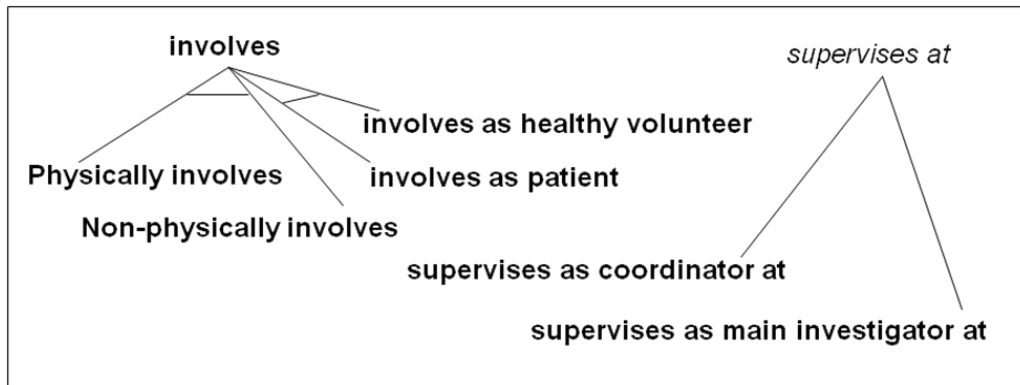


Study-OS

// Metadata

Name	Study-OS
Keywords	Clinical study, Study with examination, Multi-centre study, Medical doctor, Para-medical healthcare professional, Researcher, Coordinator, Main investigator, Centre, Ethics Committee authorization
Creation date	September 5 th , 2008
Last modification dates	v1.1: July 1 st , 2009 v1.2: February 1 st , 2009
Has contributor	Bénédicte Batrancourt (v1.1 + v1.2), Michel Dojat (v1.0 + v1.1 + v1.2), Adrien Fanet (v1.1), Bernard Gibaud (v1.0 + v1.1 + v1.2), Pascal Girard (v1.0), Gilles Kassel (v1.0 + v1.1 + v1.2), Lynda Temal (v1.0)
Revisions made in v1.1	<ul style="list-style-type: none"> - The relations ‘involves as healthy volunteer’ and ‘involves as patient’ have been added. - The concept ‘Medical doctor’ and specializations (e.g., ‘Neurologist’, ‘Psychiatrist’) have been added. - The concept ‘Health professional’ and specializations (e.g. ‘Psychomotor therapist’, ‘Speech therapist’) have been added.
Revisions made en v1.2	<ul style="list-style-type: none"> - The concepts ‘Gerontologist’, ‘Neurosurgeon’, ‘Neuroradiologist’, ‘Physical therapist’, and ‘Radiology technician’ have been added.
Used ontology engineering methodology	OntoSpec
Is of type	Domain ontology
Natural language	English
Has ontology language	OntoSpec
Has formality level	Semi-informal
Ressource locator	http://www.laria.u-picardie.fr/IC/site/IMG/pdf/Study-OS.pdf
Version	1.2
Number of concepts (classes)	32
Number of relations (properties)	7

// Relations



Involves

Properties

[EP/DR & RR] A STUDY *involves* a SUBJECT. [EP/NSMC] x *involves* y iff there exist a CONCEPTUALIZATION c and TIME INTERVALS t and t' such that x *has for data* c at t and c *references* y at t' . [EP/IVL] *Involves* mutually implies *is involved in*.

Comment

[DEF] A STUDY *involves* a SUBJECT whenever knowledge about the SUBJECT is used for the STUDY.

Involves as healthy volunteer

Properties

[EP/DR & RR] A STUDY *involves as healthy volunteer* a HEALTHY VOLUNTEER. [EP/SLD] x *involves as healthy volunteer* y implies that x *involves* y . [EP/ICL] *Involves as healthy volunteer* is incompatible with *involves as patient*.

