Supporting Statement A

Early Hearing Detection and Intervention Pediatric Audiology Links to Services (EHDI-PALS) Survey

OMB # 0920-0955

Revision

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List of Attachments

Attachment 1a: Public Health Service Act

- Attachment 1b: Early Hearing Detection and Intervention Act of 2010
- Attachment 2: 60-Day Federal Register Notice
- Attachment 2a: 30-Day FRN
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- Attachment 4: Annual Survey Reminder Email to Audiologists from University of Maine
- Attachment 5: List of EHDI-PALS Collaborators
- Attachment 6: Non-research Determination

- **Goal of the study:** The Early Hearing Detection and Intervention-Pediatric Audiology Links to Services (EHDI-PALS) survey is administered to all audiologists. It was developed to quantify the distribution of pediatric audiology facilities in the U.S. and how often providers report diagnostic hearing test results to their state newborn hearing screening jurisdiction. The goal is to increase the number of infants who are screened for hearing loss and referred to specialized diagnostic and intervention services early in life, thus minimizing preventable delays in speech, language, and cognitive development.
- Intended use of the resulting data: Data will be compiled into a distribution map for the CDC-EHDI team and the state newborn hearing screening program personnel to visualize the geographic region of the resource shortage and the distribution of infants who are lost to follow up in relationship to the pediatric audiology clinic distribution. Parents and physicians will be able to use the data to identify and locate an appropriate pediatric audiology facility that is equipped to test infants and young children.
- Methods to be used to collect data: Data will be collected on-line via a secure internet portal EHDIPALS.org.
- **The subpopulation to be studied:** Audiologists especially those who can provide services to children age 0 to 5 years.
- How data will be analyzed: Qualitative analyses will be conducted for the geo-coded facility locations, the types of services that facilities can offer, and how often each facility reports hearing evaluation results to the state EHDI program. Findings will be compiled into downloadable reports for the CDC-EHDI team and state program personnel. Information will also be made available to consumers.

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is submitted under the classification "**Revision**." The length of data collection requested for OMB-PRA approval is three years. The National Center on Birth Defects and Developmental Disabilities (NCBDDD) is making this request as authorized by the Public Health Service Act, Title 42 United States Code—The Public Health and Welfare, Chapter 6A—Public Health Service, Subchapter II—General Powers and Duties, Part A—Research and Investigations (*Public Health Service Act, 42 USC Sec. 241* Attachment 1a).

Background

NCBDDD at the Centers for Disease Control and Prevention (CDC) promotes the health of babies, children, and adults, with a focus on preventing birth defects and developmental disabilities and optimizing the health outcomes of those with disabilities. Congenital hearing loss is a common birth defect that affects 1 to 3 per 1,000 live births, or approximately 12,000 children across the United States annually.^{1, 2, 3} Studies have shown that children with a delayed diagnosis of hearing loss can experience preventable delays in speech, language, and cognitive development.^{4, 5}

Since the passage of the Early Hearing Detection and Intervention (EHDI) Act, renewed in 2010, all U.S. states, the District of Columbia, and 5 territories (American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and U.S. Virgin Islands) have implemented Early Hearing Detection and Intervention (EHDI) programs and enacted state laws and regulations related to infant hearing screening and follow up. The "1-3-6" goal has been adopted by all EHDI programs which consists of: 1) screening all infants for hearing loss by 1 month of age, 2) ensuring diagnostic audiologic evaluation by 3 months of age for those who do not pass the screening, and 3) enrollment in early intervention services by 6 months of age for those identified with a hearing loss. The Early Hearing Detection and Intervention Act of 2010 (section 399M of the Public Health Service Act 42 USC 280g-1, Attachment 1b) authorizes "(1) Centers for Disease Control and Prevention..... conduct(s) applied research related to newborn and infant hearing screening, evaluation and intervention programs and systems" and requires that these findings be made publicly available. According to the 2013 CDC-EHDI's Hearing Screening and Follow-up Survey (HSFS, OMB No. 0920-0733), the national average loss to follow up/ loss to documentation rate is 32%, varying from 4% to as high as 86% in some states. The high rate in certain states remains an area of critical concern for the states and CDC-EHDI team's goal of timely diagnosis by 3 months of age and intervention by 6 months of age.

