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## Expectant Mothers' Knowledge, Perceptions, Experiences, and Acceptance of Human Donor Milk: A Pilot Study

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EXPECTANT MOTHERS' KNOWLEDGE, PERCEPTIONS, EXPERIENCES AND  
ACCEPTANCE OF HUMAN DONOR MILK: A PILOT STUDY

by

Jennifer Lee Marshall

A Thesis

Submitted in Partial Fulfillment of the

Requirements for the Degree of

Master of Science

Major: Clinical Nutrition

The University of Memphis

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## **DEDICATION**

This thesis is dedicated to my parents, Rick and Valerie Carr for always believing in me  
and their consistent prayers over my life.

And my best friend and husband, Patrick Marshall who has worked hard to support my  
academic endeavors. His unwavering love, encouragement and patience provided my  
light at the end of the tunnel.

## **ACKNOWLEDGMENTS**

I would like to express my sincere appreciation to the members of my committee, Dr. Ruth William-Hooker (chair), Ms. Queen Cox, MS, RD, LDN and Dr. Genae Strong. Thank you for your support, encouragement and editorial reviews.

My mentor, Dr. Genae Strong who stepped in to see me through each step along the way. Thank you for the countless hours you dedicated to my education and the investment you've made in my life.

## **ABSTRACT**

Marshall, Jennifer Lee. MS. The University of Memphis. December/2014. Expectant Mothers' Knowledge, Perceptions, Experiences and Acceptance of Human Donor Milk. A Pilot Study. Major Professor: Dr. Ruth Williams-Hooker

**TITLE** Expectant Mothers' Knowledge, Perceptions, Experiences and Acceptance of Human Donor Milk. A Pilot Study

**AUTHOR** J. Marshall

**OBJECTIVE** The purpose of this study was to evaluate expectant mothers' knowledge, perceptions, experience, and acceptance of Human Donor Milk (HDM).

**SUBJECTS** The sample included 30 low-risk expecting mothers, over the age of 18, who attended prenatal classes at Baptist Memorial Hospital for Women-Memphis.

**METHOD** A researcher developed survey tool was used to collect data from a convenience sample of 30 low-risk expectant mothers attending one of a series of prenatal classes. Participation was on a volunteer basis and personal identification was not collected.

**RESULTS** Analysis of data collected is descriptive. Results showed demographics to be highly homogeneous. An overall lack of knowledge of HDM among expectant mothers was evident. With little to no self-reported knowledge regarding HDM, perceptions were limited. The majority (97%) of participants were first time mothers and had no experience to account for. However, the majority (70%) of participants reported a willingness to donate excess breastmilk showing an acceptance of HDM use to feed infants when mothers own milk is unavailable.

**CONCLUSION** In conclusion, an overall lack of self-reported knowledge, perception, and experiences regarding the use of HDM to feed infants was found among the participants. However acceptance of HDM, as it relates to knowledge, warrants further research. Additional research surveying multiple demographics might also shed more light on women's perceptions and knowledge of HDM.

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# CHAPTER I

## INTRODUCTION

Beneficial use of human milk over artificial milk has been well documented. Research regarding mothers' knowledge and perceptions of pasteurized human donor milk (PHDM) have yet to be fully discovered. The use of Human Donor Milk (HDM) as an alternative feeding option when Mother's Own Milk (MOM) is unavailable has become utilized in the hospital setting more frequently among healthcare professionals in latest years. Research regarding HDM in level 3 NICUs in the United States (U.S.) found 42% of 182 hospitals administer HDM.<sup>1</sup> Eighty-five percent of those found to have administered HDM have only done so within the last 5 years. Human Donor Milk Banks (HDMB) in the U.S. have grown since the 1980's as a result of better safety regulations, high tech screening equipment,<sup>2</sup> and stronger evidence for best practice. The Human Milk Banking Association of North America (HMBANA) continues to grow in an effort to improve infant health outcomes, which has been documented throughout the literature.<sup>3-5</sup>

Currently there are 19 established bank locations throughout the U.S. and Canada.<sup>2</sup> In spite of the rapid growth of HDM, the demand continues to outweigh supply.<sup>6-8</sup> Multiple factors such as ethics, culture and extent of awareness, influence whether the supply meets the demand.<sup>9</sup> Although HDM has been used as an alternative feeding option for infants since the early 1900's, there is still a lack of knowledge among the general public.<sup>9</sup> HDM has been found to positively influence infant health outcomes in the most vulnerable population. Due to the limited supply of donations, the at-risk infants<sup>10</sup> are the only ones warranting its current use. If there were no limits to HDM, full

term infants could have HM as the second feeding alternative option when MOMs is unavailable.

### **Purpose of Study**

The purpose of this study is to evaluate expectant mothers' knowledge, perceptions, experience, and acceptance of HDM.

## **REVIEW OF LITERATURE**

### **HDMB Regulations and Pasteurization**

Controversial safety and regulatory concerns made it imperative for HMBANA to develop practice guidelines ensuring HDM as a safe alternative when mothers are unable or unwilling to provide their own breastmilk. The Human Milk Banking Association of North America (HMBANA) is a nonprofit national organization established in the US and Canada in 1985 which accepts donated human milk from mothers who meet a certain qualification criteria.<sup>2</sup> Mothers who have excess milk or who have lost their infant within a year of birth can volunteer to donate their milk. Under this criteria donors not only undergo screening interviews regarding medical history but also are subject for laboratory blood test to identify any illnesses including but not limited to: HIV-1, HIV-2, hepatitis B and C, T-lymphotropic virus 1 and 2 and syphilis.<sup>2</sup> Once the criteria is met, the milk is held at 20°C until it is ready to be transported.

### **Nutritional Components of HDM after Pasteurization**

Before pasteurization takes place, the milk is thawed and undergoes bacterial culture test. The HDM is then pasteurized using the Holder Pasteurization Method. As far as safety measures go, the Holder method is the recommended pasteurization method for human milk banks.<sup>11</sup> Pasteurization involves heating the donated milk to 62.5°C for 30

minutes.<sup>12</sup> While there are some countries that feed raw donor milk to hospitalized infants, HMBANA uses the Holder method to remove harmful pathogens including *Escherichia coli*, and *Staphylococcus aureus*.<sup>12</sup> Unfortunately, pasteurization also inactivates some beneficial bioactive components of the milk.

