

3.1 Clinical trial documents: the set seen as a system

The clinical trial documents of this unit are one system, not six separate writing tasks: each document has a distinct reader and job, and the documents must agree with each other because monitors, auditors and inspectors will read them against each other. The protocol tells everyone what will be done and why. The investigator brochure tells the investigator what is known about the product, including its risks. The informed consent form tells the prospective participant, in plain language, what participation involves. The case report form captures, for each participant, exactly the data the protocol promises to analyse. The contracts and agreements bind the parties, their duties and their money in writing.

3.2 The protocol: guidelines for preparation

The protocol is the master document of the trial, and the guidelines for its preparation are the questions the document must answer. Its opening sections give the background and rationale and the trial's identification and version. Its objectives are the primary and secondary outcomes of Section 2.11, and its design section specifies the design family, the treatments, randomization and blinding, and the measures that keep bias out. The participant sections define eligibility, consent, the visit schedule, withdrawal and stopping rules and product accountability; the safety sections define adverse event collection and reporting; and the statistics sections state the basis of the trial's size, the analysis populations and methods, following the framework principles of ICH E9. The closing sections govern ethics, data handling and record retention, monitoring and audit access, and publication policy.

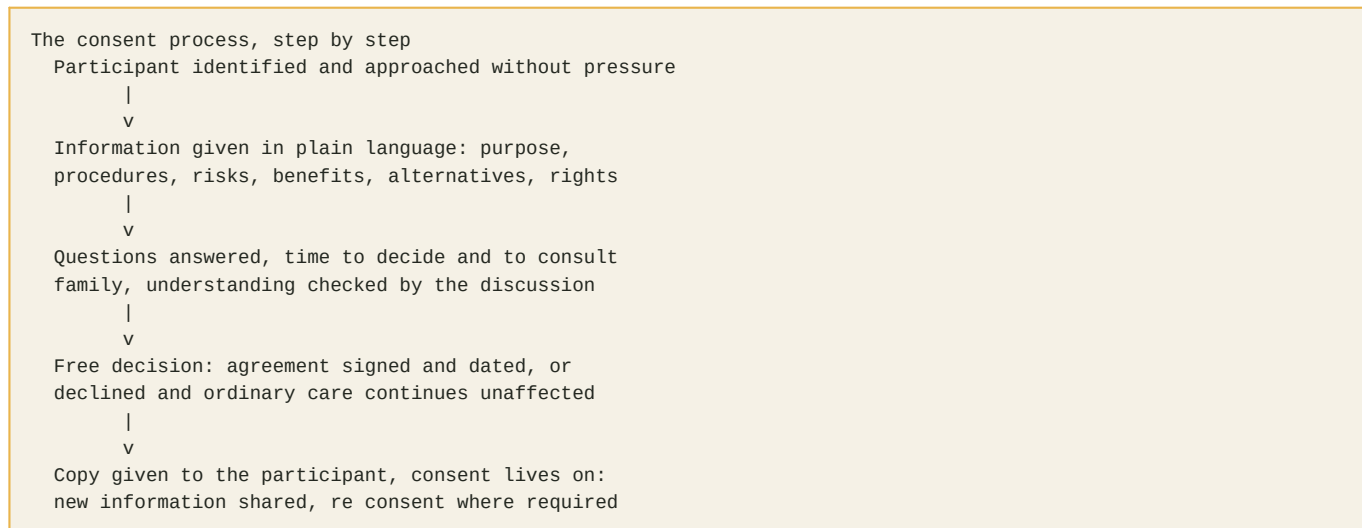
3.3 The Investigator Brochure

The Investigator Brochure is the compilation of the clinical and nonclinical data on the investigational product relevant to its study in humans, provided by the sponsor to every investigator, so that the people conducting the trial understand the product's rationale, its expected effects and, above all, its risks, independently of the sponsor's enthusiasm. Its contents follow that purpose: a summary placing the evidence in reach of a busy reader; the product's identity and pharmaceutical properties and formulation; the nonclinical pharmacology, pharmacokinetics and toxicology of Section 1.4, with margins and target organs stated plainly; any effects in humans from earlier trials, including adverse reactions and the populations in whom experience exists or is absent; and a closing guidance section for the investigator, the anticipated risks to watch for, the precautions and monitoring the protocol expects, and the populations requiring special care.

3.4 The informed consent form and the consent process

The informed consent form, with the participant information that accompanies it, is the written record of the consent process: a conversation, in a language and at a level the person understands, with time and opportunity to ask questions and to consult family, conducted by a person qualified to explain the trial, free of coercion, and completed before any trial procedure begins. The document records that process, and its required content is what a reasonable person needs for the decision: that the study is research and its purpose; what will be done, visit by visit, and how it differs from ordinary care; the foreseeable risks and discomforts and the possible benefits, stated without promise; the alternatives, including ordinary treatment

without participation; the voluntary nature of participation and the right to withdraw without loss of entitled care; confidentiality and who may see the records, including monitors, auditors, the ethics committee and regulators; the arrangements for care and for compensation for research related injury under the applicable rules; whom to contact about the trial, about rights, and in an emergency; and, where relevant, payments, costs, and what happens to samples and data. The exact version in use is ethics approved, signed and dated by the participant or legally authorised representative and by the person conducting the discussion, with witness arrangements where the guidelines require them, and a copy is given to the participant. Consent is also continuing: new risk information and amendments reopen it, and re consent uses the same discipline as the first consent.



The informed consent process



A process with a document, not a document with a signature

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Figure: Consent is a process with a document, not a document with a signature. The conversation is the safeguard; the form is its record.