Loss to follow up: Many state EHDI coordinators cite a shortage of pediatric audiologists and facilities as the main factor contributing to loss to follow-up. Prior to the initiation of the EHDI-PALS survey in 2013, this claim could not be quantified in the literature or by any survey.

Loss to documentation: Although many states have legislation requiring providers to report children diagnosed with a hearing loss to the state, the states were unable to quantify the

number of children lost to documentation (due to providers neglecting to report) prior to the initiation of the EHDI-PALS (Pediatric Audiology Links to Services) survey. The EHDI-PALS survey remains the only source of information about providers' reporting compliance.

Both the American Speech-Language-Hearing Association (ASHA) and the American Academy of Audiology (AAA) maintain membership databases, searchable by audiologist's (i.e., member's) name. Neither database is searchable by the facility where the audiologist works. However, the natural search behavior of a parent, physician, or stakeholder is to search by facility or by the type of audiology service a facility can offer. As a result, parents, physicians and stakeholders are left with information resources that are not well adapted to their needs. To compound the problem, many pediatric audiologists may be proficient in evaluating children age 5 and older but are not proficient in evaluating infants or young children, because their assessments for infants and children < 5 require a different skill set. To date there is no existing literature or database that state EHDI program personnel can use to verify and quantify the true distribution of the pediatric audiology resources in a state.

Early Hearing Detection and Intervention-Pediatric Audiology Links to Services (EHDI-PALS) is a project conceptualized by the CDC-EHDI team with input from an advisory group of external partners. The EHDI-PALS workgroup has broad representation from ASHA, AAA, the Joint Committee on Infant Hearing (JCIH), the National Center for Hearing Assessment and Management (NCHAM), the Directors of Speech and Hearing Programs in State Health & Welfare Agencies (DSHPSHWA), the University of Maine College of Education and Human Development, and Hands & Voices. Meeting since April 2010, the EHDI-PALS workgroup has sought consensus on the loss to follow up/ loss to documentation issue facing the EHDI programs.

With the originally approved EHDI-PALS data collection (OMB No. 0920-0955), a survey based on standard of care practice was developed and administered to all audiologists to quantify the pediatric audiology resource distribution within the U.S. and how often pediatric audiology providers report diagnostic hearing test results to their state EHDI jurisdiction. Both ASHA and AAA, being members of the EHDI-PALS workgroup, disseminated announcements through association e-newsletters and e-announcements to all audiologists requesting that they complete the approved EHDI-PALS survey. During the initial three years of OMB approval, we originally anticipated 1500 pediatric audiologists would complete the survey annually. As of 4-17-2016, 1005 pediatric audiologists have read through the purpose statement and completed the survey. The overall response rate is 67% (1005/1500) which is far better than a typical survey response rate of 30%. Since this method has proven very effective in reaching out to audiologists, the same survey announcement and data collection method will continue to be used for the next three years.

Facilities do change their clinical services, the types of insurance they accept and hours of operation. For example, a facility may soon offer a new service or the facility no longer accepts patients with Medicaid coverage, etc. To keep the facility information up to date for parents and physicians, we will send a reminder to all 1005 pediatric audiology facility contacts who

have previously responded to the EHDI-PALS survey, requesting that they review their previous survey answers on a yearly basis. Out of the 1005 pediatric audiologists currently in our database, we expect that 800 pediatric audiologists will review their survey answers. We will continue to invite and encourage the participation of audiologists who have not yet completed the survey.

