

# Clinical Study Authorization

Ethics · Institutional authority · Data governance · Publication

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ENGLISH

Use for retrospective or prospective studies, completed clinical trials, economic evaluations, and completed community pilots submitted to microscopIA.

Complete this document before any clinical data transfer. Do not send identifiable patient data through a public web form. microscopIA will provide an approved secure-transfer route after readiness review.

## 1 · Project and facility

|                                  |                                                        |
|----------------------------------|--------------------------------------------------------|
| Proposed study title<br>_____    | Evidence type<br>_____                                 |
| Facility / legal entity<br>_____ | Department / service<br>_____                          |
| City and country<br>_____        | Principal investigator / submitting clinician<br>_____ |
| Research director<br>_____       | Contact email and telephone<br>_____                   |

## 2 · Ethics and institutional authority

- ☐ Ethics committee approval is attached, including committee name, approval code, and date.
- ☐ If the project is exempt, the competent committee or institution has issued a documented exemption.
- ☐ The facility research director authorizes the proposed scientific use of the de-identified dataset and publication of aggregate results.
- ☐ The facility confirms lawful provenance, data-controller authority, and that permissions cover analysis, collaboration, and publication.

### 3 · Data and confidentiality

- ☐ Only the minimum necessary, de-identified information will be transferred through the route approved by both parties.
- ☐ Direct identifiers, free-text identifiers, facial images, and re-identification keys remain with the source institution unless specifically authorized and necessary.
- ☐ Access is purpose-limited, role-based, documented, and subject to the written project agreement.
- ☐ Data may not be reused for another question, shared onward, or retained beyond the approved terms without new authority.

### 4 · Scientific and publication terms

- ☐ The submitted database or case file is complete, internally consistent, and accompanied by the required variable dictionary or clinical chronology.
- ☐ This is a scientific collaboration: the submitter provides governed data and clinical expertise; microscopIA leads the remaining research, analysis, writing, and publication workflow; both teams publish together.
- ☐ Qualifying submitter authors occupy the first positions: up to five for a case report and up to eight for another output. Each additional qualifying submitter author costs USD 150, billed in COP equivalent for Colombia.
- ☐ microscopIA reserves the final four positions for qualifying microscopIA contributors and designates the corresponding author. Every named author must meet journal criteria and sign the authorship declaration.
- ☐ The journal retains independent editorial authority. microscopIA does not guarantee peer review, acceptance, publication timing, or citation impact.
- ☐ microscopIA pays 100% of an eligible mandatory APC for the approved journal directly after acceptance and invoice verification. Optional services are excluded unless agreed.

### 5 · Service clock and commercial acknowledgement

- ☐ The standard eight-week clock runs from written ready-to-start confirmation to first manuscript submission.
- ☐ Priority delivery is four weeks for COP 1,200,000 or USD 500; case reports may use a ten-business-day rapid pathway for the same supplement.
- ☐ Fifty percent is due after proposal approval and signature; the remaining 50% is due only after formal journal acceptance.
- ☐ Within scope, microscopIA conducts iterative improvements, journal reformatting, reviewer responses, and sequential submission to as many as five appropriate journals.
- ☐ The clock pauses when essential partner materials, clarifications, decisions, or approvals are outstanding. Journal peer review and acceptance are outside the service clock.

### 6 · Declarations

By signing, each signatory confirms that the statements within their authority are true, the required approvals and consents are valid, and they will promptly disclose any limitation, conflict, integrity concern, or withdrawal of authority.

## 7 · Required signatures

|                                                      |                                                                                               |
|------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| <b>Submitting clinician / principal investigator</b> | Full name: _____<br>Role / institution: _____<br>Signature: _____<br>Date (YYYY-MM-DD): _____ |
| <b>Facility research director</b>                    | Full name: _____<br>Role / institution: _____<br>Signature: _____<br>Date (YYYY-MM-DD): _____ |
| <b>Data custodian (if applicable)</b>                | Full name: _____<br>Role / institution: _____<br>Signature: _____<br>Date (YYYY-MM-DD): _____ |

## 8 · Core legal terms

- ☐ This template supports readiness screening and must be adapted to applicable law, institutional policy, ethics requirements, and the final project agreement.
- ☐ Participation does not create employment, agency, clinical responsibility, or a guarantee of authorship or publication.
- ☐ Background intellectual property remains with its owner. New results, inventions, software, databases, licenses, and publication rights must be defined in the project-specific agreement.
- ☐ Confidentiality, research integrity, conflicts of interest, corrections, security incidents, retention, deletion, suspension, and offboarding are governed by the final agreement and approved plans.
- ☐ Colombian law and agreed Bogotá jurisdiction apply unless a signed project agreement states otherwise. Electronic signatures may be used in accordance with applicable law, including Colombia's Law 527 of 1999.

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 Jorge Mario Racedo Galván · General Manager and legal representative

Template—not legal advice. The signed project agreement and competent ethics/institutional decisions control.