Research has shown a decrease in the amount of bile salt-stimulated lipase and lactoferrin, lysozyme,<sup>13-15</sup> and erythropoietin<sup>16</sup> levels are reduced as a result of pasteurization. The Holder method has also been shown to completely inactivate types 6, 16, and 18 of the human papilloma viruses<sup>17</sup> as well as maintain oligosaccharides throughout the holder pasteurization method.<sup>3</sup> There are also various growth factors that are reduced due to pasteurization such as Insulin-like-growth factor-1 (IGF-1), IGF2, insulin-like-growth-factor-binding-protein-2 (IGFBP), and IGFBP-3.<sup>18</sup> Ewaschuk JB, Unger S, O'Connor DL, et al. found a significant decrease in several immune factors including human growth factors and cytokines due to heat processing.<sup>12</sup> The need to fully understand the effects of pasteurization on human donor milk for the use of feeding high risk infants is evident.

Despite the diminishing effects the Holder method may have on human milk, HDM feeding is suggested to not only be the best alternative over artificial milk, but the first choice in feeding when Mother's Own Milk (MOM) is not available.<sup>19,20</sup> Because HMBANA currently is experiencing a short supply of donations, the available milk is allocated to the most fragile and higher acuity status infants. The Surgeon General's 2010 *Call to Action to Support Breastfeeding* set out to identify and address barriers to accessibility and availability of safe banked donor milk for fragile infants. For infants less than 1500 grams at birth, human milk is not adequate enough to supply the required

nutrients of the very low birth weight (VLBW) infant.<sup>21-23</sup> All preterm infants fed PDHM are given additional human milk fortifiers to meet estimated needs.<sup>20,21,24</sup> In a recent single center, prospective observational cohort study, feeding exclusive human milk-based diets for preterm infants weighing <1250 grams showed to meet growth standards.<sup>25</sup> Further research is needed to determine if feeding solely HDM to full term infants, provides adequate nutritional needs for optimal growth and development.

### **Known Benefits of Breast Milk**

The use of HDM may not always provide adequate nutrients needed by infants without the use of Human Milk Fortifiers (HMF). Some studies suggest that expressed breast milk (EBM) from mothers who deliver preterm babies cannot promote the same growth rate as milk from mothers of full term infants.<sup>26,27</sup> Though, some of these studies were performed on “drip milk,” which is known to have lower fat content than expressed milk.<sup>28</sup> Arslanoglu S et al. report use of unfortified donor milk to feed infants without HMF, could explain slower growth.<sup>27</sup> It could be argued that weight gain is not always the best indicator of optimal outcome. One study performed by Lucas et al. found that preterm infants who were fed human milk had higher IQ scores later in life despite having slower weight gain during infancy.<sup>29</sup>

A cohort study was started in 1982 by Lucas et al. to observe the long-term outcomes of different feeding methods.<sup>29</sup> The infants in this study were categorized into groups receiving either PDHM or pre-term artificial milk. The researchers followed up with the participants at 13-16 years of age, and found that the mean arterial blood pressure was lower in those who had been randomized to donor milk.<sup>29</sup> They also found that those who were fed donor milk had a lower ratio of LDL to HDL cholesterol.<sup>30</sup> This

study provides significant evidence for the long-term cardiovascular benefits of donor milk.<sup>27</sup> Even after pasteurization and research outcomes, human milk is a very effective intervention for the prevention of infections and necrotizing enterocolitis (NEC), and for improved neurocognitive<sup>31,32</sup> and cardiovascular outcomes in the long-term.<sup>30</sup>

A meta-analysis of eight randomized control trials comparing HDM to infant formula was conducted however all except one trial was prior to 1985 when milk fortifiers were unavailable. The outcome resulted in decreased preterm survival.<sup>33</sup> However, the benefits of breast milk have shown to reduce necrotizing enterocolitis (NEC) compared to infant formula (IF).<sup>33</sup> Studies in the 2007 Cochrane review evaluated randomized controlled trials in preterm infants. The meta-analysis of five different trials showed significantly higher rates of NEC in the formula-fed infants.<sup>33,34</sup> A study by Boyd et al. showed that a diet of solely donor milk reduces the risk of NEC by 79%.<sup>4</sup> Researchers also reported significantly fewer cases of feeding intolerance, diarrhea, urinary tract infection, and fewer days of antibiotic treatment in infants who were fed HM than formula.<sup>21</sup>

### **Feeding Option Dilemma**

With all the evidence of the protective effects of human milk, one might assume that any mother who could not provide her own milk to her infant would choose HDM as the second best option. However, most women turn to artificial milk (formula) in this situation – which is considered to be the third feeding option available. This decision may shed light on a knowledge deficit among mothers regarding HDM alternate to MOM. Miracle et al. discuss the ethical controversy related to decision-making for infants who do not have access to MOM. They reiterate that there are currently two alternatives:

Pasteurized Donor Human Milk and commercial artificial milk.<sup>9</sup> Clinicians do not offer the use of donor milk to parents, often citing “lack of evidence” regarding DHM.<sup>35</sup> Human Donor Milk with the addition of supplementation versus formula feeding has shown increasing benefits.<sup>4, 20, 33</sup> Both short-term and long-term outcomes in infants are recognized by the feeding of human milk. However, research is limited and further research is needed to identify sole effects of HDM versus artificial milk feeding. However, it can be argued that all procedures and treatment processes are based on the most current, “available scientific evidence, clinical experience and individual need of the patient.”<sup>9</sup> Miracle et al. suggest that it would be in the ethical interest of the physicians to provide information to parents regarding donor milk for feeding.<sup>9</sup>

### **Education vs Marketing**

Clinicians, however, may have reservations when it comes to offering HDM due to contracts with commercial funded research by infant formula manufacturers.<sup>9</sup> Other obstacles unknown stand in the way of increasing Human Milk (HM) donations and use in the medical field. Lack of obtaining information regarding the option to donate excess human milk and/or the use and availability of human milk as a beneficial alternate feeding option for infants could be contributed to a knowledge deficit among mothers<sup>9</sup> as well we aggressive marketing for artificial infant formula companies.<sup>36</sup> The purpose of this study is not only to evaluate expectant mothers’ knowledge and perceptions of HDM but also to understand any experience mothers may have encountered with HDM. Based on these factors, what is the level of acceptance expecting mothers have on the use of HDM. Do expecting mothers know enough to make an informed consent for the use of HDM to feed their infant if the need arises? If obstacles could be identified through an

optional survey, then further implications could take place to increase DHM knowledge, acceptance and as the second feeding option when MOM is unavailable.



