

November 9, 2018

Thomas J. Nasca, MD President and Chief Executive Officer, ACGME ACGME - Suite 2000 401 North Michigan Avenue Chicago, IL 60611

Dear Dr. Nasca:

We are writing you on behalf of the Obstetrics and Gynecology Family Planning community and the American Board of Obstetrics and Gynecology (ABOG).

The ABOG and the Family Planning GME and professional society communities request that Complex Family Planning be considered for approval as a subspecialty in OB GYN. The community has worked for 20 years to grow the stature of the field, establish excellent fellowship training programs and foster institutional divisions of Family Planning in OB GYN departments. The GME community, the Society of Family Planning and the ABOG believe that the number of fellowship programs is sufficient and the field sufficiently mature to meet standards for designation as an OB GYN subspecialty.

The ABOG Board of Directors established an ad hoc committee to examine program accreditation and certification of a new subspecialty by the board. The ABMS Board of Directors approved the request in October 2018 for a new subspecialty certificate in Complex Family Planning.

We believe that the proposed subspecialty is beyond the curriculum and training in residency programs, is important to the quality and safety of care in OB GYN and will elevate the importance of family planning in women's healthcare in our country.

The Family Planning community and ABOG request approval from the ACGME Board of Directors for a new subspecialty in Complex Family Planning and for accreditation authority by the Review Committee for Obstetrics and Gynecology. The enclosed application outlines the proposal according to ACGME policies.

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Please free to contact us if you have any questions.

Sincerely,

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George D. Wendel, Jr., M.D. Executive Director American Board of Obstetrics and Gynecology

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PROPOSAL FOR THE ACGME ACCREDITATION OF A NEW FELLOWSHIP PROGRAM IN THE SUBSPECIALTY OF COMPLEX FAMILY PLANNING

Documentation of the professional and scientific status of the new subspecialty for each of the criteria in the ACGME Policies and Procedures Manual listed on page 66 (A-H) is given below.

A. The clinical care and safety of patients will be improved through the recognition of the discipline.

Reply:

Complex Family Planning subspecialists treat women who are at risk of pregnancy or have pregnancies that are abnormal, unintended, and/or unwanted, and present with other healthand potentially life-threatening medical conditions. Contraception and pregnancy termination services for healthy women may be safely provided by OB GYN specialists. Yet, subspecialist consultants with special knowledge and skills may be required to safely provide diagnosis and treatment to women in medically- and surgically-complex situations. Subspecialists in Complex Family Planning are trained to receive referrals from generalist clinicians, OB GYN specialists, and advanced practice clinicians to provide an advanced level of care to improve the safety and reproductive health outcomes of women with co-morbid conditions and complex clinical presentations.

The increasing emphasis on healthy child-spacing and the urgent need to reverse the United States' rise in maternal-mortality highlight the need for the Complex Family Planning subspecialty. Women with comorbidities may require experts to initiate a safe and effective contraceptive plan: unintended and mistimed pregnancies in a population with comorbidities can exacerbate maternal illness and result in avoidable complications. As the pregnant population ages, cesarean delivery rate rises, and severe obesity becomes increasingly common; obstetric care has become more complex. Pregnancy termination care is no exception, and the ability to seek appropriate consultation and make timely and appropriate referrals is critical to women's health. Complex Family Planning subspecialists have a mastery of pharmacokinetics, endocrinology, and surgical techniques that are required to support community-based providers. Complex Family Planning subspecialists improve the delivery of the safest and highest level of care regardless of the complexity of patients' medical and surgical diagnoses. This tenet is incorporated into the learning objectives of the proposed subspeciality.

The Complex Family Planning subspecialist advances the science of the prevention, diagnosis, and management of early pregnancy complications. The subspecialists provide clinical training in academic centers and thus elevate the standard of care by teaching best and evidence-based practices to clinicians who will complete training and practice OB GYN. Complex Family Planning subspecialists act as advocates and champions of access to equitable family planning clinical services at local, regional, and national levels.

The proposed Complex Family Planning subspecialty is important to women's health. This is why the American Board of Medical Specialties (ABMS) approved the application submitted by the American Board of Obstetrics and Gynecology (ABOG) to recognize the subspecialty. ACGME accreditation of the training programs is the next step in ensuring high-quality care across the United States. The subspecialty will be crucial to improve care for women in vulnerable and underserved populations. When Complex Family Planning is incorporated into medical school and residency teaching curricula and access to care is available, the need for terminations of pregnancy will decrease.

B. The existence of a body of scientific medical knowledge underlying the subspecialty that is (i) clinically distinct from other areas in which accreditation is already offered, and (ii) sufficient for educating individuals in a clinical field, and not simply in one or more techniques.

