Codice etico Ethics Code

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Il Consiglio Direttivo dell’Associazione Italiana per lo Studio del Dolore
The Executive Board of the Italian Association for the Study of Pain (AISD)

Il Consiglio Direttivo della Fondazione Paolo Procacci
The Executive Board of the Paolo Procacci Foundation (FPP)

Il presente Codice Etico è stato scritto, approvato e firmato da:
The current Ethics Code has been written, approved and signed by:

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Presentation
The Italian Association for the Study of Pain (AISD) and the Paolo Procacci Foundation (FPP) present their own Ethics Code as testimony to their respective institutional activities in the study and actions against pain, and also as an expression and consequence of the importance of how the pain itself – in all of its clinical manifestations - acts on a scientific, social, economical and political level.

Preface
Pain represents one of the fundamental problems that human kind must endure and, in their diverse clinical expressions, constitutes a significant obstacle to maintaining a certain quality of life that guarantees each single individual a condition of wellness. Furthermore, on an economic level pain conditions a financial expense of absolute depth and causes significant social consequences.

Guiding Principles
The Ethics Code presented and promoted by the AISD and FPP has been inspired by a multiple of principles: The scientific mission to study a very complex problems; the moral call guaranteeing more and more adequate, diffuse and shared levels of assistance. The ethic duty of respond to the request for updated, effective and efficient therapeutic models.

Objectives
AISD and FPP are the promoters of a scientific program of assistance, united by and ethical and moral message, which has always had, as its aim, a major diffusion in the culture of pain, and the goal of fighting against pain and the improvement of analgesic treatments.
Introduction

AISD and FPP shall demonstrate their scientific, charitable, educational, cultural and political mission in its respective institutional Statutes, and shall summarize their ethical and moral principles of their activities in this Ethics Code.

The Ethics Code defines the aims and the specific objectives of AISD and FPP as follows: promotion of clinical studies and basic research; higher education and continuous training of workers and the health professions; definition of the guidelines and recommendations in the diagnostic and therapeutic field; collaboration with other Scientific Societies and with the Patients Associations; regular confrontation with political and administrative Authorities; collaboration with the Pharmaceutical Industry; support of informative campaigns.

AISD and FPP hope that this Ethics Code may constitute a useful tool in the study and in the fight against pain, to better assist those who are suffering.
Article 1
Knowledge Exploitation

The development of new biomedical knowledge is the foundation of every organization pursuing objectives at a scientific, educational and welfare level. Therefore, every effort shall be used to promote the application of knowledge relative to the various aspects of pain, taking into due consideration the elevated sense of correctness in making choices and delineate the guidelines. It is particularly recommended that the integrity and honor of those who strive for the correct use of knowledge regarding pain be safeguarded, due to the fact that they represent a common heritage to be safeguarded and respected, in the context of shared values enshrined in the Constitution of the Italian Republic. AISD and FPP reinforce their roles in enhancing their image as correct corporations, where institutional activities are inspired by the highest ethical and moral values.

Article 2
Research Exploitation

Research is defined as an intellectual activity which tends to broaden scientific knowledge and in this context, AISD and FPP promote and encourage all research activities of academic purpose to basically push the care of patients with pain as their final objective. Particular attention must be focused on the methods of research geared towards the assessment of pain in non-communicative subjects – infants of preschool age and elders with difficulty or impossibility of verbal expressions. Studies which utilize laboratory animals must respect the international norms of bioethics and Good

Articolo 1
Valorizzazione delle conoscenze

Lo sviluppo di nuove conoscenze in campo biomedico è alla base di ogni organizzazione che persegua obiettivi scientifici, formativi ed assistenziali. Si promuove dunque ogni sforzo volto alla valorizzazione delle conoscenze relative ai molteplici aspetti del dolore, tenendo in debita considerazione il mantenimento di un elevato senso del giusto nel compiere scelte e nel tracciare linee di indirizzo. Si raccomanda particolarmente la salvaguardia dell’integrità e dell’onore di quanti si adoperano correttamente per la valorizzazione delle conoscenze sul dolore, in ragione del fatto che questi rappresentano un patrimonio comune da salvaguardare e da rispettare, nell’ambito dei valori custoditi nella Carta Costituzionale della Repubblica Italiana. AISD e FPP sottolineano il loro ruolo nel rafforzamento la propria immagine di enti sani, nei quali le attività istituzionali sono ispirate ai più alti valori etici e morali.