Involves as patient

Properties

[EP/DR & RR] A STUDY *involves as patient* a PATIENT. [EP/SL] x *involves as patient* y implies that x *involves* y . [EP/ICL] *Involves as patient* is incompatible with *involves as healthy volunteer*.

Physically involves

Properties

[EP/DR & RR] A STUDY WITH EXAMINATION *physically involves* a SUBJECT. [EP/SL] x *physically involves* y implies that x *involves* y . [EP/NSMC] x *physically involves* y iff there exist an EXAMINATION e and a TIME INTERVAL t such that x *has for proper part* e and e *affects* y at t . [EP/ICL] *Physically involves* is incompatible with *non-physically involves*. [EP/IVL] *Physically involves* mutually implies *is physically involved in*.

Comment

[DEF] A STUDY *physically involves* a SUBJECT whenever the SUBJECT undergoes an EXAMINATION during the STUDY and the resulting knowledge is used for the STUDY.

Non-physically involves

Properties

[EP/DR & RR] A STUDY *non-physically involves* a SUBJECT. [EP/SL] x *non-physically involves* y implies that x *involves* y . [EP/NSMC] x *non-physically involves* y iff there exist

no EXAMINATION *e* and no TIME INTERVAL *t* such that *x* *has for proper part* *e* and *e* *affects y at t*. [EP/ICL] *Non-physically involves* is incompatible with *physically involves*. [EP/IVL] *Non-physically involves* mutually implies *is non-physically involved in*.

Comment

[DEF] A STUDY *non-physically involves* a SUBJECT whenever the SUBJECT has undergone an EXAMINATION during another STUDY and the resulting knowledge is used for the present STUDY.

Supervises as coordinator at

Properties

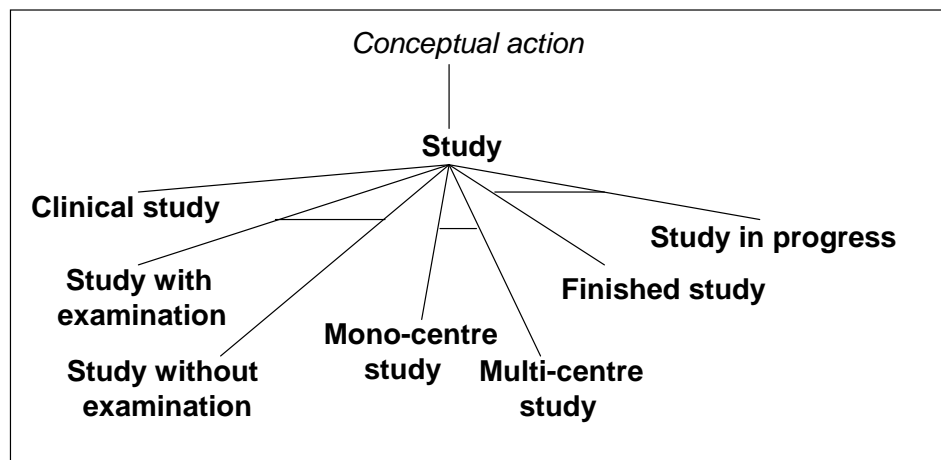
[EP/R1 & R2 & R3] A COORDINATOR *supervises as coordinator* a STUDY at a TIME INTERVAL. [EP/SL] *x supervises as coordinator y at t* implies that *x supervises y at t*.

Supervises as main investigator at

Properties

[EP/R1 & R2 & R3] A MAIN INVESTIGATOR *supervises as main investigator* a STUDY at a TIME INTERVAL. [EP/SL] *x supervises as main investigator y at t* implies that *x supervises y at t*.

// Concepts



Study

Meta-properties

STUDY is RIGID (+R). STUDY is EXTERNALLY-DEPENDENT (+D). STUDY WITH EXAMINATION and STUDY WITHOUT EXAMINATION *is a non trivial partition of* STUDY. MONO-CENTRE STUDY and MULTI-CENTRE STUDY *is a non trivial partition of* STUDY. FINISHED STUDY and STUDY IN PROGRESS *is a non trivial partition of* STUDY.