## **CHAPTER II**

### **METHODOLOGY**

#### **Sample**

A convenience sample of 30 expectant mothers over 18 years of age were recruited while attending one of a series of prenatal classes. The third largest delivering hospital in a metropolitan area served as the setting for the study. An introduction was given to explain the pilot study to the class attendees and they were given the opportunity to participate voluntarily. Prior to administering the survey, the Primary Investigator obtained informed consent (Appendix A). The paper and pencil survey (Appendix B) consisted of 26 questions including an opportunity for free response. The survey took approximately 15 minutes to complete. Because of the nature of the medical questions, the survey was handed to each participant in a closed, unmarked envelope. Participants were instructed to return the completed survey in the unmarked envelope when finished. No identifiable information was collected and survey responses were kept confidential. Once the survey had been completed, the participants were given a token of appreciation. Out of 31 subjects who were invited to participate, 30 (97%) completed the survey and 1 (3%) elected not to participate. Inclusion criteria were low-risk expectant women in any trimester. Exclusion criteria included those under the age of 18 years of age or those experiencing high risk pregnancy complications.

#### **Data Collection**

Because no survey exists in the literature to address the question in this study, a researcher-developed study tool was created. Prior to use, the survey (study tool) was validated with 50 trials, which was done via volunteers accessing the survey through a

provided electronic link. The survey was conducted during August and September, 2014 to collect data. In addition to demographic data to describe the sample, the variables measured self-reported knowledge, perception, experience and acceptance of HDM. Additionally, the survey explored the participants' interest in learning more about breastfeeding, HDM and infant nutrition. The University of Memphis, Institutional Review Board (Appendix C) as well as the Institutional Review Board of Baptist Memorial Hospital for Women (Appendix D) approved all study procedures prior to data collection.

### **Statistical Analysis**

All survey responses were entered into a survey management tool powered by Qualtrics. Descriptive statistics were analyzed using Qualtrics software.

## **CHAPTER III**

### **RESULTS**

#### **Demographics**

Overall, there were 30 participants in which data was collected. The study sample focused on expectant mothers from four different ethnicity backgrounds, ages 20-44. Demographics obtained for this study included the following: age, ethnicity, level of education, number of children not including current pregnancy and what trimester mothers were currently in. After analyzing the data, the results showed majority of participants to be between the ages of 25-34, highly educated, White/Caucasians as first time mothers in their third trimester. Demographic data presented in Table 1.

#### **Knowledge and Acceptance**

The level of expectant mothers' knowledge was evaluated by 11 questions, approximately 50% of the survey. Table 2. Six of the 11 questions were multifaceted with acceptance of HDM. In addition, Table 3 depicts an additional survey question, as it relates to expectant mothers' acceptance. The data showed an overall lack of knowledge as it pertains to HDM. Over half of the sample reported hearing about the use of HDM to feed newborns. However, when asked to identify what they know to be true regarding HDM based on 9 statements made, it was very evident all were unsure and uncertain which statement to be true by marking "unsure" in their response. The responses to each statement can be seen in Figure 1.

**Table 1.** Demographics of a 30 expectant mothers' surveyed regarding HDM

	<b>n</b>	<b>%</b>
<b>Age</b>	30	
20-24		17
25-34		67
35-44		17
<b>Ethnicity</b>	30	
White/Caucasian		73
African American		17
Asian		10
Hispanic		7
<b>Level of Education</b>	30	
Some college or technical school		23
College graduate		37
Post-graduate or professional		40
<b>Children NOT including this pregnancy</b>	30	
0		97
1		
2		3
--No one had more than 2 children--		
<b>Current Trimester</b>	30	
1st (1-13 weeks)		3
2nd (14-26 weeks)		17
3rd (27-42 weeks)		80

n = total number of responses for question asked

**Table 2.** Knowledge of a 30 expectant mothers' surveyed regarding HDM

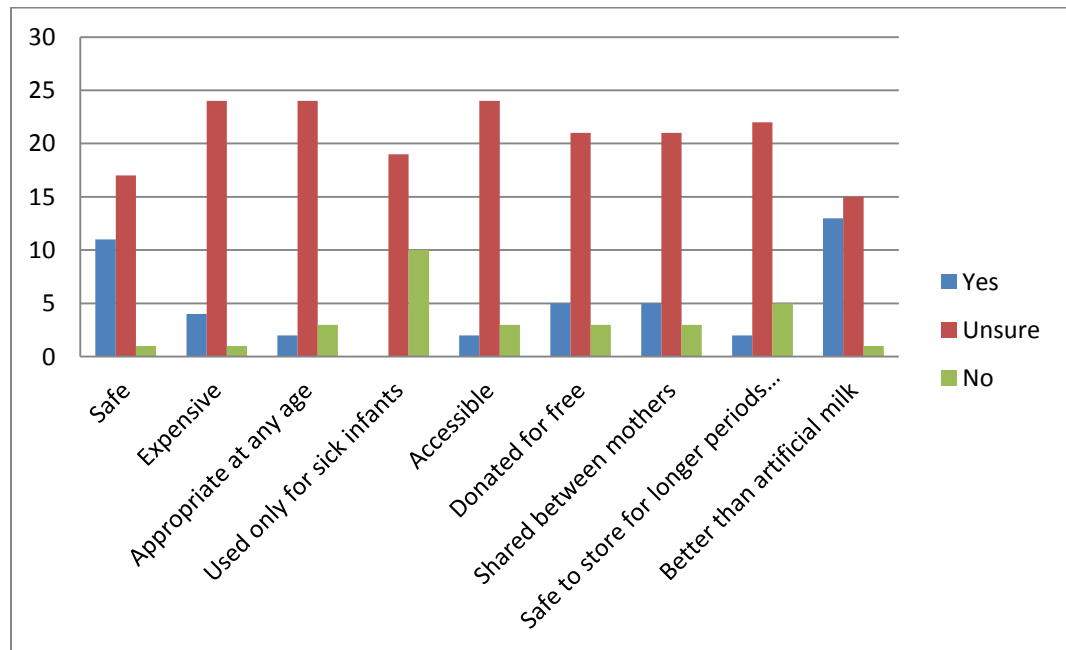
	<b>n</b>	<b>%</b>
<b>Conditions which you would choose NOT to breastfeed</b>	30	
Medically unable		73
Inability to produce enough milk		70
When drinking alcohol		47
Returning to work		17
Smoking		17
Preterm or sick infant		17
Pain or discomfort to breast/nipple		13
Prefer to pump breastmilk and give with a bottle		10
Anxiety		3
Returning to school		3
Artificial milk is just as good as breastmilk		3
<b>*If you chose/choose not to breastfeed for medical reasons, indicate which medical condition</b>		
This question does NOT pertain to me		89
Preterm or sick infant		11
Medications		4
Other		4
<b>Information received by healthcare provider regarding...</b>		
Breastfeeding		73
Human Donor Milk	29	0
Artificial milk (formula)		47
<b>Have you ever heard about using donated human milk to feed newborns</b>		
Yes		53
No		47
<b>*Would you consider donating excess breastmilk to a milk bank</b>		
Yes		70
No		30
<b>Have you known anyone that has used HDM to feed their baby</b>		
Yes		0
No		10
		0
<b>*Where would you go to get HDM</b>	29	
Healthcare provider		48
Hospital		28
Milk Bank		24
Family		10
Friend		7
Acquaintance		3
Other		7

