TOXICOLOGY ANTHROPOLOGY CRIMINALISTICS

QUESTIONED DOCUMENTS

PSYCHIATRY & BEHAVIORAL SCIENCE

PATHOLOGY / BIOLOGY

DIGITAL & MULTIMEDIA SCIENCES

ENGINEERING & APPLIED SCIENCES

GENERAL

PROCEEDINGS

American Academy of Forensic Sciences

75th Anniversary Conference

AMERICAN ACADEMY OF FORENSIC SCIENCES

75

1948 2023

Science Works

February 13-18, 2023
Orlando, Florida
Rosen Shingle Creek Resort

ODONTOLOGY FORENSIC NURSING SCIENCE JURISPRUDENCE

410 North 21st Street
Colorado Springs, CO 80904
Phone: (719) 636-1100
Fax: (719) 636-1993
Email: info@aafs.org
Website: www.aafs.org

PROCEEDINGS

of the American Academy of Forensic Sciences 75th Anniversary Scientific Conference

The *Proceedings* of the American Academy of Forensic Sciences is an official publication of the American Academy of Forensic Sciences (AAFS). It is devoted to the publication of the abstracts of technical oral papers and posters presented at the AAFS Annual Scientific Conference. These include various branches of the forensic sciences such as anthropology, criminalistics, digital evidence, forensic nursing, engineering, jurisprudence, odontology, pathology, psychiatry, questioned documents, and toxicology. Similar submissions dealing with forensic-oriented aspects of the social sciences are also included.

Please note that some of the abstracts included in the *Proceedings* deal with topics, results, and/or conclusions that are controversial. The publication of abstracts does not imply that the AAFS, its sections, or the individual section program chairs/committee members have verified or agree with the studies, results, and/or conclusions of each abstract. During the process of planning a scientific program, it is impossible to "peer-review" each abstract and presentation to the degree that is accomplished during manuscript review. Abstracts and presentations are accepted, in part, so they can be critiqued and reviewed by other scientists. Thus, a forum is created to discuss controversial issues. The views expressed in this publication are not those of the AAFS. The data and opinions appearing in the published material were prepared by and are the responsibility of the contributor(s), not of the AAFS nor its respective employees, employers, officers, and agents. The AAFS does not supply copies of meeting papers. Please write directly to individual authors to obtain copies of specific papers. Presentation of some abstracts may have been scheduled or canceled after the publication of this document.

English is the official language of the AAFS and its meetings; neither oral nor written translations will be provided.

PROCEEDINGS

of the American Academy of Forensic Sciences **February 2023**
Volume XXIX

TABLE OF CONTENTS

F13 The Role of the Ethics Committee in Research Activities During the SARS-CoV2 Pandemic

Barbara Abenante, MD, University of Turin, Italy, Turin, Piemonte, ITALY; Francesca Capello, MD*, University of Turin, Italy, Torino, Piemonte, ITALY; Giancarlo Di Vella, PhD, University of Turin, Italy, Turin, Piemonte, ITALY; Lucia Tattoli, PhD, University of Turin, Torino, Piemonte, ITALY*

Learning Objective: After attending this presentation, attendees will understand that COVID-19 epidemic had changed Ethics Committees (Ecs) activity that should respond in a timely manner to new evaluation requests by adapting its standard operating procedures to the new reality.

Impact Statement: This presentation will impact the forensic science community by showing that, in emergency conditions, it is necessary to proceed as quickly as possible in the review and assessment of the research by safeguarding, at the same time, both scientific transparency and compliance with ethical requirements.

Research participants' safety is guaranteed by ethical guidelines (e.g., Declaration of Helsinki and good clinical practice), legislation to protect participants' privacy, research ethics committees, and informed consent. "Ethics Committee," according to Directive 2001/20/EC, is an independent body consisting of health care and non-medical members responsible for protecting the rights and safety of subjects involved in a trial through "expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent". In Italy, the establishment of ECs is provided by the law in public health facilities, private hospitals, and care institutions. At the beginning of pandemic, World Health Organization and the European Commission provided indications regarding the research's evaluation by adopting an "expedited" approach of ECs approval.[1,2]

In Italy, both the Council of Ministers and the Italian Medicines Agency (AIFA—Agenzia Italiana del Farmaco) issued some measures for a national coordination of clinical trials and therapeutic programs management in COVID-19 emergency in 2020.[3] The EC of the National Institute for Infectious Diseases "Lazzaro Spallanzani" in Rome, as National Unique EC for the evaluation of clinical trials of medicines for human use and medical devices for patients with COVID-19, formulates a national opinion also on the basis of the evaluation of the AIFA Technical Scientific Committee. AIFA introduced a "fast track" for the online transmission of research documentation and the submission of request for clinical trials authorization relating to the treatment of COVID-19. The applicants were allowed to defer the sending of paper documents, which in any case must be sent as soon as possible to the Clinical Trials Office. During the COVID-19 public health emergency, applications for trials in oncology, transplants, and urgent clinical conditions requiring interventions that could not be postponed were admitted besides trials to address the COVID-19 emergency. In Turin, the Inter-Company Ethics Committee (IEC) was established in 2019 and includes three hospitals (University Hospital "City of Science and Health," Hospital "Ordine Mauriziano," and "ASL Città di Torino").

From January 2020 to December 2021, the IEC evaluated 1,100 studies of which 134 referred to COVID-19. IEC evaluated: in 2020, 472 non-COVID-19 (NCS) studies and 90 COVID-19 studies (CS); in 2021, 492 NCS and 46 CS. The trend in the number of evaluations showed two peaks, in March–July 2020 and September–November 2020, just when pandemic waves occurred and before the Comirnaty vaccine authorization. The majority of studies were observational (86.5% of CS, 59.1% of NCS). CS focused on impact on other pathologies and therapies (n=35), SARS-CoV2 characteristics (n=22), therapy (n=21), long-term effects (n=17), diagnosis (n=14), COVID-19 vaccines (n=9), epidemiology (n=8); 6.7% of total CS and 2.3% of NCS referred to emergency management research. The role of ECs is fundamental in promoting ethical values in research and in ensuring ethical protection and standards for all the individuals involved in COVID and non-COVID research, even in emergency situations. None the less, the need to accelerate the research for guiding public health interventions should not come at the expense of a thorough ethics review.

References:

1. WHO. *Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R&D*. 29 March 2020 https://www.who.int/blueprint/priority-diseases/key-action/liverecovery-save-of- ethical-standards-for-research-during-public-health-emergencies.pdf.
2. *Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic*. 2020 https://ec.europa.eu/health/documents/eudralex/vol-10_en.
3. Italian Medicines Agency (AIFA - Agenzia Italiana del Farmaco). *Clinical trials' management in Italy during the COVID-19 (coronavirus disease 19) emergency*; 2020 https://www.aifa.gov.it/documents/20142/1123276/Comunicazione_gestione_studi_clinici_in_emergenza_COVID- 19-EN_17.09.2020.pdf

Ethics Committee; COVID-19; Research