A.2. Purpose and Use of the Information Collection

The EHDI Act of 2010 explicitly requires programs across the United States to screen infants for hearing loss, audiological diagnostic evaluations, and early intervention to enhance language, communication, cognitive and social skill development. The purpose of this information collection is to identify and quantify audiologists and facilities in the U.S. that can provide services for children 5 years of age and younger. The facilities where the pediatric audiologists work and the types of pediatric services the facility can provide will be compiled into a distribution map for the CDC-EHDI team, state program personnel, and the public. The distribution map will help program personnel visualize the geographic distribution. Parents and physicians will be able to use the data to identify and locate an appropriate pediatric audiology facility that is equipped to test infants and young children. The collected data will be used in the following ways:

- The data from this survey are compiled as downloadable reports for state EHDI programs to build capacity, conduct quality improvement activities, and provide data for Healthy People 2020 objective ENT-VSL-1.2: increase the proportion of newborns who receive audiologic evaluation no later than age 3 months for infants who did not pass the hearing screening. For example, Texas state personnel have accessed the compiled reports over 1000 times and used the information to reduce their loss to follow-up rate from 74% to 61% in 3 years. This data has proven to be valuable to state EHDI programs in doing outreach.
- Sections 5 to 13 of the survey (**Attachment 3**) will inform the CDC-EHDI team and state EHDI programs the number of audiology facilities equipped to provide hearing test, hearing aid and rehabilitative services for infants and young children and the number of providers who can provide these services.
- The types of audiologic services each facility can offer will be made available for parents, pediatricians, and family physicians in a searchable directory designed according to natural internet searching behavior of a user (i.e., by types of services, state, zip code, and distance).
- Data collected from sections 5 to 13 are compiled into a distribution map shared with the state program personnel and accessible by password in the EHDI-PALS website. The map will reveal the facility distribution pattern across zip codes and the geographic regions with a dearth of audiology providers and facilities. Using the

distribution map, state personnel can also determine if distance parents have to drive in order to reach the nearest facility is contributing to their state's loss to follow up rate. For example in Iowa, both the northwest and southeast corners of the state lack pediatric audiology facilities. Parents who reside in these areas typically have to drive over 100 miles to reach the closest facility. This is likely to be the main reason for Iowa's high loss to follow up rate.

- Data collected from the survey will also be used by the CDC-EHDI team in combination with U.S. Census Bureau's household income data to study whether economic factors may also play a part in contributing to loss to follow up rate in certain geographic areas. For example in Indiana, household income appears to predict the odds ratio of a child lost to follow up. With every \$10,000 decrease in household income, the odds of a child lost to follow up increase by 20%.
- Section 4 of the survey allows the CDC-EHDI team and state EHDI programs to quantify the rate of facilities not reporting test results to the state. This is the loss to documentation rate when children have received follow up but providers fail to report the result to the states. For example, New York has the highest rate of audiologists not compliant with reporting hearing test results to the state. We are also able to discern that approximately 40% of pediatric audiology facilities in Texas report only one third of their newly identified hearing loss cases to the state; while over 95% of facilities in Iowa consistently report newly identified hearing loss cases to the state.
- Since EHDI-PALS went live in April 2013, the high usage rate demonstrated the value and usefulness of the data collected. To date the website logged over 140,000 hits for the searchable facility database.

It is imperative for us to continue the data collection because if audiology facility distribution data are not available it will be difficult, if not impossible, for CDC and state EHDI programs to continue the surveillance and tracking effort as required by the Early Hearing Detection and Intervention Act of 2010. Failure to collect updated information would also result in the elimination of a useful tool for providers and parents to ensure infants who have failed a hearing screening test receive timely diagnosis and follow up.

A.3. Use of Information Technology and Burden Reduction

In order to reduce the burden on respondents, this survey will continue to be made available via a secure password protected website. Placing the survey on the internet ensures convenient, on demand access by the audiologists. Financial cost is minimized because no mailing fee will be associated with sending or responding to the survey. As with the original data collection, data quality will remain high because it will incorporate a pediatric standard of care algorithm to ensure the survey questions are logically constructed to truly reveal a facility's follow up service capability. The data will also remain up to date because an auto-generated e-

mail will be sent to the facility contacts to remind them to review the survey answers annually (**Attachment 4**).

A.4. Efforts to Identify Duplication and Use of Similar Information

No other federal agencies collect this type of information. There have been other surveys conducted by non-governmental organizations regarding audiologists' clinical services. Both ASHA and AAA maintain a database of all their member audiologists. ASHA has an on-line tool, the ProSearch, to help consumers identify audiologists who will provide services for young children. However, this on-line tool displays only the age group the audiologist serves rather than the facility the audiologist is affiliated with. The AAA's on-line search tool is limited because it displays only the audiologist's name and does not provide information about whether the audiologist can and will see infants. Neither of the existing tools has been found helpful to parents, physicians, or EHDI coordinators who need to know which facility is truly equipped to test hearing of an infant or young child.