Reply:

The clinical **Fellowship in Family Planning** (FFP) program was started in 1991 by a nationally- and internationally-recognized leader in Family Planning at the University of California, San Francisco. Fellowships quickly grew to include departments of Obstetrics and Gynecology at Columbia University, Johns Hopkins University, University of Southern California, University of Pittsburgh, Emory University, Boston University, Northwestern University, and Oregon Health and Science University. The founding fellowship directors recognized the need for training, research, and health policy to advance women's reproductive health and create new generations of leaders dedicated to women's health. Leaders in the OB GYN subspecialty of Reproductive Endocrinology and Infertility (REI), which shifted its focus from contraception to assisted reproductive technologies such as *in vitro* fertilization, helped launch the fellowship to create a new subspecialty focused on contraceptive research and unintended pregnancy prevention and management. At the time, research related to pregnancy termination care delivery was limited, especially in the United States. The FFP program filled that void by developing leaders and scientific investigators.

Over the past 27 years, the FFP greatly expanded research in all aspects of contraception, pregnancy termination, and related areas, training students and residents and creating the evidence for professional standards for such training, providing medical practice guidelines, and guiding policy decisions. Specifically, significant advances have been made in the science, safety, and efficacy of medical pregnancy termination,^{1,2,3} the safety of second trimester surgical

¹ Goldberg AB, Greenberg MB, Darney PD. Misoprostol and pregnancy. *N Engl J Med*. 2001 Jan 4;344(1):38-47.

² Creinin MD, Darney PD. Methotrexate and misoprostol for early abortion. *Contraception*. Oct 1993;48(4):339-348.

³ Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. Mifepristone pretreatment for the medical management of early pregnancy loss. *N Engl J Med* 2018;378:2161-2170.

pregnancy termination,^{4,5} and the development of and safely expanded use of intrauterine devices.^{6,7,8} In all, FFP fellows have made a substantial contribution to the enormous increase in access to Long-Acting Reversible Contraceptives (LARC) in the U.S. over the last decade and to ensuring pregnancy termination services remain available for underserved patients and in restrictive climates.

The academic **Society of Family Planning** (SFP) was formed in 2005. The SFP produces methodologically rigorous, evidence-based clinical guidelines on a variety of topics in family planning.⁹ SFP negotiated with the journal *Contraception* to be the official journal of the SFP, providing a platform for peer-reviewed original research and clinical practice guidelines specific to contraceptive and pregnancy termination care as a distinct area for scientific investigation. The current and founding editors of *Contraception* are FFP directors, and the editorial board is largely composed of FFP directors, graduates, and researchers.

Since the launch of the fellowship, family planning experts have improved quality, safety, access, and availability of family planning, contraception, and pregnancy termination and promoted the health of women. Several texts published by the leaders of the proposed subspecialty are dedicated to complex family planning, including:

- <u>The Clinical Guide to Contraception</u>, Leon Speroff and Philip D. Darney
- <u>Contraception for the Medically Challenging Patient</u>, Rebecca Allen and Carrie Cwiak, Eds.
- <u>Contraceptive Technology</u>, Robert Hatcher, James Trussell, Anita Nelson, Willard Cates, Deborah Kowal, and Michael Policar
- <u>Managing Contraception</u>, Robert Hatcher, Mimi Zieman, Ariel Allen, Eva Lathrop, and Lisa Haddad
- <u>Management of Unintended and Abnormal Pregnancy</u>, Maureen Paul, E. Steve Lichtenberg, Lynn Borgatta, David A. Grimes, Phillip G. Stubblefield, and Mitchell D. Creinin
- Family Planning, A Global Handbook for Providers, World Health Organization

⁴ Goldberg AB, Fortin JA, Drey EA, Dean G, Lichtenberg ES, Bednarek PH, Chen BA, Dutton C, McKetta S, Maurer R, Winikoff B, Fitzmaurice GM. Cervical preparation before dilation and evacuation using adjunctive misoprostol or mifepristone compared with overnight osmotic dilators alone: A randomized controlled trial. *Obstet Gynecol.* 2015 Sep;126(3):599-609.

⁵ http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=24950

⁶ Bednarek PH, Creinin MD, Reeves MF, Cwiak C, Espey E, Jensen JT. Post-Aspiration IUD Randomization (PAIR) Study Trial Group. Immediate versus delayed IUD insertion after uterine aspiration. *N Engl J Med.* 2011 Jun 9;364(23):2208-17.

⁷ Winner B, **Peipert JF,** Zhao Q, et al. Effectiveness of long-acting reversible contraception. *N Engl J Med.* May 24 2012;366(21):1998-2007.