Properties

[EP/SL] A STUDY is a CONCEPTUAL ACTION. [EP/ER] Every STUDY *involves* at least one SUBJECT. [EP/EER] Every STUDY *is supervised by* at least one MAIN INVESTIGATOR or COORDINATOR at a TIME INTERVAL. [EP/ER] Every STUDY *has for name* a NAME.

Comment

[DEF] A STUDY is a research investigation (therefore a CONCEPTUAL ACTION) involving human subjects that is designed to answer specific questions about brain functions or dysfunctions.

[SA] STUDIES are divided into STUDIES WITH EXAMINATION and STUDIES WITHOUT EXAMINATION according to whether the STUDY includes at least one EXAMINATION.

[SA] STUDIES are divided into MONO-CENTRE STUDIES and MULTI-CENTRE STUDIES according to whether the STUDY is performed by exactly one, or at least two, CENTRE(S).

[SA] STUDIES are divided into FINISHED STUDIES and STUDIES IN PROGRESS according to whether they are finished or not.

Clinical study

Meta-properties

CLINICAL STUDY is RIGID (+**R**). CLINICAL STUDY is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A CLINICAL STUDY is a STUDY.

Comment

[DEF] CDISC Clinical Research Glossary: a clinical study is a research investigation involving human subjects that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device.

Study with examination

Meta-properties

STUDY WITH EXAMINATION is RIGID (+**R**). STUDY WITH EXAMINATION is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SLD] A STUDY WITH EXAMINATION is a STUDY which *has for proper part* at least one EXAMINATION. [EP/ER] Every STUDY WITH EXAMINATION *is referred to by* an ETHICS COMMITTEE AUTHORIZATION. [EP/ER] Every STUDY WITH EXAMINATION *is supervised by* at least one MEDICAL DOCTOR *at* a TIME INTERVAL.

Study without examination

Meta-properties

STUDY WITHOUT EXAMINATION is RIGID (+**R**). STUDY WITHOUT EXAMINATION is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SLD] A STUDY WITHOUT EXAMINATION is a STUDY which *has no EXAMINATION for proper part*.

Mono-centre study

Meta-properties

MONO-CENTRE STUDY is RIGID (+**R**). MONO-CENTRE STUDY is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SLD] A MONO-CENTRE STUDY is a STUDY which *has for agent* exactly one CENTRE *at* a TIME INTERVAL. [EP/ER] Every MONO-CENTRE STUDY is *supervised by* exactly one MAIN INVESTIGATOR *at* a TIME INTERVAL.

Multi-centre study

Meta-properties

MULTI-CENTRE STUDY is RIGID (+**R**). MULTI-CENTRE STUDY is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SLD] A MULTI-CENTRE STUDY is a STUDY which *has for agent* at least two CENTRES *at* a TIME INTERVAL. [EP/ER] Every MULTI-CENTRE STUDY is *supervised by* exactly one COORDINATOR *at* a TIME INTERVAL.

Finished study

Meta-properties

FINISHED STUDY is ANTI-RIGID (~**R**). FINISHED STUDY is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A FINISHED STUDY is a STUDY.