n = total number of responses for question asked

\* = questions considered knowledge and acceptance in nature

**Table 2.** Knowledge of a 30 expectant mothers' surveyed regarding HDM

	n	%
<b>*What would be the maximum out-of-pocket expense you would be willing to pay per ounce of HDM</b>		
None	7	
< \$2	40	
\$3 - \$5	30	
\$6 - \$10	7	
Other	17	
<b>*Certain conditions which must be met before you would consider using HDM</b>		
Discuss safety, risks, and benefits with my healthcare provider	80	
Would NOT be willing to use HDM	20	
Knew the donor	20	
Donor was a friend	13	
Donor was a relative	13	
Other	10	
Did not know the donor	3	



**Figure 1.** Graph analysis of expectant mothers' knowledge as it relates to 9 statements regarding HDM

Although 93% of mothers intended to breastfeed their infant within the first 6 months of life, many reported barriers to breastfeeding which included: medically unable, inability to produce enough milk, when drinking alcohol, smoking, returning to school and/or work, anxiety, pain or discomfort to the breast/nipple and lastly some would choose not to breastfeed because they believe breastmilk to be just as good as artificial milk (formula). Although the majority (73%) responded medically unable, 89% identified themselves as having no pertaining medical condition. In other words, many of the expectant mothers were healthy.

All expecting moms reported not ever knowing anyone to have used HDM to feed their infant. Therefore acceptance and decisions on whether or not to use HDM is not directly related to knowing someone who has used HDM. (Table 3)

**Table 3.** Acceptance of a 30 expectant mothers' surveyed regarding HDM

	<b>n</b>	<b>%</b>
<b>If you have known anyone that has used HDM, did their decision influence your decision on whether or not to use HDM</b>	30	--

n = total responses to question asked

Although the majority of mothers reported uncertainty of facts regarding HDM, the majority of mothers (70%) would consider donating their breastmilk to a milk bank, if in excess. Out of those who would donate their excess breastmilk, 57% percent commented they would do so in order to help others. discussionThese results are consistent with recent research. In a descriptive, cross-sectional study surveying 168 mothers who become human milk bank donors, 75% reported the main reason for donating was in order to help others.<sup>38</sup> The expecting mothers who answered they would

not donate, gave the following reasons: they would use their excess milk to feed their own baby, (which shows they value their breastmilk), others reported being unfamiliar and/ or uncomfortable with donating excess breastmilk to a milk bank.

Participants reported being interested in learning more about: infant nutrition as my baby grows; breastfeeding; breastmilk; Human Donor Milk and Human Milk Banks; Artificial formula; and professional support and community resources.

### **Perceptions**

This study did not find strong enough data as it relates to expecting mothers' perceptions of HDM based on questions asked. What can be reported is the majority of women would donate their excess milk in order to help others. Also, before mothers would use HDM, the majority confirmed the need to speak with their PCP regarding HDM risk, safety and benefits of its use. Lack of perception related questions prevented further data analysis. Further research regarding expecting mothers' perceptions on HDM is needed.

### **Experience**

Experiences of mothers as it relates to previously breastfeeding other children, HDM information obtained and use of HDM were highlighted and analyzed with 6 questions. The majority (97%) of subjects were first time expecting mothers. None of which have had any experiences with HDM. (Table 4)



**Table 4.** Experiences of a 30 expectant mothers' surveyed regarding HDM

	<b>n</b>	<b>%</b>
<b>Did you breastfeed any of your other children</b>	29	
Yes		3
No		
This is my first child		97
<b>Have you ever donated or given your own breastmilk to someone in order to feed their baby?</b>		
Yes		
No		10
		0
<b>To whom did you donate your milk</b>		--
<b>Have you ever received a prescription from a healthcare provider to use HDM to feed any of your previous children</b>		
Yes		
No		20
This is my first child		80
<b>Was your baby fed the HDM prescribed by the healthcare provider</b>		--
<b>Have you ever given HDM that was NOT prescribed by a healthcare provider to any of your previous children</b>	6	
Yes		
No		10
		0

n = total number of responses to questions asked

Further results of decision making regarding how mothers were fed and intend to feed their infants can be seen in table 5.

**Table 5.** Decision Making of a 30 expectant mothers' surveyed regarding HDM

	<b>n</b>	<b>%</b>
<b>Have you made plans on how you will feed your baby for the first 6 months of life?</b>	30	
Breastfeed		93
Bottle feed (my own breastmilk)		20
Bottle feed (with formula)		
I'm not sure		3
<b>How long do you intend to breastfeed?</b>		
1-3 months		3
4-6 months		27
> 6 months		70
<b>How were you fed in the first six months of life</b>		
Breastfed		37
Bottle fed (Mother's own milk)		7
Bottle fed (with formula)		57
I'm not sure		17

n = total responses to questions asked

In addition to the 26 questions participants answered, there was also opportunity for additional comments. Those comments can be seen in Table 6. Comments confirm the lack of knowledge among participants, acceptance to donating excess breastmilk and plans for breastfeeding.

**Table 6.** Comments of a 30 expectant mothers' surveyed regarding HDM

<b>This is the first time I have heard of HDM</b>
<b>I would be more than happy to donate my breastmilk if I have extra. Hope it can help other families</b>
<b>I plan to breastfeed longer than 6 months; most likely for the first year</b>
<b>This is a very informative survey</b>

## CHAPTER IV

### DISCUSSION, CONCLUSION AND RECOMMENDATIONS

#### Discussion

One hundred percent of participants reported having not received any information regarding HDM. These results tell us that the information and little knowledge expectant mothers have regarding HDM has not been provided by a primary health care provider. This may be related to the "lack of evidence"<sup>35</sup> reported in Miracle et al.<sup>9</sup> discussion on the ethical controversy related to infant feeding options informed by healthcare providers. Whether there is significant correlation between how mothers were fed in the first 6 months of life and their decision on how they intend to feed their infant in the first 6 months of life warrants more research.

It has been documented that one of the barriers to breastfeeding lies in the hands of the healthcare provider.<sup>37</sup> Additional education and training is needed for healthcare providers in order to assist women in the important decision to breastfeed.

