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**Application form for initial review of research protocols:**

**Regulatory, non-regulatory, and clinical trials.**

**Instructions to fill:**

* *Please fill out the soft copy of this form, print and take signatures, wherever applicable*
* *Incomplete files will not be accepted*
* ***Tick √ in the box for the appropriate answer***
* *Write Not Applicable (NA) if the question does not apply to this study*
* *Do not leave any questions unanswered*
* *Strictly do not edit/delete the content or formatting of this form*
* *Write annexure numbers whenever documents are referred to in the application form*

**PART A: INVESTIGATOR DETAILS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| JSSDCH IEC Protocol No. (to be filled in by the Secretariat when a protocol number is assigned): | | | | |
| Title of the protocol: | | | | |
|  | Name | Designation and qualification | Department and Institution | Email id and phone number |
| Principal Investigator |  |  |  |  |
| Co-Investigator |  |  |  |  |
| Co-Investigator |  |  |  |  |
| Co-Investigator |  |  |  |  |
| Co-ordinator |  |  |  |  |

*(Add additional rows for any category if required)*

|  |  |  |
| --- | --- | --- |
|  | **Please ensure that the following details are accurate and complete** | **Yes/ No** |
|  | The Curriculum vitae of each of the investigators and research coordinators are attached:   * Mandatory details: Titles of research conducted in the last 5 years, publications in the last 5 years, GCP training in the last 3 years, research methodology training, research ethics training, specialized training as per protocol requirement * CV updated not older than 3 months * The CV should not exceed 5 pages * The CV should be signed and dated |  |
|  | All relevant training certificates of the principal investigator and co-investigators are attached (GCP training certificates not older than 3 years) |  |
|  | Declaration of conflict of interest by each of the research team members for the present study (financial and non-financial) attached (JSSDCH IEC SOP Version-3) |  |

**PART B: SPONSOR DETAILS (IF APPLICABLE)**

|  |  |  |  |
| --- | --- | --- | --- |
| **S No** | **Sponsor Level** | **Sponsor details** | **Yes/No/NA** |
|  | International | Governmental (NIH, NHRS) |  |
|  |  | The non-governmental organization (non-pharma, non-industry for example WHO, UN, Wellcome Trust, etc) |  |
|  |  | Private organization (pharma/industry) |  |
|  | National | Central Government (ICMR, DBT, DST, etc) |  |
|  |  | State Government (VGST, etc) |  |
|  |  | Private organization (pharma/industry) |  |
|  | JSS Academy of Higher Education & Research. | Institutional support |  |
|  |  | Seed Grant |  |
|  |  | Any other |  |
|  | Status of funding approval | Applied and approved |  |
|  |  | Applied and under review |  |
|  |  | Not applied, likely to apply in future |  |
| *Please attach an approval letter from the sponsor, where applicable* | | | |

|  |  |  |
| --- | --- | --- |
| **Budget information** | | |
|  | Total Budget (in INR): | |
|  | Details of the allocation of the budget are in a separate attachment | Yes/ No |
|  | JSSDCH IEC sitting fees (if applicable): provide details of payment | Yes/ No |

**PART C: STUDY DETAILS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Details of the study (Tick whichever is applicable)** | | | | |
| Clinical drug trial (regulatory) |  | Interview/Questionnaire-based | |  |
| Clinical drug trial (academic) |  | Observational (cross-sectional or longitudinal) | |  |
| Surgical intervention (new or modified technique) |  | In vitro | |  |
| Medical device, implant, or prosthesis |  | Retrospective/Case-control | |  |
| Other interventions |  | Data in public/private domain | |  |
| Genetic/genomic/stem cell |  | Epidemiological survey | |  |
| Basic science (Proteomic/ metabolomic/ biomarker/ biochemical/ histopathological) |  | Any other: Specify | |  |
| Number of centers | Single/Multi-center | | | |
| If multi-centric (Number of centers): | India:  Global: | | Names and countries of centers: | |