Although many states have legislation requiring providers to report children diagnosed with a hearing loss, prior to implementation of the EHDI-PALS survey none of the states were able to quantify the number of children lost to documentation, i.e., the number of children that providers neglected to report to the state. This survey remains the only survey of its kind that collects information on reporting compliance and the reason(s) why providers neglect to report. Thus, there are no previous or current collections that provide the data needed by CDC and the state EHDI programs. As a result the CDC–EHDI team collaborated with the EHDI-PALS workgroup to develop this survey.

A.5. Impact on Small Businesses or Other Small Entities

According to the 2015 ASHA membership survey⁶, there were 8,963 audiologists in the U.S. Approximately 54.1% (4,852) of these audiologists provided care in a non-residential health care facility, 28.9% (2,592) in hospital settings and 21.8% (1,956) were owners of a private practice⁷. These privately owned audiology facilities can be considered small businesses. Some of these privately owned audiology facilities provide audiologic care for children age 5 and younger. The survey hopes to capture any providers or facilities capable of providing pediatric audiologic care for children age 0 to 5 years including private practice audiologists and privately owned facilities. In order to reduce the burden on respondents, this survey will continue to be made available via a secure password protected website. Placing the survey on the internet ensures convenient, on demand access by the audiologists. Financial cost is minimized because no mailing fee will be associated with sending or responding to the survey. Participation is voluntary and does not impose recordkeeping requirements or other additional burden to respondents.

A.6. Consequences of Collecting the Information Less Frequently

This tracking and surveillance effort is mandated by the federal Early Hearing Detection and Intervention Act of 2010 (section 399M of the Public Health Service Act 42 USC 280g) and jurisdiction-specific laws in all 50 states, the District of Columbia, and the U.S. territories of American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and U.S. Virgin Islands. Its purpose is to improve referrals, follow-up and early intervention efforts. To be most effective, these activities must be based on accurate information. The annual survey is necessary to capture current information about the distribution of service providers and their state-specific reporting practices.

Each respondent will be asked to respond once.

There are no legal obstacles to reduce the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with regulation 5 CFR 1320.5.

A.8. <u>Comments in Response to the Federal Register Notice and Efforts to Consult Outside</u> <u>Agency</u>

- A. A copy of the agency's 60-day Federal Register Notice is attached (Attachment 2). The notice, as required by 5 CFR 1320.8 (d), was published on September 8, 2016 (volume 81, number 174, page 62138). No substantive public comments were received in response to this notice.
- B. <u>Consultations with Individuals outside the organization</u>: Since December 2009, the CDC-EHDI team has collaborated with the EHDI-PALS workgroup on this data collection effort to maximize the quality and utility of this data collection and ensure that it provided essential information (**Attachment 5**).

A.9. Explanation of Any Payment or Gift to Respondents

There are no plans to provide any payment or gift to respondents.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by the NCBDDD Privacy Officer, who has determined that the Privacy Act does not apply. Survey respondents will be asked for information about the facility's capability and capacity to provide audiologic care for children age 0 to 5 years. The name and e-mail contact of each facility is collected so that in the event an error is noted in the facility data, the state EHDI program personnel can alert the facility contact to correct the error. The contact person's name and e-mail can only be accessed by the state EHDI program personnel and University of Maine College of Education and Human Development staff who maintain the password-protected website and database. While names of respondents will be known, respondents are not asked for personal information about themselves or about the infants they have seen.

Participation is voluntary and consent is implied by completion of the survey. Respondents can choose to stop at any time and return later to complete the survey. Respondents are advised that only the facility information portion is posted in a directory accessible by parents and the state EHDI program personnel in the EHDI-PALS website.

There is no website content directed at children under 13 years of age.