Articolo 2
Valorizzazione della ricerca

La ricerca è definita come una attività intellettuale che tende all’ampliamento delle conoscenze scientifiche ed in questo ambito AISD e FPP promuovono e stimolano ogni attività di ricerca come spinta fondamentale dell’attività accademica finalizzata alla cura dei pazienti con dolore. Deve essere posta particolare attenzione alla ricerca di metodi volti alla valutazione del dolore nei soggetti non-verbalizzanti – bambini in età prescolare ed anziani con difficoltà/im possibilità di espressione verbale. Gli studi che
utilizzano animali da laboratorio devono rispettare le norme internazionali di bioetica e di Good Practice nella sperimentazione animale, così come nella permanenza all’interno degli stabulari.

Esito della ricerca è la pubblicazione dei risultati ottenuti: si raccomanda ogni sforzo per l’impiego di metodologie di lavoro corrette che trovino ispirazione nelle norme della Good Clinical Practice e della Good Laboratory Practice, nonché nel rispetto dei principi etici e bioetici per la sperimentazione animale. È responsabilità di ogni ricercatore la garanzia di originalità e di veridicità dei dati raccolti, la riproducibilità dei risultati, l’attendibilità, la completezza e la valorizzazione delle fonti consultate, il riconoscimento delle collaborazioni interne ed esterne. Ogni ricercatore renderà inoltre noto qualsiasi finanziamento e gli eventuali diretti ed indiretti conflitti di interesse. AISD e FPP condannano il plagio e l’auto-plagio, la falsificazione e la fabbricazione di risultati, le manovre di ostruzionismo e sabotaggio del lavoro di altri ricercatori ed ogni altra forma di disonestà scientifica. Ogni componente di AISD e FPP si impegna a segnalare qualsiasi sospetta o documentata scientific misconduct.

Articolo 3
Valorizzazione della formazione

La didattica rappresenta, assieme alla ricerca scientifica, il nodo cruciale dell’attività formativa.

Nell’ambito della medicina del dolore, la formazione deve essere promossa e valorizzata ad ogni livello. Nelle aule accademiche e nei luoghi di diagnosi e cura – per la formazione degli Studenti, degli Specializzandi e degli Operatori delle Professioni Sanitarie – così come in occasione del teaching, together with scientific research, is the crux of the training. In the field of pain medicine, training must be promoted and exploited at each and every level. In academic classroom and places of diagnoses and treatment – for the training of students, specialists, trainees and practitioners in the health profession, as well as in opportunities of events and internships geared towards continuous training, it is recommended that the educators conduct them-
sione di eventi e stage volti all’aggiornamento continuo, si raccomanda ai Formatori di svolgere con coerenza, correttezza e con spirito di servizio i momenti formativi utilizzando materiali aggiornati e disegnando percorsi formativi ispirati al miglior sapere scientifico.
Particolare attenzione verrà data alle tecniche di comunicazione medico-paziente, tanto importanti nella pratica clinica quanto – a maggior ragione – fondamentali nella medicina del dolore.

**Articolo 4**
**Rapporti con le Società Scientifiche**

Le Autorità Amministrative e Politiche rappresentano interlocutori fondamentali per la medicina del dolore.
Le Società Scientifiche – in modo peculiare AISD ed FPP – manterranno stretti rapporti di confronto con le Autorità in ordine ad una continua attività di informazione, nonché ad una costante sollecitazione di iniziative normative e legislative per una sempre migliore assistenza al paziente con dolore – sia in ambito nazionale sia a livello locale.

**Articolo 5**
**Rapporti con l’Industria Farmaceutica**

Il progresso della medicina del dolore non può prescindere dalla collaborazione fra gli studiosi e l’Industria Farmaceutica, che rappresenta un interlocutore essenziale per il progresso scientifico e terapeutico.
La collaborazione con le compagne farmaceutiche deve essere informata alla massima correttezza e alla massima trasparenza. Deve essere sempre tenuto presente l’obiettivo prioritario rappresentato dall’interesse del paziente.

