

FWA #: FWA00001888  
Institution: Medical U of South Carolina  
Expires: 09/16/2026

OMB No. 0990-0278  
Approved for use through August 31, 2023

## Federalwide Assurance (FWA) for the Protection of Human Subjects

### 1. Institution Filing Assurance

Legal Name: Medical U of South Carolina  
City: Charleston State/Province: SC Country: USA

### 2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (\*) any alternate names under which the Institution operates.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below.

| Name of Component or Alternate Names Used | City             | State (or Country if Outside U.S.) |   |
|---|------------------|------------------------------------|---|
| Carolina Family Care                      | Charleston       | SC                                 | A |
| Carolina Family Care                      | James Island     | SC                                 | A |
| Carolina Family Care                      | Mt. Pleasant     | SC                                 | A |
| Carolina Family Care                      | North Charleston | SC                                 | A |
| Children's Hosp                           | Charleston       | SC                                 | A |
| Foundation for Rsch Development           | Charleston       | SC                                 | A |
| Hollings Cancer Ctr                       | Charleston       | SC                                 | A |
| Institute of Psychiatry                   | Charleston       | SC                                 | A |
| Medical U Hosp                            | Charleston       | SC                                 | A |
| Storm Eye Inst                            | Charleston       | SC                                 | A |
| U Med Associates                          | Charleston       | SC                                 | A |
| Bioprinting Center                        | Charleston       | SC                                 | A |
| Cardiovascular Translational Rsch Ctr     | Charleston       | SC                                 | A |
| Center for Medication Safety              | Charleston       | SC                                 | A |
| Phenomics Center of South Carolina        | Charleston       | SC                                 | A |
| MUSC Health Chester Medical Center        | Charleston       | SC                                 | A |
| MUSC Health Florence Medical Center       | Charleston       | SC                                 | A |
| MUSC Health Lancaster Medical Center      | Charleston       | SC                                 | A |

### 3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the following statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. (indicate below)

#### ***The Belmont Report***

### 4. Applicability

(a) This Assurance applies whenever this Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

### 5. Assurance of Compliance with the Terms of the Federalwide Assurance

(a) This Institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance (contained in a separate document on the Office for Human Research Protections (OHRP) website).

#### 6. Designation of Institutional Review Boards (IRBs)

This Institution assures that it will rely upon only IRBs registered with OHRP for review of research to which this FWA applies. This institution (a) designates the following internal IRB(s) for review of research under this Assurance; or (b) does not have an internal IRB and designates the following external IRB for review of all research to which this FWA applies or, if multiple external IRBs are relied upon, the following external IRB that reviews the largest percentage of research to which this FWA applies.

NOTE: Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies.

| HHS IRB<br>Registration<br>Number | Name of IRB as Registered with HHS                | Is the IRB Internal or<br>External to the Institution? |
|-----------------------------------|---|--|
| IRB00000027                       | Medical U South Carolina IRB #1                   | I  |
| IRB00000028                       | Medical U South Carolina IRB #2                   | I  |
| IRB00000240                       | U of SOUTH CAROLINA IRB #1                        | E  |
| IRB00000481                       | CLEMSON U IRB #1                                  | E  |
| IRB00000533                       | WCG IRB   | E  |
| IRB00000715                       | Palmetto Health IRB #1 - PH IRB #1                | E  |
| IRB00000781                       | National Cancer Inst Central IRB #1 (Adult)       | E  |
| IRB00000805                       | Greenville Hosp System IRB #1                     | E  |
| IRB00001369                       | Spartanburg Regional Healthcare System IRB #1 - 1 | E  |
| IRB00001377                       | Medical U South Carolina IRB #3                   | I  |
| IRB00004296                       | National Cancer Inst Central IRB #2 (Pediatric)   | E  |

7. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: Stacey                      Middle Initial: C    Last Name: Goretzka  
Degrees or Suffix: CIP                      Institutional Title: IRB Manager  
Institution: Med U South Carolina  
Telephone: 843 792-6527                      FAX: 843 792-7457                      E-Mail: goretzka@musc.edu  
Address: One South Park Circle, Bldg 1, Suite 401  
City: Charleston                      State/Province: SC                      Country: USA

8. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

I have read and agree to the Terms of the Federalwide Assurance.

I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) that this institution relies upon will comply with the Terms of the Federalwide Assurance when reviewing research covered by this Assurance and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Signature: Lori McMahon Ph.D.

Date: 09/16/2021

First Name: Lori Middle Initial: Last Name: McMahon

Degrees or Suffix: Ph.D. Institutional Title: Vice President for Research

Institution: Medical University of South Carolina

Telephone: 843 792-9378 FAX: 843 792-4817 E-Mail: mcmahonl@musc.edu

Address: 125 Doughty Street, Suite 100U

City: Charleston State/Province: SC Country: USA

9. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to HHS by the above Institution is hereby approved.

Assurance Number: FWA00001888

Expiration Date: 09/16/2026

Signature of HHS Approving Official: Cecilia Chirinos

Date: 09/16/2021

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