A.11. Institutional Review Board (IRB) and Justification of Sensitive Questions

I. <u>Non-research Determination</u>

The CDC IRB has determined that the EHDI-PALS survey is public health practice, not research involving human subjects. IRB approval is not required (see **Attachment 6** for the current CDC documentation). The database will not include any identifiable or personal data and is considered public health practice.

II. <u>Sensitive Questions</u>

There are no items considered to be highly sensitive for respondents in this data collection. Collected data is about the audiology services each facility can provide. No demographic, race, ethnicity, or age question is asked. The license numbers of providers who are pediatric audiologists are requested. However, this is not a sensitive question as the license numbers of all U.S. audiologists are publicly posted and obtainable from each state licensure board website, including suspended and revoked licenses. In addition to the state licensure boards, audiologists' license numbers are also publicly posted in the National Provider Identification directory in the Centers for Medicare and Medicaid website.

A.12. Estimates of Annualized Burden Hours and Costs

Information will be collected through the online EHDI-PALS survey (Attachment 3).

For first-time respondents, the estimated burden per response is 9 minutes, based on a previous timed pre-test with 6 volunteer audiologists. We estimate that we will receive 200 responses per year from first-time respondents.

Respondents who submitted information in prior years only need to verify or update their responses. The estimated burden per response for this task is 2 minutes. Currently, the EHDI-PALS database has information about 1005 facilities (as of 4-17-2016). We estimate that approximately 800 facilities will participate in the verification and update process.

We are also providing an estimated burden of 1 minute per response for respondents from each facility who will discontinue their participation after accessing the online survey and reviewing the instructions. We estimate that approximately 400 respondents will drop out annually without reporting information through the EHDI-PALS survey.

The total estimated annualized burden for all activities is 64 hours.

Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in minutes)	Total Burden Hours
Audiologist or practice representative (first- time participant)	EHDI-PALS Survey	200	1	9/60	30
Audiologist or practice representative (previous participant)	EHDI-PALS Survey	800	1	2/60	27
Audiologist or practice representative (survey dropout)	EHDI-PALS Survey Introduction	400	1	1/60	7
	Total		•	•	64

Table A.12-1 Estimates of Annualized Burden Hours

12. B. Annualized Cost to Respondents

The hourly wage for respondents was estimated using ASHA's audiology member survey publicly available in ASHA website⁷. The average annual salary for an audiologist is \$75,000. This salary divided by 40 hours per week results in an estimated hourly wage of \$36.00. The total estimated cost burden on all survey respondents is \$2,304 (64hr x \$36.00). The estimated cost per respondent who completes or reviews the survey is estimated to be \$2.05 (\$972 + \$1080 / 1000 respondents).

Table A.12-2

Respondents	Form Name	Number of Respondents	Total Burden Hours	Average Hourly Wage	Total Cost
Audiologist or practice representative (first- time participant)	EHDI-PALS Survey	200	30	\$36.00	\$1,080
Audiologist or practice representative (previous participant)	EHDI-PALS Survey	800	27	\$36.00	\$972

Audiologist or practice	EHDI-PALS				
representative (survey	Survey	400	7	\$36.00	\$252
dropout)	Introduction				
	Total				\$2,304

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital or maintenance costs to survey respondents associated with this survey.

A.14. Annualized Costs to the Federal Government

The average annualized cost to the Federal Government to collect this information is \$43,124. The federal government personnel estimate is based on cost of the Project Officer, who is responsible for the management and oversight of the project (Table A.14). These figures include the costs for material preparation, data review and clean up, result analysis, assistance to state personnel and consultation with the University of Maine programmer. The survey will be administered through the EHDI-PALS website, which greatly reduces the administrative costs to the government.

Table A.14.

