American Bar Association
Section of Family Law

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HIPAA Essentials

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Speaker Bios

Judith Hoechst lives in Denver, Colorado where she practices reproductive and family formation law. A pediatric and neonatal intensive care nurse prior to and while attending law school, her early years in law were immersed in medical negligence, personal injury, and products liability/massive tort litigation. Judith’s law practice came to exclusively focus on family formation and third party reproductive law subsequent to a personal struggle to expand her own family. Her reproductive law practice in the Denver area affords her the satisfaction of working with domestic and international clients desirous of creating or expanding their families through third party reproduction and adoption. Judith represents intended parents, surrogates, gestational carriers, ova donors, semen donors, and embryo donors in third party reproduction agreements. Her adoption practice includes stepparent adoptions, second parent adoptions, relative adoptions, and designated adoptions. Her law practice includes related and appropriate estate planning.

Judith has been admitted by examination to the State Bars of Ohio, New Mexico and Colorado. She is interested in legislative matters and advocates for state, national and international standards in the ART arena.

Andrea Bryman is a licensed Marriage and Family Therapist with a specializing in mental health assessments of egg donors and surrogates.

Andrea received undergraduate degrees in International Relations and French, and a Masters degree in Marriage, Family and Child Counseling from the University of Southern California. Andrea has over 20 years of clinical experience working in the mental health field.

Andrea’s focus on assisted reproduction stemmed from her own personal experience with infertility over 17 years ago. She has three children, two with methods of assisted reproduction. Her past and personal experience provides her with the knowledge to assess egg donors and surrogates, as well as provide compassion, support and guidance to individuals pursuing assisted reproduction. She is a professional member of the ASRM, AFA, ESHRE and CAMFT. Andrea has sat on a variety of professional advisory boards and currently serves on the board of directors for Fertile Action.


Bradford Kolb, M.D. received his training at the University of California at Irvine, Northwestern University and University of Southern California culminating board certification in both Obstetrics and Gynecology & Reproductive Endocrinology and Infertility. As a physician, he specializes in the care of complex fertility problems at HRC Fertility, where he serves as the Medical Director and Managing Partner.

He is internationally known and recognized for his expertise in advanced reproductive issues and is one of the largest providers of egg donation and surrogacy in the United States with patients traveling from more than 35 different countries to see him annually. His practice is known for helping to develop and implement cutting edge technologies in the genetic screening of embryos, the development of new laboratory technologies and the development of highly efficient treatment options. Dr. Kolb has been at the forefront of bringing equality and family building options to those seeking family building options in the LGBTQ community. As a cofounder of HART (HIV Assisted Reproductive Technologies), he has helped advance safe, ethical and unbiased options to those who previously had few options.

Dr. Kolb’s philosophy is to deliver the best possible care to each patient in a compassionate and individualized manner. Most impressive is his passion for treating each patient personally. Dr. Kolb’s patients can be assured they are being cared for with the latest cutting edge technologies while in a safe and comfortable environment. As one of the largest providers of egg donation and surrogacy for intended parents from all walks of life, Dr. Kolb has a dedicated team of nurses who are highly trained and specialized in the field of third party reproduction. From the moment you meet Dr. Kolb and his staff, you can expect to have a true partnership.

As a native of California and a true philanthropist, Dr. Kolb and his wife Judy share a real love of humanity. When time permits, they can be found traveling with their three daughters to areas of the world where they find a sense of devotion in caring for humanity. It is both Judy and Dr. Kolb’s desire to instill these core values in their children, and they find it most rewarding to watch them develop friendships and relationships that value each person’s unique individuality.
HIPAA ESSENTIALS IN THIRD PARTY REPRODUCTION

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Protected Health Information (“PHI”) : see 45 CFR 160.103 Definitions

PHI is “Individual Identifiable health information” with some exceptions. IHII is created or received by a health care provider, health plan, employer or health care clearinghouse, and relates to the past, present or future physical or mental health or condition of any individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and that identifies the individual; or with to respect to which there is a reasonable basis to believe the information can be used to identify the individual. PHI excludes education and employment records.

REMEMBER THAT MEDICAL RECORD INFORMATION IS NOT PHI UNLESS IT CONTAINS IDENTIFYING INFORMATION SUCH AS INFORMATION WHICH DIRECTLY IDENTIFIES THE PATIENT OR WHICH CAN BE USED TO IDENTIFY THE PATIENT SUCH AS THE INCLUSION OF THE PATIENT’S ADDRESS, DATE OF BIRTH, DRIVERS LICENSE NUMBER, SOCIAL SECURITY NUMBER OR OTHER SIMILAR IDENTIFYING INFORMATION.
**Fact Patterns:**

1. Is medical information sent to a Party’s attorney Protected Health Information under HIPAA?

   *Maybe – focus on identifying information aspects. But, an ART Agency is not a “covered entity” under HIPAA.*

2. If so, what should the attorney do with the medical information communicated to him/her in order to protect it?

   *Perhaps the private ART attorney has an even greater duty to protect PHI than attorney-client privileged Information due to the HIPAA standard of care applicable to the privacy of healthcare medical information which has developed over time. Watch your laptop! Is it encrypted? Consider the deletion of all identifying information from any healthcare information you receive. Remember, the risk of hacking, and even computer theft can subject you to serious breach of privacy claims. Basic security flaws such as inadequate security software can expose you to serious invasion of privacy claims based on the HIPAA standard of care, state privacy laws and common law causes of action including negligence and outrageous conduct.*
3. What should the attorney do with PHI sent with a case referred by an ART agency?

Delete it? Protect it? No re-disclosures. Assume HIPAA protects all health care information and records even though private attorneys are not health care providers and are not covered directly by HIPAA. There is a plethora of privacy laws! Note that HIPAA applies to “covered entities” per 45 C.F.R. §§ 160.102 & 160.103. HIPAA has become the gold standard for determining health care privacy violations.

4. Does an ART attorney need to have PHI in order to render legal representation to a Party?

Yes, but not much. Medical information is not PHI without identifying information attached to it. Are ART Contracts PHI? i.e. surrogacy contracts have the Parties’ names but not egg donation agreements unless identifying information is included. I would propose that ART attorneys do not need any diagnostic or other sensitive medical information in order to represent the Intended Parents, Donor or Surrogate. It is presumed of course that all Intended Parents (either the Intended Mother or the Intended Father) have a reproductive medicine infertility diagnosis. Such diagnostic information should not be delivered to ART attorneys by fertility centers and ART agencies. Delete it if delivered and advise the sender you have deleted it.
5. Should the Agency have a HIPAA authorization in its file before it can release PHI to the Parties’ attorneys?

