

# HFEA (Human Fertilisation and Embryology Authority) について

埼玉医科大学産科婦人科学

埼玉医科大学総合医療センター産婦人科

石原 理

# HFEA (Human Fertilisation and Embryology Authority) 英国における生殖医療と生殖医学研究管理運営機関

- 1984のウォーノック報告(Warnock report)を受けて1990に成立したHFEAct (Human Fertilisation and Embryology Act)に基づき設立された管理運営機関
- その機能は、当初、生殖医療と生殖医学研究実施施設へのライセンス付与と査察、情報収集保存管理と提供および広報活動、生殖医療の臨床現場で用いられる実施規範たるCode of Practiceの継続的な改訂作業など
- ただし、HFEActの改正(最終2008年)、HFEAの改組(最終2017年)、および生殖医療と生殖医学研究の進展の結果、その意義と機能は大きく変貌しつつある

# HFEAのHFEActに基づく機能 (statutory function)

- to license and inspect clinics carrying out in vitro fertilisation and donor insemination treatment; 治療施設へのライセンス交付と査察
- to license and inspect centres undertaking human embryo research; 胚研究施設へのライセンス交付と査察
- to license and inspect the storage of gametes (eggs and sperm) and embryos; 配偶子と胚保存施設へのライセンス交付と査察
- to publish a Code of Practice, giving guidance to clinics and research establishments about the proper conduct of licensed activities; COP出版による適切な指示
- to keep a register of information about donors, treatments and children born as a result of those treatments; 第三者の関与する生殖における情報の記録保持
- to keep a register of licences granted; 交付されたライセンスの記録保持
- to keep a register of certain serious adverse events or reactions; SAEの記録保持
- to investigate serious adverse events and serious adverse reactions and take appropriate control measures. SAEの調査と適切な対応

# HFEAのより一般的な機能 (more general functions)

- promoting compliance with the requirements of the 1990 act (as amended), the 2008 act and the Code of Practice;
- maintaining a statement of the general principles that we should follow when conducting our functions and by others when carrying out licensed activities;
- observing the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed;
- carrying out our functions effectively, efficiently and economically;
- publicising our role and providing relevant advice and information to donor-conceived people, donors, clinics, research establishments and patients;
- reviewing information about: – human embryos and developments in research involving human embryos – the provision of treatment services and activities governed by the 1990 act (as amended)
- advising the Secretary of State for Health and Social Care on developments in the above fields, upon request

# HFEAの現況(2018.10)

## Summary position as at 31 March 2018

	2017/18	2016/17
	£'000s	£'000s
<b>Expenditure</b>		
Staff costs	4,232	3,816
General administrative costs	1,670	1,597
Total expenditure	5,902	5,413
<b>Income</b>		
Licence fees	5,305	5,323
Other income	97	26
Total income <sup>3</sup>	5,402	5,349

- ・ライセンスは最長4年間(新規は2年)  
Licence Committeeが決定権を持つ
- ・Licence feeはDI/IVF新規申請£500  
さらにIVF周期あたり£80(2016.4改訂)
- ・新規IUIは£975、以後毎年£2950
- ・胚研究新規申請£500、幹細胞研究£750
- ・新規ライセンス交付時と2年毎に査察あり  
事故や懸念される事態のある場合臨時査察  
(事前通告のない場合もあり)
- ・Code of practice 8<sup>th</sup> edition が最新版  
(最終改訂は2017.10)

	Male	Female	Total
Authority members	4	7	11
Senior Management Team (SMT)	3	1	4
All staff (including SMT, excluding Authority)	13	51	64

HFEA Annual report and accounts 2017/18 published 29 October 2018および  
Code of practice 8<sup>th</sup> editionなどによる