3.5 Case report forms

The case report form, or CRF, is the document, paper or electronic, designed to record all of the information on each participant that the protocol requires to be reported to the sponsor. Its preparation follows from the protocol by strict derivation: every data item exists because a protocol section demands it, an endpoint, an eligibility criterion, a safety assessment, a product administration, and every protocol requirement finds its field on the form, because data the form does not capture will not exist at analysis, however faithfully the visits were conducted. The form identifies the trial, the site and the participant by code, never by name on

documents that travel. Questions are unambiguous, one item one meaning, with units, formats and allowable values printed where the answer is written, so ten sites record the same thing the same way. Corrections preserve the original entry and identify who changed what, when and why, and the investigator signs the completed form.

3.6 Contracts and agreements, and diary cards

Contracts and agreements are the legal skeleton of the trial, and their preparation guideline is that everything the parties expect of each other must be in them before the work begins. The clinical trial agreement between sponsor, institution and investigator records the scope of the work and the protocol it follows; the duties of each party, including GCP compliance, monitoring, audit and inspection access, record retention and reporting; the financial arrangements, payments and their schedule, stated transparently because undisclosed financial terms are an ethical as well as a legal defect; product supply, storage and accountability; confidentiality, data ownership and publication rights; indemnity and insurance arrangements for trial related harm; and the conditions of termination and its consequences for participants under care. The diary card, printed "Dairy Cards" in one syllabus copy and taught here in its correct form, is the only document in the set the participant writes: a card or booklet recording, at home and in real time, the doses taken, the symptoms experienced and the times of events the trial needs, returned and reviewed at each visit. Its rules are those of any participant facing document: plain instructions, space proportioned to what is asked, no more asked than the protocol will use, and review of the returned card with the participant.

3.7 Start up activities: the road from selection to activation

Clinical trial start up activities are the sequence that converts an approved protocol into a site ready to enrol its first participant, and the syllabus lists them as one connected block because their order matters. Feasibility establishes that the site can do the trial. Selection chooses sites and investigators on that evidence. The pre-study visit verifies the choice in person. The investigator meeting aligns every site on one reading of the protocol. The clinical trial agreement binds the arrangement legally and financially. The ethics submission wins the independent approval without which enrolment is forbidden. A site is activated, given formal permission by the sponsor to begin screening and enrolment, only when every gate stands open: contract executed, ethics approval in hand, regulatory requirements met, product on site and correctly stored, staff trained and delegated, systems live.

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Start up: from protocol to an activated site
Feasibility: can this site do this trial, honestly
answered by site and sponsor together
    |
    v
Selection and pre-study visit: investigators and
facilities chosen and verified in person
    |
    v
Agreement executed and ethics submission approved:
the legal gate and the ethical gate both open
    |
    v
Investigator meeting and site training: one reading
of the protocol across every site and role
    |
    v
Product, systems and files ready, initiation visit
held: sponsor activates the site for enrolment
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Start up: from protocol to activation



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Figure: Start up as a row of gates. A site enrolls only when every gate, legal, ethical and practical, stands open.

3.8 Site feasibility, selection and the pre-study visit

A site feasibility study is the structured assessment, before selection, of whether a particular site can conduct this particular trial to the required standard and timeline. On the participant side it tests whether the site's population contains the protocol's population in sufficient number, competing trials for the same patients, and the retention conditions that decide whether participants can complete the schedule. On the capability side: the investigator's experience and available time, coordinator and support staffing, the facilities and equipment the assessments require, pharmacy capacity for the product handling of Unit 4, laboratory support, ethics committee arrangements, contracting requirements, and the site's record in earlier trials, recruitment delivered against recruitment promised being the most predictive figure in the whole enquiry. Site and investigator selection then converts this evidence into the sponsor's choice: the investigator qualified, experienced, able to devote real time, and free of compromising conflicts; the site offering the population and infrastructure the feasibility study tested. The pre-study visit, also called the site selection visit, verifies all of this in person before the site is approved: facilities walked, equipment and storage seen rather than described, investigator and key staff met, source documents inspected, and its report records the evidence, the gaps, and the outcome, selection, selection with conditions to close before initiation, or non selection.

3.9 The investigator meeting and clinical trial agreement execution

The investigator meeting is the sponsor's gathering of the investigators and key site staff, held before or during start up, at which the trial is taught as one enterprise: the rationale and design, the product and its handling including pharmacy and blinding arrangements, eligibility and visit procedures, safety reporting duties, data capture and monitoring arrangements, and the GCP duties of each role, with questions answered on the record and clarifications issued to all sites alike. Attendance is documented, and the meeting's materials and clarifications become part of the trial's record. Clinical trial agreement execution, the signing of the contract of Section 3.6, runs in parallel with the meeting and the ethics submission, and it is a gate, not a formality: institutions review liability, indemnity, payment and publication terms with their own advisers.

3.10 Ethics committee document preparation and submission

Ethics committee document preparation and submission assembles the site's case for independent ethical approval, and its craft is completeness at the first attempt, because committees meet on a rhythm and an incomplete submission costs a whole cycle. The package mirrors the committee's review duties of Section 1.9: the protocol and amendments in current versions; the investigator brochure; the informed consent form and participant information in English and in the local languages of the population, with the translations the committee requires; the case report form; recruitment materials and participant payment information, exactly as participants will see them; the investigator's qualifications and GCP training evidence and the site's facilities information; the clinical trial agreement or its financial terms as the committee's rules require, since undisclosed payments are an ethical question; insurance and indemnity documents; and the regulatory status of the trial.

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