An ART agency is not a health care provider but HIPAA is construed broadly and there is a risk that an ART agency could be construed as the Business Associate of a fertility center if it works closely and frequently with a specific fertility center. Best to ensure the Agency has a HIPAA compliant authorization or an equivalent authorization, before it sends out PHI to attorneys. But is it really necessary to send out PHI to the Parties’ attorneys? I would propose that it is not necessary for an ART agency to communicate medical history, diagnostic and other similar sensitive PHI to a private ART attorney for purposes of drafting and reviewing ART contracts. Such information should be retained by the fertility center and the ART agency only.
EXAMPLES OF PROTECTED HEALTH INFORMATION FOR THE PRACTICING ART ATTORNEY

1. The ART Contract – drafts and signed copies of ART contracts. The contract must include the patient’s identifying information to be covered by HIPAA privacy or other strict privacy standards.

2. Legal Clearance Letters transmitted by the ART attorney to the fertility center.

3. Electronic communications with ART agencies, fertility centers, birthing hospitals, opposing counsel, and other third parties which concern ART contracts and identify one or more parties.

4. Not anonymous ART contracts such as anonymous ova donation agreement which identifies the Parties by pseudonyms or by an agency assigned number or code.

5. Anonymous egg donors: their identity should only be disclosed to the Donor’s attorney and not to opposing counsel. Not necessary for opposing counsel to know the Donor’s identity.

6. Emails from a fertility center referring a case to the ART practitioner. It may or may not contain PHI. The ART attorney has a duty to protect this information and not disclose it to anyone without the prospective client’s written consent.
7. **Referrals generally:** it is recommended that the ART client initiate the contact and not the ART attorney if contacted by a fertility center or agency about representing intended parents, the donor or the surrogate. Ideally the ART client's full identifying information will not be disclosed to the private ART attorney.

8. **PHI includes the fact that a child is the result of ART.** This information cannot legally be disclosed to the child (or anyone else) without the parents’ consent. It is PHI because the disclosure of this fact discloses the existence of infertility which is a medical diagnosis and is confidential medical information protected by HIPAA. Such a disclosure could subject the health care practitioner to a formal complaint being filed with the HHS Office of Civil Rights (time limit to file is 180 days from the date of the violation) or a state law or common law privacy claim.
The HIPAA Players

- The Fertility Center – may provide PHI to the ART attorney(s). Does the fertility center’s authorization signed by the patient (intended parents) authorize this disclosure? PHI is communicated by email and orally to the Parties’ attorneys at times although this is almost always unnecessary. The PHI issue can be defeated by just using first names.

- How if at all does HIPAA deal with medical information inappropriately communicated to the Parties’ attorneys or other third party? Does the ART attorney have a legal obligation to deal with this PHI in a certain way? Should the PHI be deleted? If so, who should be notified.

- The ART agency – may provide PHI to the ART attorney. Does the ART attorney have a legal obligation to confirm the delivery of this PHI was authorized by the client (patient)?

- Opposing counsel – PHI may be exchanged

- Opposing Party – limit such communications except as permitted by opposing party’s counsel.
• Your Clients – clients’ PHI will be communicated by you but only as necessary for the legal representation. But is really needed? Probably nothing more than the fact your client has an infertility diagnosis. You do not need to know the specific diagnosis and should resist the receipt of such sensitive information.

• Potential Clients – some PHI may be transmitted to you orally and/or by email by potential clients. Usually it is communicated orally. The attorney client privilege applies to protect such information and the HIPAA standard of care will likely will be applied to any inappropriate disclosures by legal counsel.

• Birthing Hospital – will receive PHI from you when you contact the hospital about the Pre-Birth Order, issuance of the birth certificate etc. Ensure the clients know this and have approved it in advance. Document this in the fee agreement.

• Sperm Bank – communications are unlikely

• Cryo Bank – communications are unlikely, but possible

• Insurance brokers and insurers – you may need to communicate PHI to them but best to not include any identifying information – just use first names. This is a frequent occurrence with specialty brokers such as New Life Agency and ART Risk Solutions. Include this possibility in your fee agreement.
• Guarantors of client fees – these communications should be strictly limited to financial issues regarding the attorney’s fees.

• Mental health providers such as psychotherapists – note that most states have strict laws re the confidentiality of mental health records; also the Federal Drug and Alcohol Abuse Regulations are more strict and specific than HIPAA, see 42 CFR Part 2; 42 U.S.C 290ee-3 and 42 U.S.C. 290dd-3. These regs should always be consulted first when dealing with drug and alcohol abuse patient records. Patient’s consent is required or a court order following a hearing (i.e. no subpoenas for such records) before drug and alcohol abuse records may be disclosed. Always follow these regs when dealing with such records. They trump HIPAA and most state privacy laws.
Your Private Practice Including Fee Agreements and HIPAA

- Should you include a separate HIPAA authorization as part of your fee agreement?

- Ideally yes even though HIPAA applies primarily to health care providers not private attorneys.

- Fee agreements should at least talk about PHI and HIPAA and advise the client that PHI will need to be disclosed by the attorney with the client’s permission, i.e. ART contracts and legal clearance letters contain medical information or PHI.

- Keep a record of all disclosures of PHI, i.e. save all transmittal emails and faxes.

- Assume HIPAA or an even stricter state privacy law applies to your private practice and PHI kept in your client files

- Bottom line: to stay out of privacy trouble with your ART clients, your fee agreement should discuss PHI and how your representation deals with it and protects it and your clients.

- Tell your clients that all of your electronic records are encrypted and backed up off site in encrypted format. Confirm this with vendors if you use Cloud backup. Ensure the encryption and storage is approved for HIPAA PHI and medical information generally.
• Familiarize yourself with your state’s privacy laws, HIPAA and other federal statutes such as The HITECH Act (“The Health Information Technology for Economic and Clinical Health Act of 2009, (see The American Recovery and Reinvestment Act of 2009, Public Law 111-5) which beefed up HIPAA enforcement considerably, i.e. minimum $50,000 fine per violation if willful and uncorrected. HIPAA preempts state privacy law unless the state law is more strict.

• Protect the information on your computer or laptop (and even your scanner and printer) if you wish to protect yourself against a HIPAA related privacy claim not to mention other privacy and negligence claims regarding privileged information and documents.

• Do not dispose of computers, copiers and scanners without hiring a computer professional to do a DOD erase of all information on the hard drive. The more sophisticated and expensive large volume copiers and scanners have hard drives which record all documents copied and scanned. Ensure you know if your scanner and copier hardware has a hard drive which has client data stored on it. FAILURE TO DO SO COULD RESULT IN A SIGNIFICANT INVASION OF PRIVACY CLAIM BASED ON HIPAA, STATE PRIVACY LAWS, NEGLIGENCE, AND COMMON LAW TORT CLAIMS, I.E. THE SCANNER IS DONATED OR SOLD TO A THIRD PARTY WHO DISCOVERS THE PHI ON THE HARD DRIVE.
• Although HIPAA does not authorize a private cause of action due to a breach of privacy (see Acara v. Banks, 2006 WL 3262444 (5th Cir. Nov. 13, 2006), and Miller v. Nichols, 586 F.3d 53 (1st Cir. 2009) private attorneys will use HIPAA’s strict privacy provisions to bolster their private state causes of action due to a breach of privacy. See also Acosta v. Byrum, 638 S.E. 2d 246 (N.C. Ct. App. 2006) where the Plaintiff cited HIPAA as the standard of care regarding the privacy of her medical information and the Court concurred.