			Total
	CDC Project Officer	Preparing OMB materials (one-time cost)	\$1,260
Federal Government Personnel	CDC Project Officer (GS- 13 at 10 % time)	Survey review, clean up and consultation with programmer	\$10,466
Costs CDC Project Officer (GS- 13 at 10 % time)		Assisting state personnel in interpreting capacity and shortage issues	\$10,466
	CDC Project Officer (GS- 13 at 20 % time)	Result analysis	\$20,932
	Annual Estimated Costs		\$43,124

A.15. Explanations for Program Changes or Adjustments

This Revision request provides a more refined estimate of respondent burden, based on our experience with the system and the availability of data collected in previous cycles of survey administration. In the initial information collection request, the estimated burden per response was 9 minutes. This estimate remains accurate for a first-time respondent, however, we have revised the number of respondents in this category. The burden per response is lower for

respondents who only need to verify or update the information that they reported in a prior year. In this Revision ICR, the number of respondents in this category is now provided as a separate estimate.

Finally, we are providing a separate estimate for the number of respondents who access the survey, then discontinue their participation after reviewing the instructions and the statement of project purpose. For dropouts the estimated burden per response is 1 minute.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The collection of this information will enable the CDC-EHDI team to quantify:

- The number of audiology facilities that can provide hearing tests, hearing aid fittings, hearing aid and cochlear implant services for infants and young children. The survey also collects information about the types of insurance accepted and the availability of interpreter services.
- The zip code areas and geographic regions that have a dearth of audiology facilities.
- The number of facilities in each state that are not reporting test results and diagnosis to the state EHDI program. This is the loss to documentation rate when children have received follow-up but providers fail to report the result to the state.

Sending our annual survey reminder and recruitment for new survey participants will continue after OMB approval. The entire study is intended to be ongoing to support parents, state EHDI program and to fulfill CDC EHDI team's congressional mandate: Early Hearing Detection and Intervention Act of 2010 (section 399M of the Public Health Service Act 42 USC 280g). See Table A16 below which outlines the project schedule by activity.

Project Time Schedule Year 1			
Activity	Time Schedule		
Notify AHSA and AAA so the third national notification	1 month after OMB approval		
to audiologists to complete survey can begin			
Notify University of Maine so they can auto-generate	1 month after OMB approval		
reminder e-mail to audiologists who have previously			
completed the approved survey			
Monitor incoming facility data and analyze data	2 to 12 th month after OMB approval		
Notify University of Maine so they can auto-generate	12 th month after OMB approval		
reminder e-mail to audiologists who have previously			
completed the approved survey			

Table A.16 Project Time Schedule

Project Time Schedule Year 2			
Activity	Time Schedule		
Notify AHSA and AAA so the fourth national notification to audiologists to complete survey can begin	13th month after OMB approval		
Monitor incoming facility data and analyze	14 to 24 th month after OMB approval		
Notify University of Maine so they can auto-generate reminder e-mail to audiologists who have previously completed the approved survey	24 th month after OMB approval		

Project Time Schedule Year 3			
Activity	Time Schedule		
Notify AHSA and AAA so the fifth national notification to audiologists to complete survey can begin	26 th month after OMB approval		
Monitor incoming facility data and data analysis	27 to 36 th month after OMB approval		
Notify University of Maine so they can auto-generate reminder e-mail to audiologists who have previously completed the approved survey	36 th month after OMB approval		

Analysis Plan:

At the conclusion of another 3-year survey period, EHDI-PALS workgroup members will collaborate with University of Maine programmers to analyze data for the following:

- The number of audiology facilities that can provide hearing services for infants and children less than 5 years of age.
- The zip code areas and geographic regions that continue to have a dearth of audiology facilities.
- The number of facilities in each state who are not reporting test results and diagnosis to the EHDI program. This is the loss to documentation rate when children have received follow up but providers fail to report the result to EHDI programs.
- Download and merge US Census Bureau's American Community Survey Household income tract data with the EHDI-PALS facility data to assess whether the following factors are predictive of the loss to follow-up rate: the overall distance to an appropriate facility a household has to travel, and/or the social economic income level of a household.

A.17. <u>Reason(s) Display of OMB Expiration Date is Inappropriate</u>

No such exemption is requested. The OMB expiration date will be displayed.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions apply to this data collection. _

References

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- 7. American Speech-Language and Hearing Association. 2010 Audiology Survey- Private Practice. <u>http://www.asha.org/research/memberdata/AudiologySurvey/</u> and <u>http://www.asha.org/uploadedFiles/2012-Audiology-Survey-Focus-Patterns.pdf</u>