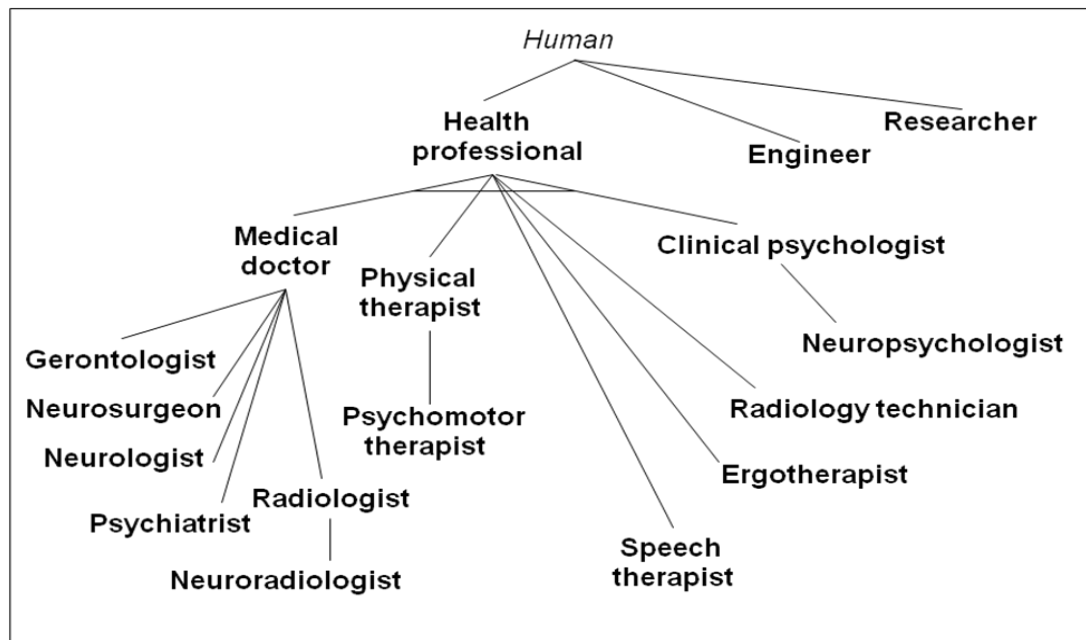
Study in progress

Meta-properties

STUDY IN PROGRESS is ANTI-RIGID (~**R**). STUDY IN PROGRESS is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A STUDY IN PROGRESS is a STUDY.



Health professional

Meta-properties

HEALTH PROFESSIONAL is ANTI-RIGID (~**R**). HEALTH PROFESSIONAL is CARRYING AN IDENTITY CRITERION (+**I**). HEALTH PROFESSIONAL is EXTERNALLY-DEPENDENT (+**D**). MEDICAL DOCTOR, PHYSICAL THERAPIST, SPEECH THERAPIST, ERGOTHERAPIST, RADIOLOGY TECHNICIAN, and CLINICAL PSYCHOLOGIST *is a disjunctive sub-division of* HEALTH PROFESSIONAL.

Properties

[EP/SL] A HEALTH PROFESSIONAL is a HUMAN.

Comment

[DEF] “A health professional is a person who delivers proper health care in a systematic way professionally to any individual in need of health care services”. (Source: Wikipedia)

[SA] HEALTH PROFESSIONALS are divided among MEDICAL DOCTORS, PHYSICAL THERAPISTS, SPEECH THERAPISTS, ERGOTHERAPISTS, RADIOLOGY TECHNICIANS, and CLINICAL PSYCHOLOGISTS according to their education, their scope of practice and their professional role.

Medical doctor

Meta-properties

MEDICAL DOCTOR is ANTI-RIGID (~**R**). MEDICAL DOCTOR is CARRYING AN IDENTITY CRITERION (+**I**). MEDICAL DOCTOR is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A MEDICAL DOCTOR is a HEALTH PROFESSIONAL.

Comment

[DEF] “Doctor of Medicine (MD, from the Latin *Medicinæ Doctor* meaning “Teacher of Medicine”) is a doctoral degree for physicians (medical doctors). The degree is granted by medical schools. A medical doctor practices the ancient profession of medicine, which is concerned with maintaining or restoring human health through the study, diagnosis, and treatment of disease or injury. This properly requires both a detailed knowledge of the academic disciplines (such as anatomy and physiology) underlying diseases and their treatment — the science of medicine — and also a decent competence in its applied practice — the art or craft of medicine”. (Source: Wikipedia).