⁸ McNicholas C, Maddipati R, Quihong Z, Swor E, Peipert J. Use of etonogestrel implant and levonorgestrel intrauterine device beyond the U.S. Food and Drug Administration approved duration. *Obstet Gynecol* 2015 Mar; 125(3): 599-604.

⁹ https://www.societyfp.org/Resources/Clinical-guidelines.aspx

A PubMed search showed the following breadth of articles for the research areas common to complex family planning, indicating a thorough history of this field as a distinct area for clinical investigation. This search reflects articles published from 2008-present.

Abortion OR "Pregnancy Termination"	19,453
Contraception OR contraceptive	32,098
"Family planning"	8,496
"Medical abortion" OR "medication abortion" OR Mifepristone OR Misoprostol	3,953
Sterilization	12,057
"Long-Acting Reversible Contraceptives" or LARC	1,179
IUD OR IUS OR IUC OR "Intrauterine Device"	4,158
"Contraceptive counseling" OR "contraception counseling"	363
"Oral contraception" OR "Oral contraceptive" OR "Oral contraceptives"	7,457
"Hormonal contraception" OR "hormonal contraceptive" OR "hormonal contraceptives"	2,295
"Contraceptive implant" OR "implantable contraception"	257
"Natural family planning"	136
"Etonogestrel implant"	97
"Emergency contraception" OR "emergency contraceptive"	1,050

Since 2008, the FFP community has published 1,972 articles in peer-reviewed publications on contraception, pregnancy termination, and complex family planning topics. These include 12 publications in the *Lancet*, 12 in *New England Journal of Medicine*, 235 in *Obstetrics and Gynecology*, 103 in the *American Journal of Obstetrics and Gynecology*, and 686 in *Contraception*.

The **NIH Contraceptive Clinical Trials Network** (CCTN) was established in 1996 to support research on male and female contraception and to conduct clinical trials of new contraceptive drugs and devices. The CCTN (<u>https://www.nichd.nih.gov/research/supported/cctn</u>) is managed through NICHD's Division of Intramural Population Health Research and includes 18 sites for clinical evaluation of new female contraceptives and two sites for male contraceptives. Sites are located at university research centers and medical centers across the country. The network is

funded through contracts and utilizes a scientific advisory committee, composed of outside experts in the fields of basic and clinical contraceptive research, pharmacology, and epidemiology, to advise on research topics and directions. CCTN clinical field centers are selected for their capacity to conduct Phase I, II, and III trials of oral, vaginal, intrauterine, injectable, implantable, or topical contraceptive drugs and devices.

Fourteen of the 18 CCTN study sites are based in Family Planning Fellowship sites or run by fellowship graduates, all focused on the promotion of the safety and efficacy of contraception. Many of these principal investigators are also FFP program directors. This enhances trainees' exposure to scientific research and supports the pipeline of future expert researchers.

Complex Family Planning subspecialists are actively engaged in disseminating the discipline's expanding body of knowledge through numerous professional meetings. Their contributions are highlighted at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists (ACOG) where FFP graduates educate the ACOG specialist community about the latest developments and emerging trends in contraception and pregnancy termination care. At the American Society of Reproductive Medicine (ASRM) annual meetings, the fellowship community has been a key contributor to a special session focused on contraception, furthering the collaborations with the REI basic scientists. The National Abortion Federation hosts a professional meeting each year focusing on clinical, safety, guality, and policy updates for physicians and other healthcare professionals. Fellowship graduates present emerging family planning research at the annual North American Forum on Family Planning meeting, a collaboration between the Society of Family Planning, Planned Parenthood Federation of America (PPFA), and Association of Reproductive Health Professionals (ARHP), which brings together domestic and global family planning experts. Fellowship graduates lead the National Medical Committee of Planned Parenthood Federation of America (PPFA) and promote the incorporation of the latest research and evidence-based care for PPFA's practitioners and clinics, thereby improving care for all segments of the population. Fellowship graduates now lead the Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report (MMWR) Abortion Surveillance and contribute to the CDC's and World Health Organization's (WHO) clinical standards in contraceptive and pregnancy termination care, ^{10,11,12} advancing women's health and pregnancy prevention with a special focus on the family planning needs of complex patient populations.

A core learning objective of Complex Family Planning is advocacy. FFP graduates champion evidence-based approaches to health care delivery systems, pregnancy prevention, and pregnancy terminations. FFP graduates are leaders in advocacy organizations and initiatives to improve access to comprehensive reproductive health care including teenage, vulnerable, and underserved populations. Complex Family Planning subspecialists provide not only the scientific

¹⁰ https://www.cdc.gov/mmwr/volumes/66/ss/ss6624a1.htm

¹¹ http://www.who.int/reproductivehealth/publications/family_planning/en/

¹² http://www.who.int/reproductivehealth/publications/unsafe_abortion/en/

evidence for testimony in state legislatures and pivotal lawsuits,¹³ but also play an active role in discussions in the media related to family planning access and advocate for their patients and women's health in popular media outlets. ^{14,15,16,17} Further, FFP graduates often become the advocacy experts in their academic departments. These experts educate OB GYN residents and fellows on advocacy tools which help to improve healthcare for all women.

