

FWA #: FWA00027320
Institution: JSS Medical College, Mysuru
Expires: 09/18/2023

OMB No. 0990-0278
Approved for use through July 31, 2020

Federalwide Assurance (FWA) for the Protection of Human Subjects

1. Institution Filing Assurance

Legal Name: JSS Medical College, Mysuru
City: Mysuru State/Province: Country: INDIA

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.)	
JSS Medical College	Mysuru	IN	A
JSS Medical College	Mysuru	IN	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

The Declaration of Helsinki

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.

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).

(b) Non-U.S. institutions only: This Institution assures that whenever it engages in research to which this Assurance applies it will comply with the following procedural standards (please check one or more of the following):

The current International Conference on Harmonization E-6 Guidelines for Good Clinical Practice (ICH-GCP-E6)

The current Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects

The current Indian Council of Medical Research Ethical Guidelines for Biomedical Research on Human Subjects

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 Registration Number	Name of IRB as Registered with HHS	Is the IRB Internal or External to the Institution?
IRB00011070	JSS Medical College, Mysuru IRB #1	I
IRB00011071	JSS Medical College, Mysuru IRB #2	I

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

First Name: **Basavanagowdappa** Middle Initial: Last Name: **Hathur**
Degrees or Suffix: **MD** Institutional Title: **Principal**
Institution: **JSS Medical College, Mysuru**
Telephone: **821-2548337** FAX: **821-2493819** E-Mail: **jssmc09@gmail.com**
Address: **JSS Medical College, Bannimantap, SS Nagar, Mysore**
Sri shivarathreeshwara nagara
Bannimantap
Mysuru
City: **Mysuru** State/Province: Country: **INDIA**

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: **Basavanagowdappa Hathur MD**

Date: **09/05/2018**

First Name: **Basavanagowdappa** Middle Initial: Last Name: **Hathur**

Degrees or Suffix: **MD** Institutional Title: **Principal**

Institution: **JSS Medical College, Mysuru**

Telephone: **821-2548337** FAX: **821-2493819** E-Mail: **jssmc09@gmail.com**

Address: **JSS Medical College, Bannimantap, SS Nagar, Mysore**
Sri shivarathreeshwara nagara
Bannimantap
Mysuru

City: **Mysuru** State/Province: Country: **INDIA**

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: **FWA00027320**

Expiration Date: **09/18/2023**

Signature of HHS Approving Official: **Christina Lindsay**

Date: **09/18/2018**

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0278 . The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance

IORG #: **IORG0009292**
Institution: **JSS Medical College, Mysuru**
Expires: **06/08/2020**

OMB No. 0990-0279
Approved for use through October 31, 2018

**U.S. Department of Health and Human Services (HHS)
Registration of an Institutional Review Board (IRB)**

This form is used by institutions or organizations operating IRBs that review:

- a) Research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research; and/or**
- b) Clinical investigations regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services**

This form is to be used for the following purposes:

- a. To register an IRB if your institution or organization has not previously registered an IRB
- b. To update or renew the registration of an IRB previously registered by your institution or organization
- c. To add another IRB to those previously registered by your institution or organization

Fields with an * are required for OHRP IRBs and FDA IRBs

Fields with an are required for OHRP IRBs but are optional for FDA IRBs

Fields with an ‡ are required for FDA IRBs but are optional for OHRP IRBs

Fields with no symbol are optional for both OHRP IRBs and FDA IRBs

- 1. *Has your institution or organization previously registered an IRB with the Office for Human Research Protections (OHRP)?**

Yes, proceed to section 2

No, proceed to section 3

- 2. *What is your institution or organization (IORG) number? IORG0009292**

This number was provided by OHRP the first time your institution or organization registered an IRB. If you do not know your IORG number, search for your institution or organization on the OHRP website at <http://ohrp.cit.nih.gov/search/search.aspx> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daqi-staff.html> or by telephone at 1-866-447-4777.

- 3. Name of Institution or Organization Operating the IRB(s)**

*Name of Institution or Organization: **JSS Medical College, Mysuru**

*Mailing Address: **JSS Medical College, Bannimantap, SS Nagar, Mysore-570015**

*Street Address (if different from the Mailing Address above):

570015

*City: **MYSORE**

*State/Province:

*Zip/Postal Code:

*Country (if outside the U.S.): **INDIA**

4. Senior Officer or Head Official of Institution or Organization Responsible for Overseeing the Activities Performed by the IRB(s)

*First Name: **Suresha**

Middle Initial:

*Last Name: **RN**

Earned Degree(s): **MD**

Title or Position: **Professor**

*Mailing Address (if different from the Mailing Address in section 3):

JSS Medical College, Bannimantap, SS Nagar, Mysore-570015

*City: **MYSORE**

*State/Province:

*Zip/Postal Code:

*Country (if outside the U.S.): **INDIA**

*Phone: **+91 821-2548337**

*FAX: **+91 821-2493819**

*E-Mail: **jssmc09@gmail.com**

5. Contact Person Providing this Registration Information

*First Name: **Praveen**

Middle Initial:

*Last Name: **Kulkarni**

Earned Degree(s): **MD**

Title or Position: **Assistant Professor**

Name of Institution or Organization (if different from the Name in section 3):

JSSMC, Mysore

*Mailing Address (if different from the Mailing Address in section 3):

Bannimantap, SS Nagar, Mysore

MYSORE

KARNATAKA

India

*City: **MYSORE**

*State/Province:

*Zip/Postal Code:

*Country (if outside the

INDIA

*Phone: **+91 821-2548337**

*FAX: **+91 821-2493819**

*E-Mail: **praveenkulkarni@
jssuni.edu.in**

6. IRB Registration Information (to be completed separately for each IRB being renewed/updated or newly registered)

A. *Is this a renewal or update of a registration for an IRB already registered with HHS?

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00011070**

(This number was provided by OHRP the first time the IRB was registered with OHRP. If you do not know the IRB registration number, search for the IRB on the OHRP website at <http://ohrp.cit.nih.gov/search/search.aspx> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daqi-staff.html> or by telephone at 1-866-447-4777)

No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

JSS Medical College, Mysuru IRB #1

C. Location of the IRB

*Mailing Address (if different from the Mailing Address in section 3):

JSS Medical College, Bannimantap, SS Nagar, Mysore-570015

*Street Address of the IRB (if different from the Mailing Address of the IRB):

570015

*City: **MYSORE**

*State/Province:

*Zip/Postal Code:

*Country (if outside the U.S.): **INDIA**

*Phone: **+91 821-2548337** *FAX: **+91 821-2493819** *E-Mail: **jssmc09@gmail.com**

D. Approximate number of full time equivalent positions devoted to the IRB's administrative activities:

4

E. Approximate number of all active protocols (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

50

F. Approximate number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, etc.) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

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G. ‡For IRBs that review, or intend to review, protocols involving products regulated by the Food and Drug Administration (FDA) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

‡i) Approximate number of active protocols involving FDA-regulated products:

‡ii) Types of FDA-regulated products involved in FDA protocols include (check all that apply):

human drugs	food additives
medical devices	color additives
biological	other
	Specify

H. IRB Chairperson

*First Name: **Premanath** Middle Initial: *Last Name: **Manjunath**

Earned Degree(s): **MD** Title or Position: **Chairman**

Mailing Address (if different from the Mailing Address in section 3):

Prem Health Care M Block Nrupatunga Road, Kuvempunagar, Mysore - 570023

City: **MYSORE** State/Province: Zip/Postal Code:

Country (if outside the U.S.): **INDIA**

*Phone: **+91-9972525114** FAX:

*E-Mail: **premanath.manjunath@gmail.com**

I. IRB Roster Form: Completion of the IRB Roster Form is required if your IRB is designated on a Federalwide assurance submitted to OHRP. Otherwise, it is optional.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Manjunath, Premanath	M	MD	S	General Medicine	N	
RN, Suresha	M	MD	S	Pharmacologist	Y	Member secretary
Rajegowda, Rajalakshmi	F	MD	S	Physiologist	Y	
Ramesh, Madan	M	PhD	S	Basic Medical Scientist	Y	
Hathur, Basavanagowdappa	M	MD	S	General Medicine	Y	
MN, Guruswamy	M	MS	S	ENT	Y	
MP, Nagendra Murthy	M	B.Com. LL.M, M.Phil	S	Legal	Y	
Phaneesh, Sudha	F	PhD	S	Sociologist	Y	
RS, Nagaraj	M	BSc, MBA	N	Lay person	Y	

Alternative Members

NOTES:

Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

Affiliation: Please indicate whether or not each individual (or a member of that person's immediate family) is affiliated (other than as an IRB member) with the institution or organization operating the IRB.

Yes = The IRB member is affiliated with the institution or organization operating the IRB.

No = The individual is not affiliated with the institution or organization operating the IRB.

Alternate Members: An alternate member(s) may be designated, as needed, for a regular voting member(s). An alternate member may vote only when the regular voting member is not voting.

When an institution or organization registers two or more IRBs, all alternate members for all IRBs may be listed on the roster of one IRB, or they may be listed separately with each IRB roster. A primary member of any IRB registered under the same IORG number may serve as an alternate for any comparably qualified member on any other IRB of that institution or organization. Primary members on registered IRBs serving as alternate members do not need to be listed as an alternate on any roster. Each alternate IRB member who replaces a primary member at any given meeting should have experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member whom the alternate will replace. Whenever an alternate member substitutes for a primary member of the IRB, the combined requirements of § 46.107(a) and 46.108(b) shall remain satisfied. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member, and include the identity of the replaced primary and the alternate members. If multiple alternate members serve at an IRB meeting, the pairing of primary and alternate members should be indicated.