**PART D: CLINICAL TRIAL DETAILS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Provide details, if it is a Clinical Trial:** | | | |
| 1 | **Nature of trial** | Medicine (new drug, new chemical entity) |  |
| Vaccine |  |
| Devices |  |
| Indian System of Medicine |  |
| Surgical |  |
| Any other: Specify: |  |
| 2 | **Whether the intervention is approved**  **(Provide reference of approvals)** | Yes | No |
| If approved, please specify the country of approval: | Yes/No |
| India |  |
| USA |  |
| UK/Europe |  |
| Other countries: Specify |  |
| **3** | **Route** | Does the study involve an existing drug with a new (unapproved) route of administration? | Yes #  No  Not applicable |
| If Yes #,  Whether DCGI/other regulatory authority’s permission was obtained (please furnish a copy) | Yes \*  No \*\*  Not applicable |
| \*If yes, the date of permission |  |
| \*\*If No, whether applied for permission (please furnish a copy of the application and submit a copy of the approval letter once it is sanctioned) | Yes  No  Not applicable |
| 4 | **Investigational New Drug** | Does the study involve a new drug, not yet approved for marketing (or is in the market for less than 4 years)? | Yes##  No  Not applicable |
| ##If yes, please provide IND No. |  |
| ##If Yes, whether DCGI/other regulatory authority permission obtained (please provide a copy) | Yes+  No++  Not applicable |
| +If yes, date of permission |  |
| ++If No, whether applied for permission (please provide a copy of the application and submit a copy of the approval letter once it is sanctioned) | Yes  No  Not applicable |
| For Ayurvedic or herbal formulations, is a copy of the marketing/ manufacturing license issued by the FDA to the company submitted? | Yes  No  Not applicable |
| Details of storage, dispensation, and retrieval of medications | Yes  No  Not applicable |
| a) Investigator’s Brochure submitted (containing details of chemical/pharmaceutical information; marketing information; BA/BE studies) | Yes  No  NA |
| b) *In vitro* studies data | Yes  No  NA |
| c) Preclinical Studies done | Yes  No  NA |
| Clinical Study Phase | I  II  III  IV |
| Please submit a package insert in case the test drug is already marketed in India | Attached  Not attached |
|  |  | Is this study or a similar study being done elsewhere?  **If yes give details** | Yes  No |
|  | Is the trial registered with Clinical Trial Registry? (mandatory only for drug trials) Clinical Trial Registry of India(CTRI)/WHO platform registry registration number/any other: | | Yes$  No$$  Not applicable |
|  | $If yes, please provide a copy of the registration | | Yes  No |
|  | $$If no, please state the reason for not registering | |  |

**PART E: PROTOCOL DETAILS**

|  |
| --- |
| **Protocol of proposal: (Submit as attachment)**  ***PI to note that all the protocol and related documents must bear the title of the document, version number, page number, date, and signatures wherever applicable*** |
| 1. Title 2. Executive summary (not more than one page) 3. Background and need for the study 4. Objectives 5. Methodology (The methodology must be in great detail): Refer to the section on methodology in SOP06/v3) 6. Sample/data collection details 7. Study tool 8. Statistical tests 9. Budget and funding details 10. Timeline (Gantt chart) 11. Study flowchart/algorithm 12. The utilization of the results **whether it is of national significance with rationale** |
| Is the PI or the Co-PI or any other research team member concurrently involved in any study with similar (or almost similar) objectives, or a similar set of participants? Yes/No  If yes, please provide the details of that study: |