For the past five years, the FFP has hosted an Academic Leadership meeting, attended by all leading OB GYN specialty, subspecialty, accreditation, and certification organizations, including pediatricians. The enthusiastic participation and outcomes, such as "A statement on abortion by 100 professors of obstetrics: 40 years later" published in the *American Journal of Obstetrics and Gynecology*, ¹⁸ and "The importance of access to comprehensive reproductive health care, including abortion: A statement from women's health professional organizations," recently published in the *American Journal of Obstetrics & Gynecology*, confirm that the subspecialty of Complex Family Planning is considered a core component of gynecologic and women's health care.¹⁹

The **Kenneth J. Ryan Residency Training Program** in Family Planning and Abortion ("Ryan Program"), ²⁰ a national initiative to integrate family planning into OB GYN residency training programs across the U.S., was launched in 1999 as a result of the FFP at UCSF, with the fellowship directors and Dr. Kenneth J Ryan serving on the advisory board. Sixty-eight of the 93 Ryan Programs are currently directed by fellowship graduates. As a result, more than 5,500 OB GYN residents have been prepared to care for common patient concerns and routine family planning needs, including uncomplicated contraception and first trimester medical and surgical pregnancy termination in their future practice.

Residency training and OB GYN specialist certification prepare for future general practice in OB GYN, but do not create expertise for meeting the needs of specific populations of medicallycomplex women who are pregnant or in need of pregnancy prevention. While the ACGME requires "access to experience with induced abortion,"²¹ this training can vary widely by program,

¹³ https://bioethicsarchive.georgetown.edu/pcbe/transcripts/sept08/prch_statement.pdf

¹⁴ <u>https://www.npr.org/sections/health-shots/2017/03/01/518000283/your-birth-control-is-working-better-or-at-least-failing-less</u>

¹⁵ <u>http://www.sacbee.com/opinion/california-forum/article143114644.html</u>

¹⁶ <u>https://www.washingtonpost.com/local/this-doctor-was-raised-to-believe-abortion-was-wrong-hes-now-an-advocate-for-reproductive-rights/2018/03/27/83e33376-31dd-11e8-8abc-</u>

²²a366b72f2d story.html?noredirect=on&utm term=.773ffe4bd082

¹⁷ https://www.vogue.com/article/house-votes-on-20-week-abortion-ban

¹⁸ http://www.ajog.org/article/S0002-9378(13)00261-5/abstract

¹⁹ Espey E, Landy U, Dennis A. The importance of access to comprehensive reproductive healthcare, including abortion: a statement from women's health professional organizations. *Am J Obstet Gynecol* 2018: Sept 26. pii: S0002-9378(18)30756-7

²⁰ https://ryanprogram.org/

²¹ http://www.acgme.org/Portals/0/PFAssets/ProgramResources/220_OBGYN_Abortion_Training_Clarification.pdf

is subject to individual participation (residents can opt out), may only include incomplete or missed abortion management, and in many cases does not address the needs of women with complex medical problems or more complex surgical cases. Indeed, research has found that while abortion training in obstetrics and gynecology residency training programs has increased since 2004, many programs graduate residents without sufficient training to terminate pregnancies for any indication.²² While most residents learn basic family planning clinical skills, those who pursue Complex Family Planning training do so to gain advanced clinical training; skills in research, teaching, advocacy; and an understanding of the public health impact of how health systems impede or improve access to care.

The current ACGME Milestones for Family Planning in OB GYN residencies include competencies in basic comprehensive family planning, basic uterine evacuation, and determining referral or transfer of women with complex complications:

Level 1	Level 2	Level 3	Level 4	Level 5
Verbalizes basic knowledge	Demonstrates a basic	Counsels on the	Formulates comprehensive	Applies innovative and
about common	understanding of the	effectiveness, risks, benefits,	management plans for	complex approaches to
contraceptive options	effectiveness, risks, benefits,	and contraindications of	patients with medical diseases	family planning and
	complications, and	available forms of	complicating their use of	implements treatment plans
	contraindications of	contraception	contraceptive methods	based on emerging evidence
	contraception, including			
	emergency contraception,	Counsels on the	Manages complications of	
	and pregnancy termination	effectiveness, risks, benefits,	contraceptive methods and	
		and contraindications for	pregnancy termination	
		male and female sterilization		
			Determines the need for	
		Performs intra-uterine and	consultation, referral, or	
		implantable contraceptive	transfer of patients with	
		placement	complex complications	
		Demonstrates ability to	Demonstrates ability to	
		perform basic first trimester	perform basic second	
		uterine evacuation (medical	trimester uterine evacuation	
		and surgical)	(medical and surgical)	