A. *Is this a renewal or update of a registration for an IRB already registered with HHS?

Yes. Provide the IRB registration number previously assigned to this IRB by OHRP: **IRB00011071**

(This number was provided by OHRP the first time the IRB was registered with OHRP. If you do not know the IRB registration number, search for the IRB on the OHRP website at <http://ohrp.cit.nih.gov/search/search.aspx> or contact OHRP using the contact information at <http://www.hhs.gov/ohrp/daqi-staff.html> or by telephone at 1-866-447-4777)

No, this is a new IRB registration.

B. Provide the IRB name, if any, used by the institution or organization (e.g., State University Behavioral IRB, University Healthcare Biomedical IRB, or XYZ Hospital IRB #1):

JSS Medical College, Mysuru IRB #2

C. Location of the IRB

*Mailing Address (if different from the Mailing Address in section 3):

JSS Medical College, Bannimantap, SS Nagar, Mysore-570015

*Street Address of the IRB (if different from the Mailing Address of the IRB):

570015

*City: **MYSORE**

*State/Province:

*Zip/Postal Code:

*Country (if outside the U.S.): **INDIA**

*Phone: **+91 821-2548337** *FAX: **+91 821-2493819** *E-Mail: **jssmc09@gmail.com**

D. Approximate number of full time equivalent positions devoted to the IRB's administrative activities:

4

E. Approximate number of all active protocols (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

50

F. Approximate number of active protocols conducted or supported by HHS (e.g., the National Institutes of Health, Centers for Disease Control and Prevention, etc.) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or

10

under an expedited review procedure during the preceding 12 months):

- G. ‡For IRBs that review, or intend to review, protocols involving products regulated by the Food and Drug Administration (FDA) (for purposes of completing this registration, an active protocol is any protocol for which the IRB conducted an initial review or continuing review at a convened meeting or under an expedited review procedure during the preceding 12 months):

‡i) Approximate number of active protocols involving FDA-regulated products:

‡ii) Types of FDA-regulated products involved in FDA protocols include (check all that apply):

human drugs	food additives
medical devices	color additives
biological	other
	Specify

H. IRB Chairperson

*First Name: **Premanath** Middle Initial: *Last Name: **Manjunath**

Earned Degree(s): **MD** Title or Position: **Chairman**

Mailing Address (if different from the Mailing Address in section 3):

Prem Health care, M Block Nrupatunga Road, Kuvempunagar, Mysore - 570023

City: **MYSORE** State/Province: Zip/Postal Code:

Country (if outside the U.S.): **INDIA**

*Phone: **+91 821-2548337** FAX: **+91 821-2493819** *E-Mail: **premanath.manjunath@gmail.com**

I. IRB Roster Form: Completion of the IRB Roster Form is required if your IRB is designated on a Federalwide assurance submitted to OHRP. Otherwise, it is optional.

Member Name (Last, First)	Sex M/F	Earned Degree(s)	Scientist (S) Non-scientist (N)	Primary Scientific or Non-Scientific Specialty	Affiliation with Institution(s) Y/N	Comments
Manjunath, Premanath	M	MD	S	General Medicine	N	
RN, Suresha	M	MD	S	Pharmacologist	Y	Member Secretary
Rajegowda, Rajalakshmi	F	MD	S	Physiologist	Y	
Ramesh, Madan	M	PhD	S	Basic Medical Scientist	Y	
Hathur, Basavanagowdappa	M	MD	S	General Medicine	Y	
MN, Guruswamy	M	MS	S	ENT	Y	
MP, Nagendra Murthy	M	B.Com. LL.M, M.Phil	N	Legal	Y	
Phaneesh, Sudha	F	PhD	S	Sociologist	Y	
RS, Nagaraj	M	PhD	N	Lay person	Y	

Alternative Members

NOTES:

Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

Affiliation: Please indicate whether or not each individual (or a member of that person's immediate family) is affiliated (other than as an IRB member) with the institution or organization operating the IRB.

Yes = The IRB member is affiliated with the institution or organization operating the IRB.

No = The individual is not affiliated with the institution or organization operating the IRB.

Alternate Members: An alternate member(s) may be designated, as needed, for a regular voting member(s). An alternate member may vote only when the regular voting member is not voting.

When an institution or organization registers two or more IRBs, all alternate members for all IRBs may be listed on the roster of one IRB, or they may be listed separately with each IRB roster. A primary member of any IRB registered under the same IORG number may serve as an alternate for any comparably qualified member on any other IRB of that institution or organization. Primary members on registered IRBs serving as alternate members do not need to be listed as an alternate on any roster. Each alternate IRB member who replaces a primary member at any given meeting should have experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member whom the alternate will replace. Whenever an alternate member substitutes for a primary member of the IRB, the combined requirements of § 46.107(a) and 46.108(b) shall remain satisfied. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member, and include the identity of the replaced primary and the alternate members. If multiple alternate members serve at an IRB meeting, the pairing of primary and alternate members should be indicated.

Public burden for this collection of information is estimated to average one hour for an initial IRB registration, and thirty minutes for updating or renewing the registration of a previously registered IRB. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Room 503, 200 Independence Avenue, SW., Washington, DC 20201. *Do not return the completed form to this address.*