Even though breastfeeding is the number one recommended feeding option for infants, with HM being a second alternative and artificial formula being third,<sup>19-20</sup> when asked about feeding option information provided by primary healthcare providers, information on only breastfeeding and artificial milk (formula) had been provided.

Currently there is no documented research regarding expectant mothers' knowledge, perception, experience and acceptance of Human Donor Milk in the U.S. Although Australian authors Mackenzie C, Javanparast S and Newman L have researched *Mothers' Knowledge of and Attitudes toward Human Milk Banking in South Australia*<sup>39</sup> which showed support of human milk banking and donating, Another report

by Coutsooudis I, Petrites A and Coutsooudis A, *Acceptability of donated breast milk in a resource limited South African setting*, concluded many obstacles to acceptance due to decreased awareness/familiarity with HDM.<sup>40</sup> Consideration of the ethical issues surrounding collection and allocation of HDM in the U.S. also gives rise to the important role physician's play in woman's' overall actions regarding HDM. As well as the impact unregulated Human Milk Banks (HMB) and infant formula have on medical advances and awareness of HDM.<sup>9</sup> By identifying expectant mothers' current knowledge, perceptions, experiences and acceptance of HDM, we may discover areas which need attention and give rise to future research regarding HDM.

### **Limitations**

There were some limitations to this study: this was a first time researcher-developed survey and study, which warrants validation. Also, the sample size was limited in number and was homogeneous throughout. Also, the majority of participants were first time expecting mothers, all of whom have received some college or technical schooling which does not allow for generalization. In the future, exploring mothers who have previous children as well as those with different education statuses and ethnicities, would be ideal.

Based on the results, 97% of mothers planned to breastfeed their infant for the first 6 months of life, so the study can only report information for mothers who intend to breastfeed and further research is need for those who intend to formula feed.

### **Conclusion and Future Recommendations**

Overall, the results of this study suggest there is a lack of knowledge among highly educated expectant mothers' in regards to HDM. Although over half of the sample

had heard information regarding HDM, none of them reported receiving information from their primary care physician (PCP). With current research supporting HDM as the second alternative to MOM, formula is still being aggressively marketed to expecting mothers and many, if not all, mothers go through their pregnancy never receiving any information regarding HDM. With interest among mothers for more information on regarding HDM and HMDBs, the importance of providing that information by the PCP should not go unacknowledged.

The study also showed the desire of expecting mothers' to help others in regards to infant feeding even without fully knowing the risk and benefits of HDM. The correlation between knowledge and acceptance of HDM has yet to be researched. There was a lack of experiences and little perceptions to report in this study as 97% were first time mothers. Overall, the absence of experience, lack of knowledge and still the leaning acceptance of HDM reveals potential in expecting mothers' willingness to learn more. With the help of PCP and prenatal care health care providers, educating expecting mothers regarding the benefits, risk and use of HDM as well as the available option to donate excess breastmilk, will have a positive outcome for infants needing HDM whether they be preterm vulnerable infants in the NICU setting or full-term infants.

## REFERENCES

1. Parker MG, et al. Pasteurized human donor milk use among US level 3 neonatal intensive care units. *J Hum Lact.* 2013; 29:381-389
2. *Human milk banking association of north america.* 6th ed. ed. Forth Worth, TX.: Human Milk Bank Association of North America, Inc; 2009 Guidelines for the Establishment and Operation of a Donor Human Milk Bank; No. 28.
3. Bertino E, Giuliani F, Occhi L, et al. Benefits of donor human milk for preterm infants: Current evidence. *Early Hum Dev.* 2009;85(10 Suppl):S9-S10.
4. Boyd CA, Quigley MA, Brocklehurst P. Donor breast milk versus infant formula for preterm infants: Systematic review and meta-analysis. *Arch Dis Child Fetal Neonatal Ed.* 2007;92(3):F169-75.
5. McGuire W, Henderson G, Fowlie PW. Feeding the preterm infant. *BMJ.* 2004;329(7476):1227-1230.
6. Updegrave K. Nonprofit human milk banking in the united states. *J Midwifery Womens Health.* 2013.
7. Johnson C., Bay area milk bank facing increased demand. *ABC KGO-TV San Francisco.*  
[http://abclocal.go.com/kgo/story?section=news/health&id=8807295&utm\\_source=buffer&buffer\\_share=e2ab6](http://abclocal.go.com/kgo/story?section=news/health&id=8807295&utm_source=buffer&buffer_share=e2ab6). Published September 11, 2012. Accessed October 20, 2014.
8. Mother's Milk Bank of Iowa submits urgent call for donations. Iowa Breastfeeding Coalition Website. [iabreastfeeding.org/2011/10/mothers-milk-bank-of-iowa-submits-urgent-callfor-donations/](http://iabreastfeeding.org/2011/10/mothers-milk-bank-of-iowa-submits-urgent-callfor-donations/). Published October 14, 2011. Accessed October 20, 2014.

9. Miracle DJ, Szucs KA, Torke AM, Helft PR. Contemporary ethical issues in human milk-banking in the united states. *Pediatrics*. 2011;128(6):1186-1191.
10. Panczuk J, Unger S, O'Connor D, Lee SK. Human donor milk for the vulnerable infant: A canadian perspective. *Int Breastfeed J*. 2014;9:4-4358-9-4. eCollection 2014.
11. Baro C, Giribaldi M, Arslanoglu S, et al. Effect of two pasteurization methods on the protein content of human milk. *Front Biosci (Elite Ed)*. 2011;3:818-829.
12. Ewaschuk JB, Unger S, O'Connor DL, et al. Effect of pasteurization on selected immune components of donated human breast milk. *Journal of Perinatology*.31(9):593-598.
13. Evans TJ, Ryley HC, Neale LM, Dodge JA, Lewarne VM. Effect of storage and heat on antimicrobial proteins in human milk. *Arch Dis Child*. 1978;53(3):239-241.
14. Czank C, Prime DK, Hartmann B, Simmer K, Hartmann PE. Retention of the immunological proteins of pasteurized human milk in relation to pasteurizer design and practice. *Pediatr Res*. 2009;66(4):374-379.
15. Ford JE, Law BA, Marshall VM, Reiter B. Influence of the heat treatment of human milk on some of its protective constituents. *J Pediatr*. 1977;90(1):29-35.
16. Untalan PB, Keeney SE, Palkowetz KH, Rivera A, Goldman AS. Heat susceptibility of interleukin-10 and other cytokines in donor human milk. *Breastfeed Med*. 2009;4(3):137-144.
17. Donalisio M, Cagno V, Vallino M, et al. Inactivation of high-risk human papillomaviruses by holder pasteurization: Implications for donor human milk banking. *J Perinat Med*. 2013:1-8.