• Attorneys are subject to HIPAA directly if they are “business associates” and do business for health care providers and insurers and handle a substantial amount of PHI for a “covered entity”. See 45 C.F.R. § 160.103 (2009). Under applicable HIPAA regulations business associates are responsible for the actions of their subcontractors who handle PHI. Subcontractors have the same HIPAA duties as business associates.

• A private law firm can and often does represent both private ART clients and “covered entities” in different transactions. Thus, HIPAA responsibilities can arise directly out of the representation of a “covered entity” such as a fertility center.

• Disclose in your fee agreement the potential conflict of interest arising out of your representation of a fertility center which is also your clients’ fertility center. This is especially important if your fertility center client is one of your larger clients.
• **SUGGESTED FEE AGREEMENT PROTECTED HEALTH INFORMATION (PHI) LANGUAGE FOR THE REPRESENTATION OF INTENDED PARENTS:**

During my representation of you, I may be provided Protected Health Information (“PHI”), as defined by HIPAA which identifies you, and about your medical condition, specifically dealing with your infertility issues. You agree that it is permissible for me to discuss and transmit as necessary (for my legal representation of you) such medical information or PHI with your Assisted Reproduction Agency and your fertility center physician and their employees and agents and other third parties such as your surrogate’s birthing hospital. It may be necessary for me to physically deliver or electronically transmit some of your PHI to your fertility center, the Agency and opposing counsel, and other third parties, and you hereby consent to my delivery of such information during my representation of you. PHI includes but is not limited to assisted reproduction contracts, legal clearance letters, agency contract terms sheets, fertility center consents and other similar health care related documents and information which contain your identifying information and refer to your infertility and other medical issues, either specifically or in general. Because I am not a health care provider, or employee or contractor of a health care provider, I am likely not directly covered by HIPAA. However, there are other state and federal privacy laws which protect your health care information which may apply during my representation of you. Any disclosures of your PHI by me will relate directly to my legal representation of you and you hereby agree and consent
to such disclosures. You have the legal right at any time to request a copy of any or all of such disclosures made by me. You also have the right to revoke your consent, as discussed above, at any time by contacting me directly in writing (including by email).
The Mental Health Assessment and the Rights of Participants in Collaborative
Reproduction Arrangements to Access the Mental Health Provider Reports Prepared for
Their Arrangements.

By Andrea Bryman1

There are many variables involved in determining whether a gamete donor or gestational carrier
is an appropriate candidate. In general, there are three main areas that a candidate is assessed –
medically, mentally and legally. From a mental health perspective, one needs to address the
various who, what, where and whys of the assessment being conducted and what the ethical
implications associated with the assessment will be.

What is the mental health assessment of Gamete Donor/Gestational Carrier and why is it
necessary?

Gamete Donors:

A psychosocial assessment should be conducted by a qualified mental health professional and
should include a clinical interview that should address the potential psychological risks
associated with the donation; the potential for financial and emotional coercion; how the

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information obtained may be disclosed; all relevant aspects of medical treatment; disposition of unused embryos; the current and future relationship of donor and recipient; and the impact of treatment failure. Psychological testing may be used in conjunction with the clinical interview to assess for potential instability and/or psychopathology.

Clinical Interview should include:

1. Family history.
2. Education background
3. Assessment of stability
4. Motivation to donate,
5. Current life stressors and coping skills
6. Difficulty or traumatic reproductive history
7. Interpersonal relationships.
8. Sexual history.
9. Travel history.
10. History of major psychiatric and personality disorders.
11. Substance abuse in donor or first-degree relatives.
12. Legal history.
13. History of neglect or abuse.

Reasons for excluding a gamete donor may include:

1. Presence of significant psychopathology
2. Positive family history of heritable psychiatric disorders
3. Substance abuse.
4. Two or more first-degree relatives with substance abuse.
5. Current use of psychoactive medications.
6. History of sexual or physical abuse with no professional treatment.
7. Excessive stress.
8. Marital instability.
9. Impaired cognitive functioning.
10. Mental Incompetence.
11. High-risk sexual practices. ²

**Gestational Carriers:**

A psychosocial assessment should be conducted by a qualified mental health professional for all potential gestational carriers and their partners. The assessment should include a clinical interview and, where appropriate, psychological testing.

The clinical psychosocial interview of a surrogate should include:

1. Social history, including family of origin.
2. Psychiatric history including prior hospitalizations, suicide attempts, medication and counseling.
3. Occupational and financial history.
4. Sexual and reproductive history.

² Fertility and Sterility® Vol. 99, No. 1, January 2013 pp 60-61
5. History of smoking, substance abuse, and physical, emotional, or sexual abuse.

6. History of postpartum disorder(s) and other unresolved negative reproductive events.

7. Religious beliefs that may influence behavior.

8. Legal history.

9. Negative medical history as it relates to the psychosocial adjustment of being a gestational carrier (e.g., bed rest, gestational diabetes, preeclampsia).

10. Personality style and coping skills, capacity for empathy.

11. Current major life stressors or anticipated changes within the next two years.

12. Previous gestational carrier experience or application to another facility.

13. Motivation to become a gestational carrier.

14. Support of significant other.

15. Social network.

16. Desire for more children of her own.

17. Anticipated impact of gestational experience upon her children and significant other.

18. Anticipated type and duration of relationship with the intended parents.

19. Ability to separate from and relinquish the child.

20. Anticipated feelings towards the child.

21. Feelings about multiple pregnancy, bed rest, hospitalization and pregnancy loss.

22. Feelings about possible sexual abstinence.

23. Feelings and decisions about termination of pregnancy, multi-fetal pregnancy reduction, amniocentesis, chorionic villi sampling, and other prenatal diagnostic testing.

24. Reactions to the possibility of becoming infertile as a result of the process.

25. Agreement with the financial compensation arrangement.
Criteria for rejection of a gestational carrier

Absolute rejection criteria include:

1. Cognitive or emotional inability to comply or consent
2. Evidence of financial or emotional coercion
3. Abnormal psychological evaluation/testing as determined by the qualified mental health professional
4. Unresolved or untreated addiction, child abuse, sexual abuse, physical abuse, depression, eating disorders, or traumatic pregnancy, labor and/or delivery.
5. History of major depression, bipolar disorder, psychosis, or a significant anxiety disorder.
6. Current marital or relationship instability.
7. Chaotic lifestyle, current major life stressor(s).
8. Inability to maintain respectful and caring relationship with intended parent(s).
9. Evidence of emotional inability to separate from/surrender the child at birth.