The current ACGME Program Requirements for Family Planning in Graduate Medical Education in OB GYN are:

IV.A.6.d) Family Planning and Contraception

(1) Programs must provide training or access to training in the provision of abortions, and this must be part of the planned curriculum. ^(Core)

(2) Residents who have a religious or moral objection may opt-out, and must not be required to participate in training in or performing induced abortions. (Core)

²² https://www.sciencedirect.com/science/article/pii/S0002937818302928

(3) Residents must have experience in managing complications of abortions and training in all forms of contraception, including reversible methods and sterilization. ^{(Outcome)23}

All ABOG-certified obstetricians and gynecologists have been trained to provide basic comprehensive family planning care for patients. The overall experience in family planning, however, is highly variable, as indicated in the attached "Clarification on Requirements Regarding Family Planning and Contraception" from ACGME. Complex Family Planning subspecialists will provide advanced care for complex patients and in complicated situations that are beyond the scope of practice of most OB GYN specialists, and a subspecialty designation will serve to ensure these women with complex needs are receiving a high standard of care.

In order to differentiate the practices of these subspecialists from OB GYN specialists, the ABOG plans to use the term "Complex Family Planning". Furthermore, the ABOG wants to ensure that OB GYN specialists can continue to provide basic comprehensive medical and surgical family planning to most women with common requests and conditions. The term Complex Family Planning will help differentiate these two types of practices.

Creation of a Complex Family Planning subspecialty is not meant to imply that certified OB GYN specialists and clinical providers in other specialties (i.e., Family Medicine, Internal Medicine, Pediatrics) are not capable of providing basic and minimally-complex family planning to women. The intent of fellowship training is to build upon the foundation of basic knowledge and experience obtained in OB GYN residency training to develop subspecialists with advanced knowledge, expertise, and skills in complex family planning.

C. The existence of a sufficiently large group of physicians who concentrate their practice in the proposed subspecialty.

Reply:

According to its national office, the FFP has graduated 300 OB GYN physicians. In addition, there are 57 current and 26 incoming fellows. There are an additional 50 OB GYN members of the Society of Family Planning who did not obtain training through the FFP but dedicate a significant proportion of their practice to complex family planning activities in teaching hospitals and private practice settings.

In addition, according to the ABOG Annual Maintenance of Certification (MOC) survey, an increasing proportion of OB GYNs have a focused practice in family planning:

²³ http://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/220_obstetrics_and_gynecology_2017-07-01.pdf?ver=2017-05-25-084930-787

Year	Diplomates responding to MOC survey	Percent with focused practice in family planning	Number of diplomates with focused practice in family planning*
2015	2709	0.85%	298
2016	1363	0.95%	333
2017	1643	1.03%	361

*Estimate based on the 35,000 OB GYNs currently in MOC

D. The existence of national medical societies with a principal interest in the proposed subspecialty.

Reply:

The SFP advances sexual and reproductive health through research, education, advocacy, and professional development.²⁴ According to its membership records, the SFP has almost 800 members. Membership in the SFP is open to any qualified individual who is in good professional standing and has an interest in family planning demonstrated through post-doctoral training, a substantial clinical or laboratory practice, or academic presentations and publications within this field. This includes persons who conduct clinical, basic science, epidemiologic, social science, demographic, statistical, or related studies. The essential criterion for selection is continuing focus in the field of family planning.

According to the SFP internal membership records, members come from a range of fields, most commonly obstetrics and gynecology, followed by the social sciences, family medicine, and public health. A smaller number of members come from other fields such as adolescent medicine, nursing, midwifery, and pediatrics. The majority of members have an MD or DO as their highest degree (63%), followed by 20% with a doctorate and 11% with a master's degree. Less than 2% of members have a law degree, nursing degree, or bachelor's degree as their highest degree. More than one third of members are currently enrolled in or graduates of the FFP. Of those with an MD or DO as their highest degree, approximately 75% are OB GYNs.

Leaders of the FFP created the blueprint for the SFP in 2002. In 2004, the FFP created its first bylaws and constituted the SFP's Board of Directors. Over the last 14 years, the FFP and the SFP have continued to work together closely. The SFP administers clinical and research grants to those participating in the FFP, both during and after their fellowship training. The FFP trainees and graduates present their research and clinical findings and are often key speakers at the SFP's annual conference. Additionally, the FFP trainees and graduates have led the development of clinical practice guidelines for the SFP. Currently, five members of the SFP's Board of Directors are FFP Directors or graduates. The SFP and the FFP continue to identify new ways to collaborate.