18. Goelz R, Hihn E, Hamprecht K, et al. Effects of different CMV-heat-inactivation-methods on growth factors in human breast milk. *Pediatr Res*. 2009;65(4):458-461.
19. Biasini A, Stella M, Malaigia L, et al. Establishment, operation and development of a donor human milk bank. *Early Hum Dev*. 2013;89, Supplement 2(0):S7-S9.
20. Gibbins S, Wong SE, Unger S, O'Connor D. Donor human milk for preterm infants: Practice considerations. *Journal of Neonatal Nursing*. 2013;19(4):175-181.
21. Morales Y, Schanler RJ. Human milk and clinical outcomes in VLBW infants: How compelling is the evidence of benefit? *Semin Perinatol*. 2007;31(2):83-88.
22. Wojcik KY, Rechtman DJ, Lee ML, Montoya A, Medo ET. Macronutrient analysis of a nationwide sample of donor breast milk. *J Am Diet Assoc*. 2009;109(1):137-140.
23. Leaf A, Winterson R. Breast-milk banking: Evidence of benefit. *Paediatrics and Child Health*. 2009;19(9):395-399.
24. Simmer K, Hartmann B. The knowns and unknowns of human milk banking. *Early Hum Dev*. 2009;85(11):701-704.
25. Hair AB, Hawthorne KM, Chetta KE, Abrams SA. Human milk feeding supports adequate growth in infants  $\leq$  1250 grams birth weight. *BMC Res Notes*. 2013;6:459-0500-6-459.
26. Stein H, Cohen D, Herman AA, et al. Pooled pasteurized breast milk and untreated own mother's milk in the feeding of very low birth weight babies: A randomized controlled trial. *J Pediatr Gastroenterol Nutr*. 1986;5(2):242-247.



27. Arslanoglu S, Ziegler EE, Moro GE, World Association of Perinatal Medicine Working Group On Nutrition. Donor human milk in preterm infant feeding: Evidence and recommendations. *J Perinat Med*. 2010;38(4):347-351.
28. Garza C, Nichols BL. Studies of human milk relevant to milk banking. *J Am Coll Nutr*. 1984;3(2):123-129.
29. Lucas A, Morley R, Cole TJ, Lister G, Leeson-Payne C. Breast milk and subsequent intelligence quotient in children born preterm. *The Lancet*. 1992;339(8788):261-264.
30. Fewtrell MS. Breast-feeding and later risk of CVD and obesity: Evidence from randomised trials. *Proc Nutr Soc*. 2011;70(4):472-477.
31. Horwood LJ, Darlow BA, Mogridge N. Breast milk feeding and cognitive ability at 7-8 years. *Arch Dis Child Fetal Neonatal Ed*. 2001;84(1):F23-7.
32. Horwood LJ, Fergusson DM. Breastfeeding and later cognitive and academic outcomes. *Pediatrics*. 1998;101(1):E9.
33. Quigley MA, Henderson G, Anthony MY, McGuire W. Formula milk versus donor breast milk for feeding preterm or low birth weight infants. *Cochrane Database Syst Rev*. 2007;(4)(4):CD002971.
34. Unger S, Gibbins S, Zupancic J, O'Connor DL. DoMINO: Donor milk for improved neurodevelopmental outcomes. *BMC Pediatr*. 2014;14:123-2431-14-123.
35. Szucs KA, Axline SE, Rosenman MB. Quintuplets and a mother's determination to provide human milk: It takes a village to raise a baby--how about five? *J Hum Lact*. 2009;25(1):79-84.

36. Rosenberg KD, Eastham CA, Kasehagen LJ, Sandoval AP. Marketing infant formula through hospitals: The impact of commercial hospital discharge packs on breastfeeding. *Am J Public Health*. 2008;98(2):290-295.
37. Strong G. Barriers to breastfeeding during the neonatal period. *Journal of Neonatal Nursing*. 19(4):134-138.
38. Sierra Colomina G, Garcia Lara N, Escuder Vieco D, Vazquez Roman S, Cabanes Alonso E, Pallas Alonso CR. Profile of human milk bank donors and relationship with the length of the donation. *An Pediatr (Barc)*. 2014; 80(4):236-241.
39. Mackenzie C, Javanparast S, Newman L. Mothers' knowledge of and attitudes toward human milk banking in south australia: A qualitative study. *Journal of Human Lactation*. 29(2).
40. Coutsoudis I, Petrites A, Coutsoudis A. Acceptability of donated breast milk in a resource limited South African setting. *Int Breastfeed J*. 2011; 6:3-4358-6-3.

## APPENDIX A

### **Consent for Participation in a Research Study The University of Memphis Expectant Mothers' Knowledge, Perceptions, Experiences and Acceptance of Human Donor Milk: A Pilot Study**

Thank you, for taking part in this research study.

You are being asked to participate because you are 1) expecting a baby 2) attending prenatal class and 3) you are over the age of 18yr. This study is being conducted at Baptist Women's Hospital in conjunction with the University of Memphis.

My name is Jennifer Marshall and I am the lead investigator for this study. The purpose of this research is to explore expectant mothers' knowledge and experiences with breastfeeding and human donor milk. There are 26 survey questions and 1 comment section at the end that will take approximately 10-15 minutes.

Feel free to answer truthfully and to the best of your knowledge. Researchers in this study will not be able to identify you and only those within the research team will have access to survey data.

During the survey, you may be asked to skip certain questions based on your answers. This survey is completely voluntary. By completing the survey, you are agreeing to participate. You may choose not to participate or withdraw at any time. You will not be penalized in any way should you decide not to complete the survey or withdraw from this study.

You are free to ask questions or voice concerns at any time during or after the study. Please contact Jennifer Marshall at [Marshall..Jenn23@gmail.com](mailto:Marshall..Jenn23@gmail.com) or her advisor, Dr. Ruth Williams-Hooker, MS, RD, EdD (901-678-3108) at [mrwillia@memphis.edu](mailto:mrwillia@memphis.edu). If you have any questions regarding your rights as a participant in this study please contact the University of Memphis Institutional Review Board (901-678-2705) at [irb@memphis.edu](mailto:irb@memphis.edu). Please check one:

I have read this consent form and I give my consent to participate in this study.

I do not wish to participate in this study.

