NOVARTIS

# Operations Manager, Informed Consent Form (ICF)

Job ID
REQ-10056032
Jun 24, 2025
Mexico

## Summary

The Operations Manager, Informed Consent Form (ICF) Specialist will be the reviewer for business sections and responsible for adhering to USA legal/privacy requirements. The specialist will have full knowledge of consents as well as secondary responsibility executing study related agreements such as confidential agreement (CDA) for research trials and will be trained extensively on business sections of the ICF and CDA and will have oversight from Subject Matter Experts on the C&BS team.

## About the Role

This role is based in Mexico City, Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

**Key Responsibilities:**

- Reviews high volumes of ICF business and legal sections of the ICF documents (initial and amendments), including legal sections of the ICF pre/post-IRB submission, comments, confirms the language used in the approved ICF is acceptable and works on amended ICFs.
- Ensures approved ICF is used as the base for the Customized ICF template for business sections aligned with the protocol/study to support the US organization.
- Follow guidelines governing the review of ICFs, HIPAA, IRB, CDAs, CTAs and the FDA Code of Federal Regulations as well as GCPs and Privacy regulations.
- Works with C&BS leads to Ensures study ICF-templates for central IRB sites contain approved pre-negotiated language and collaborates internally w/legal/privacy teams to develop alternate, approved language
- Interfaces with internal stakeholders, including but not limited to contract managers, clinical leads, and medical directors. NPC legal (including Privacy Officer).
- Contributes to study site start-up process including execution of CDAs,
- Works with internal colleagues to revise/update standard template language
- Maintains workload metrics and tracking for electronic ICF database, ACE
- Makes necessary enhancements to the electronic database of approved ICFs.
- Helps to develop training tools and processes for CDA and ICF manuals
- Works under the direction of the lead for NOCC C&BS Associates to facilitates processes
- Processes, collects, and tracks documentation as per GxPs.
- Facilitates site level problem solving by providing alternative or innovative solutions to meet aggressive study start-up timelines.
- Ability to execute study documents associated with ICF, such as but not limited to site agreements, MAPS, confidentiality agreements.
- Collaborator: ability to collaborate with US Privacy, Legal and Patent departments to Lead and to answer

questions regarding ICF business and CDA terms, scopes of work, within the framework of the US legal and compliance requirements.
- Knowledge management: US laws and regulations associated with business sections of the ICF, contract language regarding Phama regulations to GxP, with specific knowledge of Phase 1-IV, Registries, MAPs, and IIT studies.

**Essential Requirements:**

- Advanced English, level C1 – C2.
- The candidate must have 7-10 years of experience in the Pharmaceutical Industry and 5 years operational roles associated with informed consents; and 3 years' experience with contracting Function.
- Bachelor's degree.
- Strong Communication Skills.
- Experience with ICF language for research projects with academic/community centers and IRBs.
- Experience with legal and privacy language in ICF to support the Us organization.
- Full Knowledge of HIPAA laws in US.
- GCP certification preferred
- Full knowledge of Phase 1-IV clinical trial development and clinical trial privacy regulations
- Experience with executing confidentiality agreements associated with research trials.
- Strong written, oral & presentation skills, with an ability to make professional and credible first impressions with internal and external customers.
- High degree of organizational, review/edit and analytical skills.
- Knowledge of different types of research projects, such as HEOR/clinical trial/, NIS/registries, IITs, and sponsored trials.

**Commitment to Inclusion**

Novartis is committed to building an outstanding, inclusive work environment and diverse teams representative of the patients and communities we serve.

Novartis is committed to work with and provide reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to tas.mexico@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

**Why Novartis:** Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

**Join our Novartis Network:** Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:

https://talentnetwork.novartis.com/network

**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Operations
Business Unit
Universal Hierarchy Node
Location
Mexico
Site
INSURGENTES
Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

## Accessibility and accommodation

Novartis is committed to work with and provide reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to tas.mexico@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10056032

## Operations Manager, Informed Consent Form (ICF)

Apply to Job

**Source URL:** *https://prod1.id.novartis.com/careers/career-search/job/details/req-10056032-operations-manager-informed-consent-form-icf*

**List of links present in page**

1. mailto:tas.mexico@novartis.com
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://talentnetwork.novartis.com/network
4. https://www.novartis.com/careers/benefits-rewards
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/INSURGENTES/Operations-Manager--Informed-Consent-Form--ICF-_REQ-10056032
6. mailto:tas.mexico@novartis.com
7. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/INSURGENTES/Operations-Manager--Informed-Consent-Form--ICF-_REQ-10056032