[SA] MEDICAL DOCTORS may be GERONTOLOGISTS, NEUROLOGISTS, NEUROSURGEONS, PSYCHIATRISTS, and RADIOLOGISTS according to their main specialty. “A specialty in medicine is a branch of medical science. After completing medical school, physicians or surgeons usually further their medical education in a specific specialty of medicine by completing a multiple year residency. Medical practitioners who engage in a medical specialty are known as medical specialists”. (Source: Wikipedia).

Gerontologist

Meta-properties

GERONTOLOGIST is ANTI-RIGID (~**R**). GERONTOLOGIST is CARRYING AN IDENTITY CRITERION (+**I**). GERONTOLOGIST is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A GERONTOLOGIST is a MEDICAL DOCTOR.

Comment

[DEF] A GERONTOLOGIST is a specialist physician who focuses on the diagnosis and non-surgical treatment of disease among elderly patients.

Neurologist

Meta-properties

NEUROLOGIST is ANTI-RIGID (**~R**). NEUROLOGIST is CARRYING AN IDENTITY CRITERION (**+I**). NEUROLOGIST is EXTERNALLY-DEPENDENT (**+D**).

Properties

[EP/SL] A NEUROLOGIST is a MEDICAL DOCTOR.

Comment

[DEF] A NEUROLOGIST is a specialist medical doctor who focuses on the diagnosis and non-surgical treatment of the disorders of the nervous system.

Neurosurgeon**Meta-properties**

NEUROSURGEON is ANTI-RIGID (**~R**). NEUROSURGEON is CARRYING AN IDENTITY CRITERION (**+I**). NEUROSURGEON is EXTERNALLY-DEPENDENT (**+D**).

Properties

[EP/SL] A NEUROSURGEON is a MEDICAL DOCTOR.

Comment

[DEF] A NEUROSURGEON is a specialist surgeon who focuses on the surgical treatment of the nervous system.

Psychiatrist**Meta-properties**

PSYCHIATRIST is ANTI-RIGID (**~R**). PSYCHIATRIST is CARRYING AN IDENTITY CRITERION (**+I**). PSYCHIATRIST is EXTERNALLY-DEPENDENT (**+D**).

Properties

[EP/SL] A PSYCHIATRIST is a MEDICAL DOCTOR.

Comment

[DEF] A PSYCHIATRIST is a specialist physician who focuses on the diagnosis and non-surgical treatment of cognitive, perceptual, emotional and behavioural disorders.

Radiologist**Meta-properties**

RADIOLOGIST is ANTI-RIGID (**~R**). RADIOLOGIST is CARRYING AN IDENTITY CRITERION (**+I**). RADIOLOGIST is EXTERNALLY-DEPENDENT (**+D**).

Properties

[EP/SL] A RADIOLOGIST is a MEDICAL DOCTOR.

Comment

[DEF] A RADIOLOGIST is a specialist medical doctor who focuses on diagnosis of disorders and the use of radiation in diagnosis and treatment purposes.

Neuroradiologist**Meta-properties**

NEURORADIOLOGIST is ANTI-RIGID (**~R**). NEURORADIOLOGIST is CARRYING AN IDENTITY CRITERION (**+I**). NEURORADIOLOGIST is EXTERNALLY-DEPENDENT (**+D**).

Properties

[EP/SL] A NEURORADIOLOGIST is a RADIOLOGIST.

Comment

[DEF] A NEURORADIOLOGIST is a RADIOLOGIST who focuses on disorders of the central nervous system, peripheral nervous system, and spinal column.

Physical therapist**Meta-properties**

PHYSICAL THERAPIST is ANTI-RIGID (~**R**). PHYSICAL THERAPIST is CARRYING AN IDENTITY CRITERION (+**I**). PHYSICAL THERAPIST is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A PHYSICAL THERAPIST is a HEALTH PROFESSIONAL.