²⁴ https://www.societyfp.org

E. The regular presence in academic units and health care organizations of educational programs, research activities, and clinical services such that the subspecialty is broadly available nationally.

Reply:

According to its national office, Fellowship in Family Planning sites are located in 27 medical schools in the U.S.: Albert Einstein College of Medicine, New York, NY Boston University, Boston, MA Columbia University, New York, NY Emory University, Atlanta, GA Harvard Medical School, Boston, MA Johns Hopkins University, Baltimore, MD Mount Sinai School of Medicine, New York, NY Northwestern University, Chicago, IL Oregon Health & Science University, Portland, OR Stanford University, Palo Alto, CA University of California, Davis, Sacramento, CA University of California, Los Angeles, Los Angeles, CA University of California, San Diego, San Diego, CA University of California, San Francisco, San Francisco, CA University of Chicago, Chicago, IL University of Colorado, Denver, CO University of Hawaii, Honolulu, HI University of Michigan, Ann Arbor, MI University of New Mexico, Albuquerque, NM University of North Carolina, Chapel Hill, NC University of Pennsylvania, Philadelphia, PA University of Pittsburgh, Pittsburgh, PA University of Southern California, Los Angeles, CA University of Utah, Salt Lake City, UT University of Washington, Seattle, WA Washington University, St. Louis, MO Yale University, New Haven, CT

Most large urban areas have networks of family planning clinics funded by Title X grants through the Office of Population Affairs. Title X is the only federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services. Title X is designed to prioritize the needs of low-income families or uninsured people who might not otherwise have access to these health care services at reduced or no cost. Several of the fellowship sites are recipients of this funding and contribute to the care of vulnerable populations working in large healthcare systems. These funds are distributed by the **National Family Planning and Reproductive Health Association** (NFPRHA), for whom many in the FFP community are consultants. Complex Family Planning subspecialists take referrals from these clinics for medically complex patients. Additionally, many pediatric hospitals have specialized adolescent health clinics which focus largely on family planning.

F. A projected number of programs sufficient to ensure that ACGME accreditation is an effective method for quality evaluation.

Reply:

According to the FFP national office, there is one trainee position per year per site, for a total of 27 fellows per year or 54 U.S. OB GYN fellows at a time. Each year the number of FFP applicants is greater than the number of open positions.

Year	Number of Applicants	Number of Fellowship positions
2018	38	26
2017	43	28
2016	37	27
2015	36	29
2014	30	28
2013	31	29
2012	30	24
2011	26	25
2010	28	22
2009	36	19

The 27 current OB GYN FFP fellowship sites produce graduates who accept positions as family planning subspecialists in academic medical centers, women's health clinics, and the CDC in the U.S. A small number of graduates work in the global arena as medical directors and consultants for non-profit organizations (non-governmental and governmental organizations, including the World Health Organization). As the requests for Complex Family Planning experts continue to increase, available FFP graduates cannot keep pace in filling the positions.

With the continually growing number of Ryan Residency Training Programs and the increase in the number of OB GYN graduates, more trainees will likely be interested in pursuing subspecialty training. It is likely that ACGME accreditation will increase the number of fellowship programs providing training to help fill this gap.

The majority of current OB GYN departments with Ryan Residency Training programs, which focus on institutional training in contraception and pregnancy termination for OB GYN residents, have indicated interest in establishing a fellowship in Complex Family Planning program in their institutions. The data from the FFP suggests this number will be 30-40 additional sites. Each year, there are an average of five new Ryan Residency programs approved (currently at 93 OB GYN accredited residency training programs), which lays the groundwork for demand for future fellowship sites and training.

G. The duration of the subspecialty program is at least one year beyond education in the core specialty.

Reply:

The proposed fellowship program will include clinical, educational, and research components. This format has been a successful program fulfilling all educational requirements within a 24 month timeframe for 25 years. The broad clinical training includes counseling, screening, diagnosis, ambulatory patient care, management of complications, and technical and surgical skills.

H. The educational program is primarily clinical.

Reply:

Similar to the certification standards for the other four ABOG subspecialties, the candidate will be required to meet clinical training and research standards. The ABMS recently approved the following certification requirements for the 24-month program:

- 1. A minimum of 12 and up to 18 months of clinical Complex Family Planning experience
- 2. A minimum of 6 months of protected time for research experience
- 3. Up to 6 months of electives in additional clinical experience; research; advocacy; or public health, vulnerable, or underserved population service.