**PART F: PARTICIPANT DETAILS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Provide details about research participants** | | | |
| **Sample Size :**  The number of research participants at this center:  The number of research participants who will receive intervention:  The number of research participants who will receive a placebo:  The number of participants who will receive standard-of-care treatment:  The number of research participants at other sites in India :  The number of research participants at other sites outside India:  The total number of research participants at all sites: | | | |
| Duration of study: Less than 6 months / more than 6 months to 1 year / more than 1 year  No. of visits that each participant is anticipated to make for screening and research: | | | |
| Is there a plan for the management of screen failures? | Yes | No | NA |
| Will participants be recruited in multiple studies concurrently? | Yes | No | NA |
| Is there a plan for the randomization of participants?  If yes, please provide details in the methodology section | Yes | No | NA |
| Is there a plan for blinding (and unblinding)?  If yes, provide details in the methodology section | Yes | No | NA |
| Will study subject management include check-in/check-out procedures?  If yes, please provide details in the methodology section | Yes | No | NA |
| Is there a participant number assignment plan?  Please provide details in the methodology section | Yes | No | NA |
| Will research participants from both genders be recruited | Yes | No | NA |
| Inclusion / exclusion criteria given | Yes | No | NA |
| Type of research participants:  (\* If a vulnerable population is included, the PI must submit the appropriate checklist for the involvement of the vulnerable population in research available in SOP19/v3 and provide the attachment number) | | | |
| Volunteers | Yes | No | NA |
| Patients | Yes | No | NA |
| Vulnerable participants | Yes | No | NA |
| Pregnant women\* | Yes | No | NA |
| Elderly | Yes | No | NA |
| Mentally challenged\* | Yes | No | NA |
| Fetus\* | Yes | No | NA |
| Illiterate | Yes | No | NA |
| Handicapped | Yes | No | NA |
| Children\* | Yes | No | NA |
| Captives | Yes | No | NA |
| Terminally ill | Yes | No | NA |
| Seriously ill | Yes | No | NA |
| Economically or socially backward | Yes | No | NA |
| Dependent staff \* | Yes | No | NA |
| Institutionalized students\* | Yes | No | NA |
| Employees \* | Yes | No | NA |
| HIV | Yes | No | NA |
| Any other | Yes | No | NA |
| Will any advertising be done for the recruitment of research participants? (posters, flyers, brochures, websites, notices, letters  – if so kindly attach a copy) | Yes | No | NA |
| Is there a compensation plan for participation  If Yes, (tick appropriate)  Monetary  In-kind  Specify amount and type: | Yes | No | NA |
| Is there a compensation plan for injury?  If Yes,  (tick appropriate)  by Sponsor  by Investigator by insurance  by any other company | Yes | No | NA |

**PART G: PRIVACY AND CONFIDENTIALITY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Privacy and confidentiality** | | | |
| Direct identifiers (Name, address, phone numbers, photographs, videography) | Yes | No | NA |
| Indirect identifiers (coded) | Yes | No | NA |
| Completely anonymized (delinked) | Yes | No | NA |

**PART H: USE OF BIOLOGICAL/ HAZARDOUS MATERIAL**

|  |  |  |  |
| --- | --- | --- | --- |
| **Use of biological/hazardous materials (Tick)** |  |  |  |
| Fetal tissue or abortus | Yes | No | NA |
| Human organs or body fluids | Yes | No | NA |
| Recombinant /gene therapy  If yes: DBT approval obtained | Yes | No | NA |
| Pre-existing/stored/left-over samples | Yes | No | NA |
| Collection from banking/future research | Yes | No | NA |
| Collection for banking/future research | Yes | No | NA |
| Use of ionizing radiation/radioisotopes  If yes, has Bhabha Atomic Research Centre (BARC) approval for radioactive isotopes been obtained? | Yes  Yes | No  No | NA  NA |
| Use of Infectious/biohazardous specimens | Yes | No | NA |
| Proper disposal of the material | Yes | No | NA |
| **Will any samples collected from the patients be sent abroad?** | Yes | No | NA |
| **If yes**  The sample will be sent abroad because (Tick appropriate option):            Facility not available in India            The facility in India is inaccessible            Facility available but not being accessed                 If so, reasons…………………………………..                  Lab. Address: | | | |
| **If no,**  Test on samples will be carried out (tick appropriate option):  In institution  Outside institution  If an outside institution, Address:  Specify with details of collaborators | | | |
| Is the proposal being submitted for clearance from  Health Ministry’s Screening Committee (HMSC) for International collaboration? (required  in case of studies involving collaborations with foreign Laboratories/ Clinic/Institutions) | Yes | No | NA |
| In case of studies involving collaborations with other Indian or foreign Laboratories/Clinics/Institutions has administrative sanction from the Dean been obtained/ applied for? If yes, details: | Yes | No | NA |
| Memorandum of Understanding:  If yes, the details | Yes | No | NA |
| Material Transfer Agreement  If yes, the details | Yes | No | NA |