Relative rejection criteria include:

1. Failure to exhibit altruistic commitment to become a gestational carrier.
2. Problematic personality disorder.
3. Insufficient emotional support from partner/spouse or support system.
4. Excessive stressful family demands.
5. History of conflict with authority.
6. Inability to perceive and understand the perspective of others.
7. Motivation to use compensation to solve own fertility.

8. Unresolved issues with a negative reproductive event.³

Who is qualified to perform a mental health assessment?

Guidelines were developed by the Mental Health Professional Group of the American Society for Reproductive Medicine to help determine the qualifications and training for mental health professionals working in reproductive medicine.

The following guidelines suggest minimum qualifications and training of mental health professionals providing infertility counseling and psychological services. The mental health professional should have:

1. *Graduate Degree in a Mental Health Profession*

   A master’s or doctorate degree from an accredited program in the field of psychiatry, psychology, social work, psychiatric nursing, or marriage and family therapy. Curriculum and training should include psychopathology; personality theory; life cycle and family development; family systems theory; bereavement and loss theory; crisis intervention; psychotherapeutic interventions; individual, marital, and group therapy; and a supervised clinical practicum or internship in counseling.

³ Fertility and Sterility® Vol. 97, No. 6, June 2012 p. 1307

2. License to Practice

A license (or registration/certification, where applicable) to practice in the mental health field in which the professional holds a graduate degree and as required by the state in which the individual practices.

3. Training in the Medical and Psychological Aspects of Infertility

Training in the medical aspects of infertility indicating knowledge of:

1. basic reproductive physiology
2. testing, diagnosis, and treatment of reproductive problems
3. etiology of male and female infertility
4. etiology of the assisted reproductive technologies

Training in the psychology of infertility indicating knowledge of:

1. marital and family issues associated with infertility, and the impact on sexual functioning
2. approaches to the psychology of infertility including psychological assessment, bereavement/loss, crisis intervention, post traumatic stress, and typical/atypical responses
3. family building alternatives including adoption, third-party reproduction, child-free lifestyle
4. psychological and couple treatments
5. the legal and ethical issues of infertility treatments.
4. Clinical Experience

The mental health professional should have a minimum of one-year clinical experience providing infertility counseling, preferably under the supervision of or in consultation with a qualified and experienced infertility counselor.

5. Continuing Education

Continuing education helps ensure continued growth in knowledge and skills. Regular attendance at courses offered by the American Society for Reproductive Medicine or other professional organizations and educational institutions is recommended to provide continuing education in both the medical and psychological issues in reproductive health care. ⁴

Dissemination of mental health assessments:

Typically a mental health assessment is requested by a donor/surrogacy agency, a physician or an attorney. The assessment may be conducted through a medical practice or by a clinician in a private practice. Once the assessment is completed it can be sent to the requesting party. The donor/carrier can be told the clinician’s impressions but the evaluation is not released to them. The assessment is typically paid for by the intended parents, clinic or agency. There are no regulations as to who reads the assessment. The assessment could be potentially read by

⁴ Qualifications Guidelines for Infertility Counselors - Sharon N. Covington, M.S.W., Chair Linda D. Applegarth, Ed.D., Vice-Chair Suzan A. Aydinel, Ph.D. Judith Parkes, M.S.W., R.N. Linda Hammer Burns, Ph.D., Vice-Chair Paul R. Feldman, M.D. Deidra T. Rausch, M.S.N., R.N.C. September 1995
employees of an egg donation/surrogacy agency, third party coordinators, attorneys, physicians and nurses.

**Mental health assessment and HIPAA**

One is left wondering if a mental health assessment requested by a third party on a donor/carrier, is considered to be performing a health care service. Is the service/clinician considered a “covered entity” in terms of the Health Insurance Portability and Accountability Act (HIPAA)? Covered entities are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons. One needs to determine if the primary reason for assessment is forensic in nature or therapeutic.

According to Mary Connell and Gerald P. Koocher, in their article [HIPAA & Forensic Practice](http://privacyruleandresearch.nih.gov/pr_06.asp), “Forensic services do not constitute health services, we argue, as they are intended to serve a legal purpose, often in response to court order or mandate, and are not recognized for payment purposes by third party health insurers. While forensic service may include formulation of a

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diagnosis, the purpose is not to provide health care or treatment, but rather, to address a question before the court.”

Another aspect to consider is if the mental health assessment is similar to an “employment” evaluation. In the article by Connell and Koocher, it is noted that “Given that the sole purpose of such assessment is to formulate an opinion to be used by the employer in a non-treatment capacity, a sound argument can be made that pre-employment assessment does not constitute provision of health care and the information garnered, while potentially relevant to the examinee for treatment purposes, will not be released for such purposes, and is not Protected Health Information.”

Thus, if it is agreed that a clinician is providing a forensic assessment and/or a pre-employment assessment, then it can be reasonably argued that “their forensic assessments in private practice do not fall within the ambit of HIPAA for the following reasons. First, the services provided via forensic practice are provided not for therapeutic purpose, but rather to respond to a psycho-legal question or need. Second, the services are provided not at the request of the person being evaluated, but instead at the request of another party or entity outside the health care system. Third, forensic services fall outside health insurance coverage, because they do not constitute health care. Fourth, forensic psychologists do not ordinarily transmit data electronically except in

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the specific ways for which consent has historically been obtained from the litigant. Fifth, no new protections or rights accrue to examinees by way of HIPAA compliance, that fail to flow if we do not achieve compliance (i.e., no new right of access and amendment of information gathered in anticipation of litigation, no additional opportunities beyond those presently extant to control the flow of information). Finally, it can be noted that forensic practitioners have historically handled information amassed in forensic work with at least as much regard for the individual's privacy as the laws governing such transactions permit.”

However, in the event that the outcome of the mental health assessment resulted in the need for the clinician to provide additional therapeutic services or provide a referral for additional healthcare, then the clinician would be required to be HIPAA compliant. If the assessment was conducted in a medical practice and being included in the donor/Carrier’s medical record, then it would also require HIPAA compliance. If the clinician bills a health insurance company for the assessment, then it too would be required to be HIPAA compliant.

Ethical issues for further consideration

1. Who “owns” the Assessment?

Once the mental health assessment is completed and forwarded to the requesting party, the question remains who owns the assessment. Is it the property of the agency, the intended parents, 

the clinic? A legal colleague recently suggested that he thought that the mental health professional owned the assessment. How is this defined?

Often mental health professionals receive requests from donors/carriers to send a copy of their assessments to other agencies or clinics for future cycles. Should another agency or intended parent get access to a “free” assessment that was paid for by another party?

2. Should/Can An Assessment be Waived?
Periodically intended parents have been told they can waive their right to having a mental health assessment done on their donor/carrier. This often occurs with experienced donors/carriers. The question remains, who gets to decide if the assessment should be waived – the agency, the attorney, the physician’s office? Are intended parents offered the option of waiving a medically screening and/or legal consult? One successful donation or surrogacy experience does not necessarily predict further positive outcomes.