**selves with consistency, correctness and in the spirit of service during the course, using updated resources and materials so that the course of studies is inspired by the highest form of scientific knowledge.**

**Particular attention must be given to the of doctor-patient communication techniques, as essential in clinical practice – and even more so – as it is in pain medicine.**

**Article 4**
**Relationship With The Scientific Societies**

Pain medicine has a place in numerous Scientific Societies as a necessity of operating in an intellectual environment in which exchange of ideas, projects and programs can be carried out. Each Society may express their mission, in its respective statutory provisions, forms or any other means deemed most suitable for the advancement of pain medicine.
It is hoped and recommended that the relationships between the various Societies are formed based on the highest mode of mutual collaboration and cooperation, and dismissing those means and methods which are honest and transparent. In this context and with these goals, it is strongly recommended that all Scientific Societies involved make the time necessary in order to discuss and share their respective researches, the preservation of their rights, and their scientific achievements.

**Article 5**
**Relationship With The Administrative And Political Authorities**

The administrative and political Authorities are considered to be the key interlocutors in the
Articolo 6
Relationship With The Pharmaceutical Industry

The advancement of pain medicine must not prescind from the collaboration between researchers and the Pharmaceutical Industry, which represents an essential partner for the improvement of scientific and therapeutic progress. Collaboration with the Pharmaceutical Companies must be informed at the highest level of correctness and maximum transparency. The overriding objective represented by the interest of the patients must always be taken into consideration. In this context, particular ethical considerations must be dedicated at testing of new molecules in human beings. Strict observance of the regulations relative to Good Clinical Practice (see also article 2) an of the decisions made by various Ethical Committees (Regional, Health Agencies, Universities and individual Faculties - when present) must be expressed in the supreme interest of those patients with pain.

Articolo 7
Cooperation With The Patients Association

Cooperation with the patients associations is widely advocated. Emphasis is placed on the field of pain medicine.

The Scientific Societies – more specifically AISD and FPP – maintain a tight relationship of exchange with the Authorities for continuous activity of information, as well as for a constant solicitation of regulations and legislative initiatives to provide for an ever better assistance to patients suffering from pain – both on a national and local level.
importance of collaboration with the patients, for a better understanding of the demands and expectations of those who are suffering, their families and caregivers.

Improving the quality of life of these patients is the top priority of AISD and FPP, which consider the patients associations to the privileged figure and to be given preference to in the clinics and in the fight against pain.

Article 8
The Study And Design Of Guidelines And Recommendations

National and International Guidelines, Recommendations and Codes of Conduct founded on Evidence Based Medicine, constitute the foundation upon which modern medicine, as well as pain medicine, are built. However, other evaluations, criticisms and operatives, on the grounds of Experts' Opinion and Experience Based Medicine must not be neglected. Likewise, it is the duty of each individual scholar and caring doctor to utilize any effective and modern updating at his disposition with correctness, awareness and consciousness, without neglecting the holistic view of the suffering patient – in the prospective of the medical view which puts the subject as the center of the art of medicine, and which transforms the actions of the doctor from “treating” to “taking care of.”

Article 9
Contrast To The Conflict Of Interests

A conflict of interest occurs when the interest of an individual comes into conflict with those of the institution in which the very individual is operating.

In this Ethics Code, it is recommended that
each component of AISD and FPP, alone or as an association, lays particular attention in ensuring that scientific information, collaboration contracts, consulting services, or rather any profits due to personal position – real or perceived – do not condition the progress of pain medicine, delaying, for example, the use of analgesic drugs, as well as the circulation of ideas and scientific outcomes which may be of relief to those who are suffering.

Likewise, a doctor who finds himself in a position of conflict between his own personal interests (as an auditor or as a member of the financial committee, etc.) with those of the general progress of pain medicine, (abandoning the office) will need to communicate with his superior. Each component of AISD and FPP, yet at the same time, is required to respect the confidentiality relative to the individual, society or authority with whom he collaborates – before the information is disclosed in a manner or time which complies with the regulations on the ownership of the creative works or rather the norms on copyright.