The fellow must design and conduct a study with division mentorship that produces a thesis during the fellowship. The thesis must be a scholarly work that is related to the field of family planning and meet the thesis requirements outlined for all ABOG subspecialty certification (attached). The thesis should be completed and presented to the Complex Family Planning division faculty before graduation from the fellowship program.



Clarification on Requirements Regarding Family Planning and Contraception Review Committee for Obstetrics and Gynecology

Clarification of Program Requirement: IV.A.6.d).(1)-(3)

The ACGME accredits graduate medical education programs. It establishes and maintains accreditation standards (Program Requirements) that reflect the practice of medicine in each specialty, as well as the program resources necessary to educate physicians in all elements of each specialty.

In the past, consistent with its role as an educational accreditor, the ACGME has not stated a "pro" or "con" position on pending legislation addressing state funding of family planning and elective abortion. Instead, it has responded to government inquiries relating to the potential accreditation effect of such pending legislation. It will continue to do this.

ACGME Obstetrics and Gynecology Program Requirements IV.A.6.d).(1)-(3) state:

IV.A.6.d) Family Planning and Contraception

IV.A.6.d).(1) Programs must provide training or access to training in the provision of abortions, and this must be part of the planned curriculum. ^(Core)

IV.A.6.d).(2) Residents who have a religious or moral objection may opt-out, and must not be required to participate in training in or performing induced abortions. ^(Core)

IV.A.6.d).(3) Residents must have experience in managing complications of abortions and training in all forms of contraception, including reversible methods and sterilization. (Outcome)

The ACGME Review Committee for Obstetrics and Gynecology examines each obstetrics and gynecology residency program's curriculum on contraception, family planning, and abortion to determine its substantial compliance with the above requirements. All programs must have an established curriculum for family planning, including for complications of abortions and provisions for the opportunity for direct procedural training in terminations of pregnancy for those residents who desire it.

Access to experience with induced abortion must be part of residency education. Programs with restrictions to the provision of family planning services or the performance of abortions at their institutions must make arrangements for such resident training to occur at another institution. Programs must allow residents to "opt out" rather than "opt in" to this curriculum, education, and training.

For those residents who do not desire to participate in an aspect of family planning training, the program must allow them to "opt out" of this experience. Even if no residents have requested the family planning experience or procedural training, the Committee would consider a program with an "opt out" curriculum to be in substantial compliance with the requirements.

If a program does not have a specific family planning curriculum that includes direct procedural training in abortions, this may prevent a resident from acquiring desired competency in family planning and uterine evacuation techniques. In this situation, there would be no structured curriculum or experience in the program, unless it is requested by and developed for a resident desiring training. Such a program would be considered to have an "opt in" curriculum, and the Committee would find this program to be non-compliant with the requirements.

Resident Case Log experience with abortions may include a range of surgical or medical uterine evacuation techniques. This experience can include uterine aspirations, medical abortions, incomplete abortions, missed abortions, therapeutic abortions, and elective abortions.

If you have any additional questions, please contact Review Committee Executive Director Kathleen Quinn-Leering, PhD: <u>kquinn@acgme.org</u>.

Thesis

A thesis is required by the Division of Complex Family Planning and must be submitted by the date listed in this *Bulletin* and according to the guidelines for preparation listed below. The Division will review the thesis and make a decision concerning acceptability. Prior publication of a thesis by a refereed journal does not guarantee acceptance of the thesis for the certifying examination. It is not necessary for the thesis to have been published.

One copy of the completed Thesis Affidavit Form must be submitted with 4 copies of the thesis.

Preparation

1. *Format:* The format of the thesis must comply with the instructions for authors for a major peer-reviewed print journal in a field related to Complex Family Planning except as noted below. The name of the journal must be identified clearly on the cover page of the manuscript. Theses that are not in the proper journal format will be rejected.

The cover page of the thesis should only show the thesis title, the name of the candidate and the journal format.

The thesis must be type-written in 12 point type, single-spaced, and double-sided on standard 8 $1/2 \times 11$ paper.

Reprints of published manuscripts are not acceptable.

Some journals require a "Summary" in addition to the "Discussion" section.

- 2. *Hypothesis:* The thesis must clearly state the hypothesis to be tested and must be in the form of a simple declarative sentence. The hypothesis must be included in the body of the paper, not just in the Abstract. Whenever possible, the hypothesis should include a statement such as, "Our hypothesis is that XXX is statistically significantly different from YYY." Conversely, the null hypothesis may be stated. The hypothesis must appear in the body of the thesis.
- 3. **De-identification and Authorship:** The candidate must remove all wording in all areas of the thesis that would allow an examiner to be able to identify the institution where the study was performed.

The cover page should only list the title of the thesis, the candidate's name (no coauthors) and the journal format.