**PART I: INFORMED CONSENT PROCESS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Details of consent form & participation information sheet** | Yes | No | NA |
| Tick which elements are included:  Simple language  Regional language understood by the participant  Alternatives to participation  A statement that this consent is for research and not therapy  Sponsor of study  Contact information  Purpose and procedures in detail  Risks & Discomforts  Benefits  A statement that consent is voluntary  Right to withdraw  Confidentiality of records  Compensation for study-related injuries  Compensation for participation  Benefits, if any, on future commercialization  Consent for future use of biological material  Consent for photographs, if applicable  Consent for publication/ conference presentation |  |  |  |
| **Details of the informed consent process** | Y | N | NA |
| **Who will obtain consent?**  PI/Co-PI  Nurse/Counselor trained in ICH-GCP guidelines  Research team member  Any other, specify |  |  |  |
| Where will the consent be taken? Specify the room |  | | |
| 1. General ward |  |  |  |
| 1. Private ward |  |  |  |
| 1. OPD |  |  |  |
| 1. Community setting |  |  |  |
| 1. Admission counter of the hospital |  |  |  |
| 1. Procedure room |  |  |  |
| 1. Laboratory |  |  |  |
| 1. Radiology room (X-ray, USG, CT, or MRI) |  |  |  |
| 1. Pre-operative holding area |  |  |  |
| 1. Operation theatre |  |  |  |
| 1. Any other (please specify) |  |  |  |
| Whether audio-visual recording of consent will be done? |  |  |  |
| Whether audio recording of consent will be done? |  |  |  |
| Whether surrogate consent will be obtained? |  |  |  |
| Whether written or oral assent will be obtained? |  |  |  |
| Whether electronic consent will be obtained? |  |  |  |
| If written consent will not be obtained, give reasons: |  | | |
| Whether applied for waiver of Consent: |  |  |  |

**PART J: RISK AND BENEFIT**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **13** | **Risks & Benefits**: | | | |
| Will the risk to the participants be reasonable compared to the anticipated benefits to research participants/community/country? | Yes | No | NA |
| Will the research participant experience physical/social/psychological risk/discomfort?  If Yes,  ·         Minimal or no risk  ·         More than minimum risk  ·         High risk | Yes | No | NA |
| Will there be a benefit to the research participants?  ·         Direct  ·         Indirect | Yes | No | NA |
| Will there be a benefit to society? | Yes | No | NA |

**PART K: DATA SAFETY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **14** | **Data Monitoring** | **Yes** | **No** | **NA** |
| Is there a data & safety monitoring committee/ Board (DSMB)? |  |  |  |
| Is there a plan for reporting adverse events? |  |  |  |
| If yes, reporting is done to:  Sponsor  JSSDCH IEC  DSMB |  |  |  |
| Is there a plan for interim analysis of data? |  |  |  |
| Are there plans for the storage and maintenance of all trial databases? |  |  |  |
|  | If yes, for how long? |  | | |

|  |
| --- |
| **Declaration for responsible conduct of research by PI and other Co-PI’s/Co-I’s:**    We hereby declare that the information given above is true and that we will comply with all the stipulations/recommendations mentioned in the New Drugs and Clinical Trials Rules 2019, the current ICMR guidelines, any other recent notification/s from CDSCO (updated as applicable), the Indian GCP Guidelines and the Declaration of Helsinki while conducting the research study.  We hereby declare that neither the PI, the Co-PI, nor any other members of the research team are concurrently involved as research team members in a similar study or another study using the same set of participants, as this one.  We also ensure that the Principal Investigator/Institution (for non-funded studies) will pay for the expenses for the treatment and/or compensation of research-related injury, as deemed necessary by the JSS Dental College & Hospital Institutional Ethics Committee.  Signature of Principal Investigator with date:    Signature/s of Co-investigators with date:  1.  2.    3.    4.    5.  Signature of coordinator:  1.    2. |
| Forwarded by Heads of Department(s)  Signature/s with the date of Heads of Department(s):  Stamp/Seal of the Department(s) |