Comment

[DEF] A PHYSICAL THERAPIST is a HEALTH PROFESSIONAL who provides treatment to individuals to develop, maintain and restore maximum movement and function throughout life. This includes providing treatment in circumstances where movement and function are threatened by aging, injury, disease or environmental factors.

Psychomotor therapist**Meta-properties**

PSYCHOMOTOR THERAPIST is ANTI-RIGID (~**R**). PSYCHOMOTOR THERAPIST is CARRYING AN IDENTITY CRITERION (+**I**). PSYCHOMOTOR THERAPIST is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A PSYCHOMOTOR THERAPIST is a PHYSICAL THERAPIST.

Comment

[DEF] A PSYCHOMOTOR THERAPIST is a PHYSICAL THERAPIST who provides treatment according to the relationship between cognitive functions and physical movement.

Speech therapist**Meta-properties**

SPEECH THERAPIST is ANTI-RIGID (~**R**). SPEECH THERAPIST is CARRYING AN IDENTITY CRITERION (+**I**). SPEECH THERAPIST is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A SPEECH THERAPIST is a HEALTH PROFESSIONAL.

Comment

[DEF] A SPEECH THERAPIST is a HEALTH PROFESSIONAL who focuses on the screening, assessment, diagnosis, and treatment for disorders of speech and language.

Ergotherapist**Meta-properties**

ERGOTHERAPIST is ANTI-RIGID (~**R**). ERGOTHERAPIST is CARRYING AN IDENTITY CRITERION (+**I**). ERGOTHERAPIST is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] An ERGOTHERAPIST is a HEALTH PROFESSIONAL.

Comment

[DEF] An ERGOTHERAPIST is a HEALTH PROFESSIONAL who focuses on the evaluation and treatment in order to improve a person's functional independence through the use of work activities.

Radiology technician

Meta-properties

RADIOLOGY TECHNICIAN is ANTI-RIGID (~**R**). RADIOLOGY TECHNICIAN is CARRYING AN IDENTITY CRITERION (+**I**). RADIOLOGY TECHNICIAN is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A RADIOLOGY TECHNICIAN is a HEALTH PROFESSIONAL.

Comment

[DEF] A RADIOLOGY TECHNICIAN is a HEALTH PROFESSIONAL who is usually responsible for acquiring medical images of diagnostic quality, although some radiological interventions are performed by radiologists.

Clinical psychologist

Meta-properties

CLINICAL PSYCHOLOGIST is ANTI-RIGID (~**R**). CLINICAL PSYCHOLOGIST is CARRYING AN IDENTITY CRITERION (+**I**). CLINICAL PSYCHOLOGIST is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A CLINICAL PSYCHOLOGIST is a HEALTH PROFESSIONAL.

Comment

[DEF] “Clinical psychology includes the scientific study and application of psychology for the purpose of understanding, preventing, and relieving psychologically-based distress or dysfunction and to promote subjective well-being and personal development. Central to its practice are psychological assessment and psychotherapy, although clinical psychologists also engage in research, teaching, consultation, forensic testimony, and program development and administration. In many countries clinical psychology is a regulated mental health profession.” (Source: Wikipedia).

Neuropsychologist

Meta-properties

NEUROPSYCHOLOGIST is ANTI-RIGID (~**R**). NEUROPSYCHOLOGIST is CARRYING AN IDENTITY CRITERION (+**I**). NEUROPSYCHOLOGIST is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SL] A NEUROPSYCHOLOGIST is a CLINICAL PSYCHOLOGIST.

Comment

[DEF] “A neuropsychologist holds an advanced degree in clinical psychology and will have completed further studies in neuropsychology, or in some countries, neurology. Neuropsychologists use models of brain-behavior relationships to determine whether expected neurobehavioral function is different from normal, or has changed to a degree that is consistent with impairment. Thus, the domain of neuropsychologists is expressed brain function: for example, reasoning/problem-solving, learning/recall processes, selective attention/concentration processes, perception, sensation, language processes, controlled/directed movement processes”. (Source: Wikipedia).