Conclusion
As the field of third party family building continues to grow, our industry will continue to be faced with many new concepts that will continue to challenge us from medical, legal and ethical perspectives. It seems that while mental health assessments remain a critical aspect of the determining suitability of a gamete donor/gestational carrier, one must establish the reasoning why the assessment is being completed and then determine whether it is required to be HIPAA compliant. If the assessment will be part of a medical record, then HIPAA compliance should be
followed. If the assessment is necessary for pre-employment and/or forensic in nature, then perhaps HIPAA compliance is not mandated.
Business Associate Contracts

SAMPLE BUSINESS ASSOCIATE AGREEMENT PROVISIONS
(Published January 25, 2013)

Introduction

A “business associate” is a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to protected health information. A “business associate” also is a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of another business associate. The HIPAA Rules generally require that covered entities and business associates enter into contracts with their business associates to ensure that the business associates will appropriately safeguard protected health information. The business associate contract also serves to clarify and limit, as appropriate, the permissible uses and disclosures of protected health information by the business associate, based on the relationship between the parties and the activities or services being performed by the business associate. A business associate may use or disclose protected health information only as permitted or required by its business associate contract or as required by law. A business associate is directly liable under the HIPAA Rules and subject to civil and, in some cases, criminal penalties for making uses and disclosures of protected health information that are not authorized by its contract or required by law. A business associate also is directly liable and subject to civil penalties for failing to safeguard electronic protected health information in accordance with the HIPAA Security Rule.

A written contract between a covered entity and a business associate must: (1) establish the permitted and required uses and disclosures of protected health information by the business associate; (2) provide that the business associate will not use or further disclose the information other than as permitted or required by the contract or as required by law; (3) require the business associate to implement appropriate safeguards to prevent unauthorized use or disclosure of the information, including implementing requirements of the HIPAA Security Rule with regard to electronic protected health information; (4) require the business associate to report to the covered entity any use or disclosure of the information not provided for by its contract, including incidents that constitute breaches of unsecured protected health information; (5) require the business associate to disclose protected health information as specified in its contract to satisfy a covered entity’s obligation with respect to individuals' requests for copies of their protected health information, as well as make available protected health information for amendments (and incorporate any amendments, if required) and accountings; (6) to the extent the business associate is to carry out a covered entity’s obligation under the Privacy Rule, require the business associate to comply with the requirements applicable to the obligation; (7) require the business associate to make available to HHS its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity for purposes of HHS determining the covered entity’s compliance with the HIPAA Privacy Rule; (8) at termination of the contract, if feasible, require the business associate to return or destroy all protected health information received from,
or created or received by the business associate on behalf of, the covered entity; (9) require the
business associate to ensure that any subcontractors it may engage on its behalf that will have
access to protected health information agree to the same restrictions and conditions that apply to
the business associate with respect to such information; and (10) authorize termination of the
contract by the covered entity if the business associate violates a material term of the
contract. Contracts between business associates and business associates that are subcontractors
are subject to these same requirements.

This document includes sample business associate agreement provisions to help covered
entities and business associates more easily comply with the business associate contract
requirements. While these sample provisions are written for the purposes of the contract
between a covered entity and its business associate, the language may be adapted for purposes of
the contract between a business associate and subcontractor.

This is only sample language and use of these sample provisions is not required for
compliance with the HIPAA Rules. The language may be changed to more accurately reflect
business arrangements between a covered entity and business associate or business associate and
subcontractor. In addition, these or similar provisions may be incorporated into an agreement for
the provision of services between a covered entity and business associate or business associate
and subcontractor, or they may be incorporated into a separate business associate agreement.
These provisions address only concepts and requirements set forth in the HIPAA Privacy,
Security, Breach Notification, and Enforcement Rules, and alone may not be sufficient to result
in a binding contract under State law. They do not include many formalities and substantive
provisions that may be required or typically included in a valid contract. Reliance on this sample
may not be sufficient for compliance with State law, and does not replace consultation with a
lawyer or negotiations between the parties to the contract.

**Sample Business Associate Agreement Provisions**

Words or phrases contained in brackets are intended as either optional language or as
instructions to the users of these sample provisions.

**Definitions**

**Catch-all definition:**

The following terms used in this Agreement shall have the same meaning as those terms in the
HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care
Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health
Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected
Health Information, and Use.

**Specific definitions:**
(a) **Business Associate.** “Business Associate” shall generally have the same meaning as the term “business associate” at 45 CFR 160.103, and in reference to the party to this agreement, shall mean [Insert Name of Business Associate].

(b) **Covered Entity.** “Covered Entity” shall generally have the same meaning as the term “covered entity” at 45 CFR 160.103, and in reference to the party to this agreement, shall mean [Insert Name of Covered Entity].

(c) **HIPAA Rules.** “HIPAA Rules” shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

**Obligations and Activities of Business Associate**

Business Associate agrees to:

(a) Not use or disclose protected health information other than as permitted or required by the Agreement or as required by law;

(b) Use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of protected health information other than as provided for by the Agreement;

(c) Report to covered entity any use or disclosure of protected health information not provided for by the Agreement of which it becomes aware, including breaches of unsecured protected health information as required at 45 CFR 164.410, and any security incident of which it becomes aware;

[The parties may wish to add additional specificity regarding the breach notification obligations of the business associate, such as a stricter timeframe for the business associate to report a potential breach to the covered entity and/or whether the business associate will handle breach notifications to individuals, the HHS Office for Civil Rights (OCR), and potentially the media, on behalf of the covered entity.]

(d) In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information;

(e) Make available protected health information in a designated record set to the [Choose either “covered entity” or “individual or the individual’s designee”] as necessary to satisfy covered entity’s obligations under 45 CFR 164.524;

[The parties may wish to add additional specificity regarding how the business associate will respond to a request for access that the business associate receives directly from the individual (such as whether and in what time and manner a business associate is to provide the requested access or whether the business associate will forward the individual’s request to]
the covered entity to fulfill) and the timeframe for the business associate to provide the information to the covered entity.

(f) Make any amendment(s) to protected health information in a designated record set as directed or agreed to by the covered entity pursuant to 45 CFR 164.526, or take other measures as necessary to satisfy covered entity’s obligations under 45 CFR 164.526;

[The parties may wish to add additional specificity regarding how the business associate will respond to a request for amendment that the business associate receives directly from the individual (such as whether and in what time and manner a business associate is to act on the request for amendment or whether the business associate will forward the individual’s request to the covered entity) and the timeframe for the business associate to incorporate any amendments to the information in the designated record set.]

(g) Maintain and make available the information required to provide an accounting of disclosures to the [Choose either “covered entity” or “individual”] as necessary to satisfy covered entity’s obligations under 45 CFR 164.528;

[The parties may wish to add additional specificity regarding how the business associate will respond to a request for an accounting of disclosures that the business associate receives directly from the individual (such as whether and in what time and manner the business associate is to provide the accounting of disclosures to the individual or whether the business associate will forward the request to the covered entity) and the timeframe for the business associate to provide information to the covered entity.]

