research Operations Manager, the HRPP Director and the HRRC Executive Chair to budget any financial needs, which shall, as part of the UNM Health Sciences Center normal budgeting processes, be communicated to me and the Senior Executive Financial Officer for the UNM Health Sciences Center;
- Reviewing and signing memoranda of understanding and cooperative agreements between the institution and other organizations, including those that establish reliance on IRBs of record for collaborative research (e.g., IRB Authorization Agreements, Individual Investigator Agreements). The Vice President for Research for Health Sciences is delegated authority and responsibility to determine whether or not the University may rely on one or more external IRBs and/or central IRBs and to sign all necessary documents and instruments as may be necessary to carry out this determination, consistent with the provisions of the *Investigator's Manual*;
- Being the point of contact for correspondence addressing human subjects research with the OHRP, the FDA and other agencies as applicable, including reports to federal agencies;
- Ensuring that HRRC members and investigators are knowledgeable to conduct research in accordance with ethical standards and all applicable regulations;
- Developing and implementing an initial and continuing educational plan for HRRC members, staff and investigators. I would anticipate and expect that the Vice President for Research for Health Sciences would consult and collaborate with the HRRC Chairs, and appropriate individuals in the HSC Office of Research (which includes the HRPO) in developing and implementing those educational plans;

- Recruiting qualified members that encompass adequate expert, non-scientific and unaffiliated representation on the HRRCs. I would anticipate and expect that the Vice President for Research for Health Sciences would consult and collaborate with the HRRC Chairs, and appropriate individuals in the Office of Research for Health Sciences (which includes the HRPO) in developing and implementing such a recruitment plan;
- Reviewing and approving Standard Operating Procedures (SOPs) for HRRCs and the HRPO;
- Overseeing daily operations of the HRRCs and the HRPO in accordance with the SOPs. In this connection, I have asked the Vice President for Research for Health Sciences to establish, in consultation with the HRRC Executive Chair, metrics and benchmarking statistics to ascertain the operational performance of the HRRCs, the HRPO and the HRPO staff including processing timelines and productivity reporting, which shall be reported to me on a semi-annual basis. Additionally, the Vice President for Research shall report to me the results of compliance oversight reviews of the HRPO and the HRRCs that are or may be conducted by the UNM HSC Compliance Office.

Pursuant to Federal Regulations, neither I nor the Vice President for Research for Health Sciences may approve research that has not been approved by the HRRCs.

Please note that I am not delegating my responsibility for:

- Signatory authority for the Federalwide Assurance for the University;
- Completing recommended Assurance training for the IO;
- Ensuring that the HRRCs function with independence in their review of research and that their Chairs and members have direct access to me for appeal if they experience undue influence or if they have concerns about the operation of the HRRCs;
- Ensuring that adequate resources, including funds, space, and personnel are provided to support the operation of our Human Research Protection Program.

The above and foregoing delegations of authority are effective immediately.

Michael Richards, MD, MPA
Executive Vice President of UNM Health Sciences
& Chief Executive Officer of the UNM Health System

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