Engineer

Meta-properties

ENGINEER is ANTI-RIGID ($\sim\mathbf{R}$). ENGINEER is CARRYING AN IDENTITY CRITERION ($+\mathbf{I}$). ENGINEER is EXTERNALLY-DEPENDENT ($+\mathbf{D}$).

Properties

[EP/SL] An ENGINEER is a HUMAN.

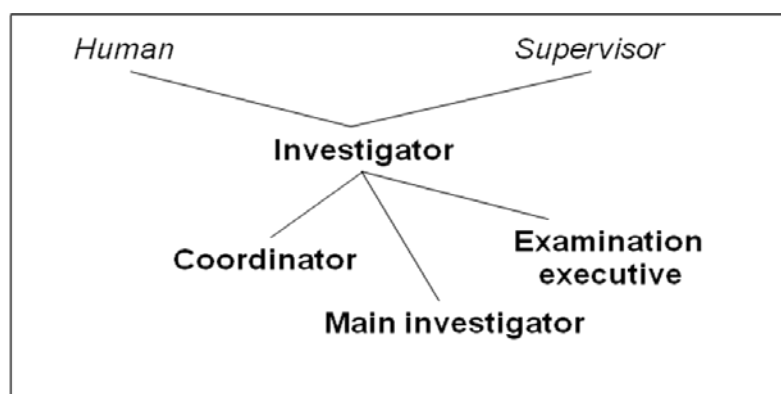
Researcher

Meta-properties

RESEARCHER is ANTI-RIGID ($\sim\mathbf{R}$). RESEARCHER is CARRYING AN IDENTITY CRITERION ($+\mathbf{I}$). RESEARCHER is EXTERNALLY-DEPENDENT ($+\mathbf{D}$).

Properties

[EP/SL] A RESEARCHER is a HUMAN.



Investigator

Meta-properties

INVESTIGATOR is ANTI-RIGID ($\sim\mathbf{R}$). INVESTIGATOR is CARRYING AN IDENTITY CRITERION ($+\mathbf{I}$). INVESTIGATOR is EXTERNALLY-DEPENDENT ($+\mathbf{D}$).

Properties

[EP/SLD] An INVESTIGATOR is a HUMAN and a SUPERVISOR who *supervises* a STUDY or an EXAMINATION *at* a TIME INTERVAL.

Comment

[DEF] An INVESTIGATOR is a person responsible for the conduct of a STUDY or an EXAMINATION at a CENTRE.

Main investigator

Meta-properties

MAIN INVESTIGATOR is ANTI-RIGID ($\sim\mathbf{R}$). MAIN INVESTIGATOR is CARRYING AN IDENTITY CRITERION ($+\mathbf{I}$). MAIN INVESTIGATOR is EXTERNALLY-DEPENDENT ($+\mathbf{D}$).

Properties

[EP/SL] A MAIN INVESTIGATOR is an INVESTIGATOR who *supervises at* a TIME INTERVAL *as main investigator* either a MONO-CENTRE STUDY or the *part of* a MULTI-CENTRE STUDY which has for agent one CENTRE at a TIME INTERVAL.

[EP/NMC] Every MAIN INVESTIGATOR who *supervises as main investigator* a STUDY WITH EXAMINATION *at* a TIME INTERVAL is necessarily a MEDICAL DOCTOR.

Comment

[DEF] Modified from CDISC Clinical Research Glossary: when a STUDY (either Mono or Multi-centre) is conducted by a team of individuals at a CENTRE, the responsible leader of the team is called the MAIN INVESTIGATOR.

Coordinator

Meta-properties

COORDINATOR is ANTI-RIGID ($\sim\mathbf{R}$). COORDINATOR is CARRYING AN IDENTITY CRITERION ($+\mathbf{I}$). COORDINATOR is EXTERNALLY-DEPENDENT ($+\mathbf{D}$).