(h) To the extent the business associate is to carry out one or more of covered entity's obligation(s) under Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to the covered entity in the performance of such obligation(s); and

(i) Make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules.

**Permitted Uses and Disclosures by Business Associate**

(a) Business associate may only use or disclose protected health information

[Option 1 – Provide a specific list of permissible purposes.]

[Option 2 – Reference an underlying service agreement, such as “as necessary to perform the services set forth in Service Agreement.”]

[In addition to other permissible purposes, the parties should specify whether the business associate is authorized to use protected health information to de-identify the information in accordance with 45 CFR 164.514(a)-(c). The parties also may wish to specify the manner in which the business associate will de-identify the information and the permitted uses and disclosures by the business associate of the de-identified information.]
(b) Business associate may use or disclose protected health information as required by law.

(c) Business associate agrees to make uses and disclosures and requests for protected health information

[Option 1] consistent with covered entity’s minimum necessary policies and procedures.

[Option 2] subject to the following minimum necessary requirements: [Include specific minimum necessary provisions that are consistent with the covered entity’s minimum necessary policies and procedures.]

(d) Business associate may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by covered entity [if the Agreement permits the business associate to use or disclose protected health information for its own management and administration and legal responsibilities or for data aggregation services as set forth in optional provisions (e), (f), or (g) below, then add “, except for the specific uses and disclosures set forth below.”]

(e) [Optional] Business associate may use protected health information for the proper management and administration of the business associate or to carry out the legal responsibilities of the business associate.

(f) [Optional] Business associate may disclose protected health information for the proper management and administration of business associate or to carry out the legal responsibilities of the business associate, provided the disclosures are required by law, or business associate obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and the person notifies business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(g) [Optional] Business associate may provide data aggregation services relating to the health care operations of the covered entity.

**Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions**

(a) [Optional] Covered entity shall notify business associate of any limitation(s) in the notice of privacy practices of covered entity under 45 CFR 164.520, to the extent that such limitation may affect business associate’s use or disclosure of protected health information.

(b) [Optional] Covered entity shall notify business associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her protected health information, to the extent that such changes may affect business associate’s use or disclosure of protected health information.
(c) [Optional] Covered entity shall notify business associate of any restriction on the use or disclosure of protected health information that covered entity has agreed to or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect business associate’s use or disclosure of protected health information.

**Permissible Requests by Covered Entity**

[Optional] Covered entity shall not request business associate to use or disclose protected health information in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by covered entity. [Include an exception if the business associate will use or disclose protected health information for, and the agreement includes provisions for, data aggregation or management and administration and legal responsibilities of the business associate.]

**Term and Termination**

(a) **Term.** The Term of this Agreement shall be effective as of [Insert effective date], and shall terminate on [Insert termination date or event] or on the date covered entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.

(b) **Termination for Cause.** Business associate authorizes termination of this Agreement by covered entity, if covered entity determines business associate has violated a material term of the Agreement [and business associate has not cured the breach or ended the violation within the time specified by covered entity]. [Bracketed language may be added if the covered entity wishes to provide the business associate with an opportunity to cure a violation or breach of the contract before termination for cause.]

(c) **Obligations of Business Associate Upon Termination.**

[Option 1 – if the business associate is to return or destroy all protected health information upon termination of the agreement]

Upon termination of this Agreement for any reason, business associate shall return to covered entity [or, if agreed to by covered entity, destroy] all protected health information received from covered entity, or created, maintained, or received by business associate on behalf of covered entity, that the business associate still maintains in any form. Business associate shall retain no copies of the protected health information.

[Option 2—if the agreement authorizes the business associate to use or disclose protected health information for its own management and administration or to carry out its legal responsibilities and the business associate needs to retain protected health information for such purposes after termination of the agreement]

Upon termination of this Agreement for any reason, business associate, with respect to protected health information received from covered entity, or created, maintained, or received by business associate on behalf of covered entity, shall:
1.

1. Retain only that protected health information which is necessary for business associate to continue its proper management and administration or to carry out its legal responsibilities;

2. Return to covered entity [or, if agreed to by covered entity, destroy] the remaining protected health information that the business associate still maintains in any form;

3. Continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information to prevent use or disclosure of the protected health information, other than as provided for in this Section, for as long as business associate retains the protected health information;

4. Not use or disclose the protected health information retained by business associate other than for the purposes for which such protected health information was retained and subject to the same conditions set out at [Insert section number related to paragraphs (e) and (f) above under “Permitted Uses and Disclosures By Business Associate”] which applied prior to termination; and

5. Return to covered entity [or, if agreed to by covered entity, destroy] the protected health information retained by business associate when it is no longer needed by business associate for its proper management and administration or to carry out its legal responsibilities.

[The agreement also could provide that the business associate will transmit the protected health information to another business associate of the covered entity at termination, and/or could add terms regarding a business associate’s obligations to obtain or ensure the destruction of protected health information created, received, or maintained by subcontractors.]

(d) **Survival.** The obligations of business associate under this Section shall survive the termination of this Agreement.

**Miscellaneous [Optional]**

(a) [Optional] **Regulatory References.** A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

(b) [Optional] **Amendment.** The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.

(c) [Optional] **Interpretation.** Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.
HIPAA Compliance
Bradford Kolb, MD FACOG
• Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). The Privacy Rule standards address the use and disclosure of individuals’ health information—called “protected health information” by organizations subject to the Privacy Rule — called “covered entities,” as well as standards for individuals’ privacy rights to understand and control how their health information used.
Covered Entities

- Health care providers (including individuals and organizations).
- Health plans (including insurers and other payers).
- Health care clearinghouses (entities, such as billing services, that process health information from nonstandard into standard forms or vice versa).
- Business associates - defined as individuals or entities outside of the Partners system that receive, create, or have access to individually identifiable health information and (1) perform a service on behalf of Partners or its affiliates, or (2) fit within the list of specific service providers (i.e., outside legal, actuarial, accounting, consulting, management, administrative, accreditation, data aggregation, and financial services).
Business Associates

• Business associates are required to have business associate agreements in place with their subcontractors, including certain provisions prescribed by the rules.

• Although covered entities are required to contract with their business associates they are not required to contract directly with their business associates’ subcontractors.
What is a Business Associate?

• A “business associate” is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. A member of the covered entity’s workforce is not a business associate. A covered health care provider, health plan, or health care clearinghouse can be a business associate of another covered entity. The Privacy Rule lists some of the functions or activities, as well as the particular services, that make a person or entity a business associate, if the activity or service involves the use or disclosure of protected health information. The types of functions or activities that may make a person or entity a business associate include payment or health care operations activities, as well as other functions or activities regulated by the Administrative Simplification Rules.