Thanks again,

*Jennifer Marshall*

University of Memphis Graduate Student  
Clinical Nutrition

Regional One Health Graduate Assistant  
901-494-1589

**APPENDIX B**

**EXPECTANT MOTHERS' KNOWLEDGE, PERCEPTIONS,  
EXPERIENCES AND ACCEPTANCE OF HUMAN DONOR MILK: A  
PILOT STUDY.**

Q1. **What is your age?**

<input type="radio"/>	< 18
<input type="radio"/>	18 to 19
<input type="radio"/>	20 to 24
<input type="radio"/>	25 to 34
<input type="radio"/>	35 to 44
<input type="radio"/>	45 to 54
<input type="radio"/>	55 to 64
<input type="radio"/>	>65

Q2. **With which race and ethnicity do you most associate with? (Mark all that apply)**

<input type="radio"/>	White/Caucasian
<input type="radio"/>	African American
<input type="radio"/>	Hispanic
<input type="radio"/>	Asian
<input type="radio"/>	Native American
<input type="radio"/>	Pacific Islander
<input type="radio"/>	Other

Q3. **Please indicate the highest level of education**

<input type="radio"/>	Some high school
<input type="radio"/>	High school graduate
<input type="radio"/>	Some college or technical school
<input type="radio"/>	College graduate
<input type="radio"/>	Post-graduate or professional

**Q4. How many children do you have NOT including this pregnancy?**

<input type="radio"/>	0
<input type="radio"/>	1
<input type="radio"/>	2
<input type="radio"/>	3
<input type="radio"/>	4
<input type="radio"/>	5
<input type="radio"/>	6
<input type="radio"/>	7
<input type="radio"/>	8
<input type="radio"/>	9
<input type="radio"/>	10+

**Q5. What trimester are you currently in?**

<input type="radio"/>	1 <sup>st</sup> (1-13 Weeks)
<input type="radio"/>	2 <sup>nd</sup> (14-26 Weeks)
<input type="radio"/>	3 <sup>rd</sup> (27- 42 Weeks)

**Q6. Have you made plans on how you will feed your baby for the first 6 months of life?**

<input type="radio"/>	Breastfeed
<input type="radio"/>	Bottle feed (my own breastmilk)
<input type="radio"/>	Bottle feed (with formula)
<input type="radio"/>	I'm not sure
<input type="radio"/>	Other _____

**Q7. How long do you intend to breastfeed?**

<input type="radio"/>	1-3 months
<input type="radio"/>	4-6 months
<input type="radio"/>	>6 months
<input type="radio"/>	I do NOT intend to breastfeed

**Q8. Did you breastfeed any of your other children? If Yes, please indicate about how long. Example: 3 Months. If No, why?**

<input type="radio"/>	Yes, for how long? _____
<input type="radio"/>	No, why not?
<input type="radio"/>	This is my first child

Q9.

Under which conditions would you choose <u>NOT</u> to breastfeed? (Mark ALL that apply)	
<input type="radio"/>	Artificial milk is just as good as Breast milk
<input type="radio"/>	Not sure how to breastfeed
<input type="radio"/>	Pain or discomfort (breasts/nipple)
<input type="radio"/>	Breasts (structurally small/big/abnormal)
<input type="radio"/>	Breast changes (sagging, unattractive etc.)
<input type="radio"/>	Prefer to pump breastmilk and give with a bottle
<input type="radio"/>	Lack of pump equipment
<input type="radio"/>	Lack of appropriate storage
<input type="radio"/>	Inability to produce enough milk
<input type="radio"/>	Preterm or sick infant
<input type="radio"/>	Medically unable
<input type="radio"/>	Disapproving spouse or family member
<input type="radio"/>	Siblings present during nursing
<input type="radio"/>	Cultural beliefs or practices
<input type="radio"/>	Returning to school
<input type="radio"/>	Returning to work
<input type="radio"/>	Not enough privacy
<input type="radio"/>	Embarrassment
<input type="radio"/>	Anxiety
<input type="radio"/>	Inconvenient
<input type="radio"/>	When drinking alcohol
<input type="radio"/>	Smoking
<input type="radio"/>	Other _____

Q10.

If you chose/choose not to breastfeed for medical reasons, please indicate which medical condition. (Mark ALL that apply)	
<input type="radio"/>	This question does NOT pertain to me
<input type="radio"/>	HIV/AIDS
<input type="radio"/>	Active Tuberculosis
<input type="radio"/>	Radiation Therapy (Cancer)
<input type="radio"/>	Medications
<input type="radio"/>	Illicit drug use
<input type="radio"/>	Mastectomy
<input type="radio"/>	Implants
<input type="radio"/>	Mastitis
<input type="radio"/>	Preterm or sick infant
<input type="radio"/>	Other _____

**Q11. How were you fed in the first six months of life? (Mark all that apply)**

<input type="radio"/>	Breastfed
<input type="radio"/>	Bottle fed (mother's own breastmilk)
<input type="radio"/>	Bottle fed (with formula)
<input type="radio"/>	I'm not sure
<input type="radio"/>	Other _____

**Q12. Have you received healthcare provider information regarding.....**

	Please choose an answer for each option	
	Yes	No
Breastfeeding	<input type="radio"/>	<input type="radio"/>
Human Donor Milk	<input type="radio"/>	<input type="radio"/>
Artificial milk (formula)	<input type="radio"/>	<input type="radio"/>

**Q13. Have you ever heard about using donated human milk to feed newborns?**

<input type="radio"/>	Yes
<input type="radio"/>	No

**Q14. Based on your knowledge regarding Human Donor Milk, please select the answer you most agree with for EACH of the nine statements.**

Human Donor Milk Is...		Yes	Unsure	No
1	Safe when prescribed by a healthcare provider			
2	Expensive to purchase			
3	Appropriate at any age			
4	Used only for sick infants			
5	Easily accessible			
6	Donated for free			
7	Shared between mothers to feed their infants			
8	Safe to store for longer periods of time than Artificial Milk (formula)			
9	Better than Artificial milk (formula)			



**Q15. Have you ever donated or given your own breastmilk to someone in order to feed their baby?**

<input type="radio"/>	Yes
<input type="radio"/>	No (skip to Q.17)

**Q16. If yes, to whom did you donate your milk? (Mark all that apply)**

To whom	Mark all that apply
Friend	<input type="radio"/>
Family	<input type="radio"/>
Acquaintance	<input type="radio"/>
Church Member	<input type="radio"/>
Community/Support Group	<input type="radio"/>
Hospital	<input type="radio"/>
Milk Bank	<input type="radio"/>
Other	<input type="radio"/>

**Q17. In the instance you had excess breastmilk, would you consider donating to a milk bank? Why or why not?**

<input type="radio"/>	Yes, Why? _____
<input type="radio"/>	No, Why not? _____

**Q18. Have you known anyone that has used Human Donor Milk to feed their baby?**

<input type="radio"/>	Yes
<input type="radio"/>	No (skip to Q.20)