Properties

[EP/SLD] A COORDINATOR is an INVESTIGATOR which *supervises as coordinator* a MULTI-CENTRE STUDY *at* a TIME INTERVAL. [EP/NMC] Every COORDINATOR who *supervises as coordinator* a STUDY WITH EXAMINATION *at* a TIME INTERVAL is necessarily a MEDICAL DOCTOR.

Comment

[DEF] Modified from CDISC Clinical Research Glossary: an INVESTIGATOR assigned the responsibility for the coordination of INVESTIGATORS at different CENTRES participating a MULTI-CENTRE STUDY.

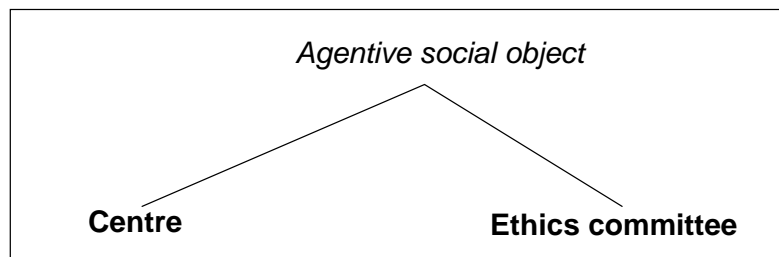
Examination executive

Meta-properties

EXAMINATION EXECUTIVE is ANTI-RIGID ($\sim\mathbf{R}$). EXAMINATION EXECUTIVE is CARRYING AN IDENTITY CRITERION ($+\mathbf{I}$). EXAMINATION EXECUTIVE is EXTERNALLY-DEPENDENT ($+\mathbf{D}$).

Properties

[EP/SLD] An EXAMINATION EXECUTIVE is an INVESTIGATOR who *supervises as examination executive* an EXAMINATION *at* a TIME INTERVAL.



Centre

Meta-properties

CENTRE is RIGID ($+\mathbf{R}$). CENTRE is not EXTERNALLY-DEPENDENT ($-\mathbf{D}$).

Properties

[EP/SL] A CENTRE is an AGENTIVE SOCIAL OBJECT. [EP/ER] Every CENTRE *has for name* a NAME.

Ethics committee, Independent ethics committee, independent review board (IRB), Consultative committee for the protection of human subjects, in France: Comité de Protection des Personnes (CPP)

Meta-properties

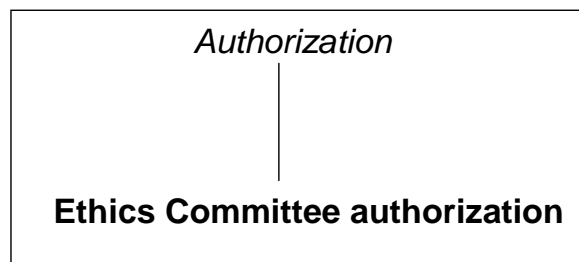
ETHICS COMMITTEE is RIGID (+**R**). ETHICS COMMITTEE is not EXTERNALLY-DEPENDENT (-**D**).

Properties

[EP/SL] An ETHICS COMMITTEE is an AGENTIVE SOCIAL OBJECT.

Comment

[DEF] CDISC Clinical Research Glossary: An independent body (a review board or a committee, institutional, regional, national, or supranational) constituted of medical/scientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial and to provide public assurance of that protection by, among other things, reviewing and approving/providing favourable opinion on the trial protocol, the suitability of the investigator(s), facilities, and the methods and material used in obtaining and documenting informed consent of the trial subjects.



Ethics Committee authorization

Meta-properties

ETHICS COMMITTEE AUTHORIZATION is RIGID (+**R**). ETHICS COMMITTEE AUTHORIZATION is EXTERNALLY-DEPENDENT (+**D**).

Properties

[EP/SLD] An ETHICS COMMITTEE AUTHORIZATION is an AUTHORIZATION which *has for author* an ETHICS COMMITTEE.