**Article 10
Popularization Of The Culture Of Pain**

It is hoped that all necessary steps are taken to ensure that Academic Institutions, Scientific Societies and Administrative and Political Authorities, the Patients Association and Pharmaceutical Industry pursue and increase every effort so that the culture of pain – in order to understand the epidemiological, diagnostic and clinical, social and economical problems, as well as basic and applied research - are supported, encouraged, sponsored and shared in the primary interests of the population of patients suffering from pain.
ne alla conoscenza delle problematiche epide-
miologiche, diagnostiche e cliniche, sociali ed
economiche, nonché la ricerca di base ed ap-
plicata siano sostenute, incoraggiate, sponso-
rizzate, condivise, nell’interesse primario del-
la popolazione di soggetti con dolore.

Articolo 11
Commissione Etica

I Consigli Direttivi di AISD e di FPP provve-
deranno, entro 30 giorni dall’approvazione di
questo CE a nominare una Commissione Etica
composta da illustri studiosi estranei ai Consigli
Direttivi di AISD e di FPP e presieduta da una
personalità di assoluto rilevo istituzionale e di
ricognosciuta posizione culturale ed accade-
ma a salvaguardia delle prerogative ed a garan-
zia dei compiti assegnati alla Commissione
Etica stessa.
La Commissione Etica vigila sul rispetto e sul-
l’osservanza di ogni singolo articolo di questo
CE e, in mancanza di una normativa stabilità,
provvede a colmare eventuali lacune non pre-
viste da questo CE. La Commissione Etica se-
gnala eventuali controversie insorte all’inter-
no dei componenti le due Società (AISD e FPP),
cosi come con componenti di altre realtà societ-
arie ovvero istituzionali, provvedendo ad ope-
rare ogni sforzo per la soluzione del disaccor-
do, del contrasto di opinioni o delle dispute.
La Commissione Etica mantiene stretti rap-
porti con le Commissioni Etiche di altre socie-
tà in ordine alla ricerca di un percorso etico con-
diviso ed accettato.
La Commissione Etica resta in carica 4 anni e
i componenti non sono confermabili.

Article 11
Ethics Commission

The executive boards of AISD and FPP shall
provide for, within 30 days of the approval of
this Ethics Code, a nomination of an Ethics
Committee composed of figures ranging from
distinguished foreign scholars to members of
the Executive Board of AISD and FPP, and is
chaired by a figure of absolute institutional pro-
minence who holds a position of cultural and
academic recognition, whose duties are to sa-
feguard and guarantee the tasks assigned to
this Ethics Committee.
The Ethics Committee shall monitor complian-
ce with and observance of each and every arti-
cle of this Ethics Code and, in the absence of
established regulations, shall fill any gaps not
covered by this Ethics Code. The Ethics
Committee shall report any eventual disputes
between the components of the two Societies
(AISD and FPP), as well as with members of
other corporate or institutional and scientific
realities, ensuring every effort to work to resol-
ve the disagreement, conflict of opinions or dis-
putes.
The Ethics Committee shall maintain close re-
lationships with the Ethics Committees of other
Scientific Societies in order to search for a sha-
red and accepted ethical path.
The Ethics Committee shall remain in office for
a period of 4 years, and members may not be
re-elected.
Il presente Codice Etico, stilato da AISD e FPP, può essere condiviso ed adottato da altre Società Scientifiche, purché non venga modificato. AISD e FPP, in quanto Società Scientifiche con un consolidato curriculum di ricerca e formazione, mettono a disposizione il proprio patrimonio di esperienze per esaminare i progetti o le pubblicazioni di altre società scientifiche italiane, con un ruolo particolare di “revisore etico”, come in un processo di “audit” riguardante solo l’aspetto etico del lavoro. Chi adotta il Codice Etico di AISD e FPP diventa una Ethics Evidence Based Scientific Society (EEBSS), Società Scientifica Basata sull’Evidenza dell’Etica.