• Business associate functions and activities include: claims processing or administration; data analysis, processing or administration; utilization review; quality assurance; billing; benefit management; practice management; and re-pricing. Business associate services are: legal; actuarial; accounting; consulting; data aggregation; management; administrative; accreditation; and financial. See the definition of “business associate” at 45 CFR 160.103.
Examples of Business Associates

• A third party administrator that assists a health plan with claims processing.
• A CPA firm whose accounting services to a health care provider involve access to protected health information.
• An attorney whose legal services to a health plan involve access to protected health information.
• A consultant that performs utilization reviews for a hospital.
• A health care clearinghouse that translates a claim from a non-standard format into a standard transaction on behalf of a health care provider and forwards the processed transaction to a payer.
• An independent medical transcriptionist that provides transcription services to a physician.
• A pharmacy benefits manager that manages a health plan’s pharmacist network.
Business Associates

- The written assurance (which may be in a stand-alone agreement or part of a larger contract) must include several provisions: for example, restrictions on how the business associate may use or release identifiable health care information, promises to protect such information and to return or destroy it at the end of the contract, and assurances to make such information available for compliance purposes. If a covered entity knows that its business associate has violated these provisions, the covered entity must take reasonable steps to correct the problem and terminate the contract (in most cases) if such steps fail.

- As a result of the most recent changes to the Privacy Rule, Business Associates are now directly regulated by the Rule and directly responsible for compliance with certain of its provisions.
Business Associate Contracts

• A covered entity’s contract or other written arrangement with its business associate must contain the elements specified at 45 CFR 164.504(e). For example, the contract must:
  – Describe the permitted and required uses of protected health information by the business associate;
  – Provide that the business associate will not use or further disclose the protected health information other than as permitted or required by the contract or as required by law; and
  – Require the business associate to use appropriate safeguards to prevent a use or disclosure of the protected health information other than as provided for by the contract.

• Where a covered entity knows of a material breach or violation by the business associate of the contract or agreement, the covered entity is required to take reasonable steps to cure the breach or end the violation, and if such steps are unsuccessful, to terminate the contract or arrangement. If termination of the contract or agreement is not feasible, a covered entity is required to report the problem to the Department of Health and Human Services (HHS) Office for Civil Rights (OCR).
What is the difference between Privacy and Security?

• The **Privacy Rule** sets the standards for how covered entities and business associates are to maintain the privacy of Protected Health Information (PHI)
  
  – A major goal of the Privacy Rule is to assure that individuals’ health information is properly protected while allowing the flow of health information needed to provide and promote high-quality health care and protect the public's health and well-being.

• The **Security Rule** defines the standards which require covered entities to implement basic safeguards to protect electronic Protected Health Information (e-PHI)
  
  – A major goal of the Security Rule is to protect the privacy of individuals’ health information while allowing covered entities to adopt new technologies to improve the quality and efficiency of patient care
Safeguards

- Electronic vs. oral and paper: It is important to note that Privacy Rule applies to all forms of patients’ protected health information, whether electronic, written, or oral. In contrast, the Security Rule covers only protected health information that is in electronic form.
  
  - Standard: safeguards. A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.
  
  - Implementation specification: safeguards.
    
    • A covered entity must reasonably safeguard protected health information from any intentional or unintentional use or disclosure that is in violation of the standards, implementation specifications or other requirements of this subpart.
    
    • A covered entity must reasonably safeguard protected health information to limit incidental uses or disclosures made pursuant to an otherwise permitted or required use or disclosure.
Safeguards

- Electronic Medical Records
- Emails & texts
- Mobile communication
- Device security
  - Safety
    - Encryption
    - Password
    - Site storage of data (recommend no storage of mobile devices)
    - Time out limits
    - Control physical access
What Information is Identifiable?

• Protected health information
  – The Privacy Rule applies to all protected health information, which includes, when held or transmitted by a covered entity
  – Past/present/future physical or mental health or condition
  – The provision of health care to the individual
  – Information that identifies the individual or for which there is a reasonable basis to believe disclosed information can be used to identify the individual
Information

• Patients have the right to decide how their information is to be used or shared
  – Signed authorization
  – Insurance payments (does not require authorized release)
  – Provider may release information if in the patient’s best interest
  – Minors
  – Genetic information
  – Psychological evaluations

• Third Party Dilemmas
  – Disclosure to Intended Parents
  – Disclosure to agencies
Exchange of Information

• Intended Parents
  – What information can be shared with surrogates?
    • Affects their health
    • Informational, but no impact on their health

• Surrogates
  – Psychological screens/information
  – Health screens/Medical history

• Oocyte Donors
  – Health screens/Medical history
  – Genetic data

• Exchange of Medical Data
  – Agencies
  – Attorneys
  – Receiving Obstetrician

* These relationships should be mentioned in the agreements and consents with the intended patients and sub-contractors
Enforcement and Penalties

- HHS has retained the high penalty structure currently in effect, meaning that penalties can range from $100 to $50,000 per violation depending on culpability, up to an annual maximum cap of $1.5 million on a per provision basis. Business associates and subcontractors are directly liable for their violations, but covered entities also can be penalized for their violations. HHS is now required to conduct compliance reviews if willful negligence is indicated following a preliminary review of the facts.

- The HIPAA Breach Notification Rule, 45 CFR §§ 164.400-414, requires HIPAA covered entities and their business associates to provide notification following a breach of unsecured protected health information.
  - an impermissible use or disclosure under the Privacy Rule that compromises the security or privacy of the protected health information.
  - Requires log of breaches and steps to remediate
Summary

• Be Aware
• Be Cognizant
• Be Circumspect and Conscientious
• Don’t be Paranoid
NOTICE OF PRIVACY PRACTICES
As Required by the Privacy Regulations Created as a Result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

This notice describes how health information about you, as a patient of this practice, may be used and disclosed, and how you can get access to your individually identifiable health information.

Our Commitment to Your Privacy
Our practice is dedicated to maintaining the privacy of your individually identifiable health information (PHI). In conducting our business, we will create records regarding you and the treatment and services we provide to you. We are required by law to maintain the confidentiality of health information that identifies you. We also are required by law to provide you with this notice of our legal duties and the privacy practices that we maintain in our practice concerning your PHI. By federal and state law, we must follow the terms of the notice of privacy practices that we have in effect at the time.

We realize that these laws are complicated, but we must provide you with the following important information:
• How we may use and disclose your PHI
• Your privacy rights in your PHI
• Our obligations concerning the use and disclosure of your PHI

The terms of this notice applies to all records containing your PHI that are created or retained by our practice. We reserve the right to revise or amend this Notice of Privacy Practices. Any revision or amendment to this notice will be effective for all of your records that our practice has created or maintained in the past, and for any of your records that we may create or maintain in the future. The following categories describe the different ways in which we may use and disclose your PHI:

Treatment: Your health information may be used by staff members or disclosed to other health care professionals for the purpose of evaluating your health, diagnosing medical conditions, and providing treatment. For example, results of laboratory tests and procedures will be available in your medical record to all health professionals who may provide treatment or who may be consulted by staff members.