Acknowledgements are not allowed.

- 4. **Subject Matter:** The subject matter must clearly relate to the area of Complex Family Planning
- 5. *Research:* The thesis must be based on clinical or basic research performed during the fellowship period. A review of work performed by others is not acceptable.

- 6. *IRB Approval:* All research involving humans and animals must be reviewed and approved by the human or animal institutional review boards (IRBs) of the sponsoring institution. If the research is considered to be exempt from IRB approval, a statement from the IRB to that effect must be included with the thesis.
- 7. Unacceptable Papers: The following are not acceptable for a Fellow's thesis:
 - a. book chapters
 - b. case reports
 - c. case series
- 8. **Potentially Acceptable Papers:** Whenever possible, it is suggested that the submitted thesis be the result of work performed by the candidate in a laboratory setting. The study must have a clearly designated hypothesis to be tested. The hypothesis must be stated in the form of a null hypothesis.

In addition to laboratory studies, the following are potentially acceptable study types, but **must represent a substantial research effort** consistent with the time spent on research rotations. Reports of the results of treatment of patients from a practice or department are not acceptable as these are considered to be case series.

- a. Randomized Controlled Trial: The report must represent subject matter that is of significant importance to the field, and must adhere to the CONSORT guidelines.
- b. Meta-analysis and Systemic Review: The report must represent subject matter that is of significant importance to the field, and must adhere to the PRISMA or MOOSE guidelines.
- c. Cost-effective analysis: The study must represent subject matter that is of significant importance to the field, and must conform with the principles set forth in the "WHO guide to Cost-Effective Analysis."
- d. Case-control study: If there is a well-defined objective with a specific hypothesis to be tested, and if the subject matter is of significant importance to the field, the thesis will be reviewed by the subspecialty division for possible acceptance. The submitted thesis must conform to the STROBE guidelines for observational studies.
- e. Cohort study: The subspecialty division will review the thesis for possible acceptability if (a) the candidate developed the cohort [ie, data-mining of established datasets is rarely acceptable], (b) there is a well-defined hypothesis to be tested, and (c) the subject matter is of significant importance to the field. The submitted thesis must conform to the STROBE guidelines for observational studies.
- f. Survey-collected data: The subspecialty division will review the thesis for possible acceptability if (a) the candidate developed the questionnaire or used a previously validated questionnaire, (b) the subject matter is of significant importance to the field, (c) there is a well-defined hypothesis to be tested, (d) the recipients of the questionnaire are selected to avoid bias, and (e) there is at least 50% return and completion of the questionnaire. The submitted thesis must conform to the STROBE guidelines for observational studies.

- 9. *Thesis Defense:* During the certifying examination, the candidate may be asked one or all of the following questions. Additional questions may be asked which are not listed in this outline.
 - a. Hypothesis
 - 1) What were the study objectives?
 - 2) What was the population studied?
 - 3) What was the population to which the investigators intended to apply their findings?
 - b. Design of the investigation
 - 1) Was the study an experiment, case control study, randomized clinical trial, planned observations, or a retrospective analysis of records?
 - 2) Were there possible sources of sample selection bias?
 - 3) How comparable was the control group?
 - 4) What was the statistical power of the study?
 - 5) Was the design of the study appropriate for the hypothesis to be tested?
 - c. Observations
 - 1) Were there clear definitions of the terms used (i.e., diagnostic criteria, inclusion criteria, measurements made and outcome variables)?
 - 2) Were the observations reliable and reproducible?
 - 3) What were the sensitivity, specificity and predictive values of the methods?
 - d. Presentation of findings
 - 1) Were the findings presented clearly, objectively, and in sufficient detail?
 - 2) Were the findings internally consistent (i.e., did the numbers add up properly and could the different tables be reconciled, etc.)?
 - e. Analysis of the results
 - 1) Were the data worthy of statistical analysis? If so, were the methods of analysis appropriate to the source and nature of the data?
 - 2) Were the analyses correctly performed and interpreted?
 - 3) Were there analyses sufficient to ascertain whether "significant differences" might, in fact, have been due to a lack of comparability of the groups (e.g., age, clinical characteristics, or other relevant variables)?
 - 4) Were the statistical analytic techniques, and the significance level described?
 - 5) Was there use of measured sensitivity without specificity?

- f. Conclusions or summary
 - 1) Which conclusions were justified by the findings?
 - 2) Were the conclusions relevant to the hypothesis?
- g. Redesign of the study

If the study could be repeated, how could the experimental design be revised to provide better reliability and validity of the conclusions?

h. Knowledge of the breadth and depth of subject matter

A candidate may be asked about specific references cited in the thesis. The candidate will be judged on their knowledge of the literature related to the subject of the thesis.