**Q19. If yes, do you feel their decision influenced your decision on whether or not to use Human Donor Milk?**

<input type="radio"/>	Yes
<input type="radio"/>	No

**Q20. Have you ever received a prescription from a healthcare provider to use Human Donor Milk to feed any of your previous children?**

<input type="radio"/>	Yes
<input type="radio"/>	No (skip to Q.22)
<input type="radio"/>	This is my first child (skip to Q.23)

**Q21. Was your baby fed the Human Donor Milk prescribed by the healthcare provider?**

<input type="radio"/>	Yes
<input type="radio"/>	No, Why not? _____

**Q22. Have you ever given Human Donor Milk that was NOT prescribed by a healthcare provider to any of your previous children?**

<input type="radio"/>	Yes
<input type="radio"/>	No

**Q23. In the event you needed Human Donor Milk, where would you most likely get it?**

<input type="radio"/>	Friend
<input type="radio"/>	Family
<input type="radio"/>	Acquaintance
<input type="radio"/>	Community/Support Group
<input type="radio"/>	Church Member
<input type="radio"/>	Hospital
<input type="radio"/>	Healthcare provider
<input type="radio"/>	Milk Bank
<input type="radio"/>	Other _____

**Q24. In the event you needed Human Donor Milk, what would be the maximum amount you would be willing to pay out-of-pocket for each ounce (oz)?**

<input type="radio"/>	None
<input type="radio"/>	< \$2
<input type="radio"/>	\$3 - \$5
<input type="radio"/>	\$6 - \$10
<input type="radio"/>	Other _____

**Q25. Are there certain conditions that MUST be met before you would consider using Human Donor Milk? (Mark ALL that apply)**

<input type="radio"/>	Discuss safety, risks, and benefits with my healthcare provider
<input type="radio"/>	Donor was a friend
<input type="radio"/>	Donor was a relative
<input type="radio"/>	Knew the donor
<input type="radio"/>	Did not know the donor
<input type="radio"/>	Other _____
<input type="radio"/>	I would NOT be willing to use Human Donor Milk

Q26.

Indicate any topics you would be interested in learning more about..... (Mark all that apply)	
<input type="radio"/>	Breastmilk
<input type="radio"/>	Breastfeeding
<input type="radio"/>	Artificial milk (formula)
<input type="radio"/>	Human Donor Milk
<input type="radio"/>	Human Milk Banks
<input type="radio"/>	Infant nutrition as my baby grows
<input type="radio"/>	Professional Support and Community Resources
<input type="radio"/>	None
<input type="radio"/>	Other _____

---

**Please let us know if you have any additional comments.**

**Thank you for completing the survey. The data from this survey will help to identify potential barriers based on the knowledge and experiences of expectant women on the use of Human Donor Milk. We would like to thank you for participating with a small token of our appreciation. Please feel free to contact me with future questions or concerns. Thanks again.**

**Jennifer Marshall**

**Marshall.Jenn23@gmail.com**

## APPENDIX C

Hello,

The University of Memphis Institutional Review Board, FWA00006815, has reviewed and approved your submission in accordance with all applicable statutes and regulations as well as ethical principles.

**PI NAME:** Jennifer Marshall

**CO-PI:** Queen Cox, Emily West

**PROJECT TITLE:** Perceptions of Expectant Women Regarding the use of Donated Human Milk: A Pilot Study

**FACULTY ADVISOR NAME (if applicable):** Ruth Williams-Hooker

**IRB ID:** #2391

**APPROVAL DATE:** 7/18/2014

**EXPIRATION DATE:** 9/12/2014

**LEVEL OF REVIEW:** Full Board Modification

**RISK LEVEL DETERMINATION:** More than minimal

*Please Note: Modifications do not extend the expiration of the original approval*

**Approval of this project is given with the following obligations:**

- 1. If this IRB approval has an expiration date, an approved renewal must be in effect to continue the project prior to that date. If approval is not obtained, the human consent form(s) and recruiting material(s) are no longer valid and any research activities involving human subjects must stop.**
- 2. When the project is finished or terminated, a completion form must be completed and sent to the board.**
- 3. No change may be made in the approved protocol without prior board approval, whether the approved protocol was reviewed at the Exempt, Exedited or Full Board level.**
- 4. Exempt approval are considered to have no expiration date and no further review is necessary unless the protocol needs modification.**

**Approval of this project is given with the following special obligations:**

**Thank you,**

**Pamela M. Valentine**

**Interim Institutional Review Board Chair**

**The University of Memphis.**

## APPENDIX D



J Cameron Hall, MD Chair  
Grace Miller, IRB Coordinator  
grace.miller@BMHCC.org  
Chanta Williams, IRB Admin. Asst.  
chanta.williams@BMHCC.org

July 7, 2014

Jennifer Marshall  
University of Memphis Graduate Student  
Clinical Nutrition  
Regional One Health Grade Assistant

[marshall.jenn23@gmail.com](mailto:marshall.jenn23@gmail.com)

RE: *Perceptions of Expectant Women Regarding the use of Donated Human Milk: A Pilot Study*  
Expectant Mothers' Knowledge, Perceptions, Experiences and Acceptance of Human Donor  
Milk - A Pilot Study

**BMH-IRB 13-46**

Dear Ms. Marshall:

Thank you for submitting the Amendment for your project entitled, "*Expectant Mothers' Knowledge, Perceptions, Experiences and Acceptance of Human Donor Milk - A Pilot Study*". I have reviewed the materials you submitted outlining your project

It is noted that you continue to follow Good Clinical Practice in regards to the HIPPA regulations in your subject survey. This pilot study will only be conducted at the Baptist Memorial Hospital for Women

As an anonymous survey this pilot study does not meet the Common Rule definition of research at 45CFR46.101(b) Exemption 2, or the FDA definition of a clinical trial at 21CFR50.3(c). Therefore, this project does not need to be reviewed by the Baptist Memorial Health Care Corporation Institutional Review Board per Patty Claiborne, Pharm.D. BMH-IRB Vice-Chair July 7, 2014.

A digital signature of Patty Claiborne, written in a cursive script. The signature is overlaid on a background of a colorful, pixelated pattern with the word "MEMPHIS" repeated in various colors.

Patty Claiborne, Pharm.D., BMHCC-IRB Vice-PC/gam

6025 Walnut Grove Road, Suite 404, Memphis, Tennessee 38120  
Phone (901) 226-1677 Fax (901) 226-1680

Document Security. The signature is in a multicolored block and the watermark is based on the Baptist logo.