Payment: Your health information may be used to seek payment from your health plan, from other sources of coverage such as an automobile insurer, or from credit card companies that you may use to pay for services. For example, your health plan may request and receive information on dates of service, the services provided, and the medical condition being treated. You may flag procedures you do not want submitted to your insurance company, if you pay for the procedures yourself.

Health Care Operation: We may use and disclose your PHI to operate our business. As examples of the ways in which we may use and disclose your information for our operations, we may use your PHI to evaluate the quality of care you received from us, or to conduct cost-management and business planning activities for our practice. We may disclose your PHI to other health care providers and entities to assist in their health care operations.

Appointment Reminders: We may use and disclose your PHI to contact you and remind you of an appointment.

Treatment Options: We may use and disclose your PHI to inform you of potential treatment options or alternatives.

Health-Related Benefits and Services: We may use and disclose your PHI to inform you of health-related benefits or services that may be of interest to you.

Anesthesia Services: We may contact you regarding financial matters involving anesthesia, and we may provide your information to the anesthesiologist, if applicable.

Release of Information to Family/Friends: We may release your PHI to a friend or family member who is involved in your care, or who assists in taking care of you.

Deceased Patients: Our practice may release PHI to a medical examiner or coroner to identify a deceased individual or to identify the cause of death. If necessary, we also may release information in order for funeral directors to perform their jobs.

Disclosures Required By Law: We will use and disclose your PHI when we are required to do so by federal, state or local law.

Use and Disclosure of Your PHI in Certain Circumstances
Public Health Risks: We may disclose your PHI to public health authorities that are authorized by law to collect information for the purpose of:
• Maintaining vital records, such as births and deaths
• Reporting child abuse or neglect
• Preventing or controlling disease, injury or disability
• Notifying a person regarding potential exposure to a communicable disease

continued
- Notifying a person regarding a potential risk for spreading or contracting a disease or condition
- Reporting reactions to drugs or problems with products or devices
- Notifying individuals if a product or device they may be using has been recalled
- Notifying appropriate government agencies and authorities regarding the potential abuse or neglect of an adult patient, including domestic violence; however, we will only disclose this information if the patient agrees or we are required or authorized by law to disclose this information.
- Notifying your employer under limited circumstances related primarily to workplace injury or illness or medical surveillance.

**Health Oversight Activities:** We may disclose your PHI to a health oversight agency for activities authorized by law. Oversight activities can include, for example, investigations, inspections, audits, surveys, licensure and disciplinary actions; civil, administrative, and criminal procedures or actions; or other activities necessary for the government to monitor government programs, compliance with civil rights laws and the health care system in general.

**Lawsuits and Similar Proceedings:** We may use and disclose your PHI in response to a court or administrative order, if you are involved in a lawsuit or similar proceeding.

**Law Enforcement:** Your health information may be disclosed to law enforcement agencies to support government audits and inspections, to facilitate law-enforcement investigations, and to comply with government mandated reporting.

**Research:** We may use and disclose your PHI for research purposes in certain limited circumstances. We will obtain your written authorization to use your PHI for research purposes except when an Institutional Review Board or Privacy Board has determined that the waiver of your authorization satisfies the following: (i) the use or disclosure involves no more than a minimal risk to your privacy based on the following: (a) an adequate plan to protect the identifiers from improper use and disclosure; (b) an adequate plan to destroy the identifiers at the earliest opportunity consistent with the research (unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law); and (c) adequate written assurances that the PHI will not be re-used or disclosed to any other person or entity (except as required by law) for authorized oversight of the research study, or for other research for which the use or disclosure would otherwise be permitted; (ii) the research could not practicably be conducted without the waiver; and (iii) the research could not practicably be conducted without access to and use of the PHI.

**Serious Threats to Health or Safety:** We may use and disclose your PHI when necessary to reduce or prevent a serious threat to your health and safety or the health and safety of another individual or the public. Under these circumstances, we will only make disclosures to a person or organization able to help prevent the threat.

**Military:** We may disclose your PHI if you are a member of U.S. or foreign military forces (including veterans) and if required by the appropriate authorities.

**National Security:** We may disclose your PHI to federal officials for intelligence and national security activities authorized by law. We also may disclose your PHI to federal officials in order to protect the President, other officials or foreign heads of state, or to conduct investigations.

**Inmates:** We may disclose your PHI to correctional institutions or law enforcement officials if you are an inmate or under the custody of a law enforcement official. Disclosure for these purposes would be necessary: (a) for the institution to provide health care services to you, (b) for the safety and security of the institution, and/or (c) to protect your health and safety or the health and safety of other individuals.

**Right to Provide an Authorization for Other Uses and Disclosures:** We will obtain your written authorization for uses and disclosures that are not identified by this notice or permitted by applicable law. Any authorization you provide to us regarding the use and disclosure of your PHI may be revoked at any time in writing. After you revoke your authorization, we will no longer use or disclose your PHI for the reasons described in the authorization. Please note: we are required to retain records of your care.

**Individual Rights:** You have certain rights under the federal privacy standards including:
- The right to request restrictions on the use and disclosure of your protected health information
- The right to receive confidential communications concerning your medical condition and treatment
- The right to file a complaint – We will provide you with the address.
- The right to inspect and receive a copy of your protected health information – Contact the front office receptionist for the form.
- The right to amend or submit corrections to your protected health information
- The right to receive an accounting of how and to whom your protected health information has been disclosed
- The right to receive a printed copy of this notice.

*If you have any questions regarding this notice or our health information privacy policies, please contact HRC Fertility’s Pasadena Office at (626) 440-9161.*
Request for Limitations and Restrictions of Protected Health Information

FOR INTERNAL PURPOSES ONLY:
Date Request Received: ___________________ * Put in “Alert Notes”

This form is for our own internal purposes only and is in compliance with the HIPAA Act. We need documentation to verify the most successful ways of communicating with you.

Please Note: If we are not able to reach you at the numbers below, we may need to try alternate numbers.

Name ____________________________________________ Date of Birth ______________________

What are the best numbers to contact you? Please provide two options in case we are not able to reach you at one of the numbers:

☐ Home phone # ______________________________________

Is it okay to leave a message? ☐ Yes ☐ No

☐ Work phone # ______________________________________

Is it okay to leave a message? ☐ Yes ☐ No

☐ Cell phone # ______________________________________

Is it okay to leave a message? ☐ Yes ☐ No

☐ Fax home # ______________________________________

☐ Fax work # ______________________________________

☐ Email – Primary _____________________________________

(this email will be used for all email communication contact from HRC unless you elect not to receive as specified below)

☐ I do not wish to receive clinical and billing emails

☐ I do not wish to receive the HRC e-Newsletter

☐ I do not wish to have my anonymous demographic information used by HRC’s marketing division.

☐ I do not wish to receive HRC social media (Facebook, Twitter, etc.)

☐ Email – Secondary _____________________________________

Comments __________________________________________

☐ I give permission for my partner to receive my test results.

Signature of Patient __________________________________ Date ______________________

Signature of Partner __________________________________ Date ______________________