



National Registry of Myotonic Dystrophy and Facioscapulohumeral Muscular Dystrophy Patients
and Family Members

Dear Registry Applicant,

Thank you for your interest in the **National Registry of Myotonic Dystrophy and Facioscapulohumeral Muscular Dystrophy Patients and Family Members!** The Registry was established through a contract with the National Institutes of Health to link people with Myotonic Dystrophy and FSHD with researchers who are studying these rare diseases. At this time, we are registering individuals with FSHD and DM, as well as unaffected family members. Therefore, we invite you to encourage other family members to apply.

In this packet, you will find the forms necessary to apply to the Registry. To apply, please complete the following steps:

1. There are two identical *Consent Forms*. Please read and sign one of these forms. The **entire copy** of the signed *Consent Form* must be returned to us in order for us to review your information. The second *Consent Form* is for your files.
2. Please complete the *Patient Information Form* and return it to us.
3. Please complete the *Request for Medical Information Form* and return it to us. This form gives us your permission to communicate directly with your neurologist and/or primary care physician. We would be happy to request your medical records on your behalf once we receive this signed form.
4. Optional: If you would like to communicate with us via email, you must sign an additional consent form, the *Patient Email Consent Form*. This form is optional, but must be completed if you want to use email to communicate with National Registry staff. There are two copies of this form – return one signed copy to us. The second copy is for your files.

For your convenience, we have enclosed a postage paid envelope. Please place all signed forms into this envelope and return the packet to us. Once all of your information is received, it will be reviewed carefully. You may receive a phone call or letter from one of the study coordinators to clarify information.

If you have any questions as you complete this process, please do not hesitate to call us. Our toll free number is 1-888-925-4302. Once we have your signed email consent form, you may email us at dystrophy_registry@URMC.rochester.edu.

We sincerely appreciate your willingness to participate in this important endeavor!

Sincerely,

James Hilbert, MS
Health Project Coordinator

Elizabeth Luebbe
Health Project Coordinator



National Registry of Myotonic Dystrophy and Facioscapulohumeral Muscular Dystrophy Patients and Family Members

National Registry of Myotonic Dystrophy and Facioscapulohumeral Muscular Dystrophy Patients and Family Members

Consent Form

Principal Investigator: Rabi Tawil, MD Study
Coordinator: James Hilbert, MS
Study Coordinator: Elizabeth Luebbe, MS

This consent form describes a study, what you may expect if you decide to take part, and important information to help you make your decision. Please read this form carefully. Please ask questions about anything that is not clear before you agree to participate.

Please note:

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- There are risks from participating and you should understand what these mean to you.

INTRODUCTION:

You are being asked to participate in this study because you or a family member has myotonic dystrophy (DM), facioscapulohumeral muscular dystrophy (FSHD), or a related disease (whose symptoms are similar to those of DM or FSHD).

This study is a patient registry, which collects and stores medical information, family history, and other related information from patients for medical research.

This study has been established at the University of Rochester with the support from the National Institutes of Health (NIH). This study has been operational since September 2000 and is being conducted by Dr. Tawil of the University of Rochester's Department of Neurology (Rochester, NY).

PURPOSE

The purpose of this study is to collect information about the symptoms of DM and FSHD and to connect patients with researchers. This study's main goals are to:

- 1) Help researchers collect and study accurate, firsthand information on how DM and FSHD affect people;
- 2) Help researchers recruit patients with DM and FSHD into clinical trials;
- 3) Share information about exciting opportunities and advances in DM and FSHD with patients, care providers, and researchers.

What do I do?

1.) Complete questionnaires and other forms on DM and FSHD

Participation involves completing questionnaires about DM or FSHD. Unaffected family

members will complete a shortened questionnaire. With your permission, we will request your medical records about your DM or FSHD. Once you are enrolled, the study staff will send you a questionnaire through mail, email, or social media each year to update your information.

One way the study helps advance knowledge of DM and FSHD is by sharing this detailed medical and other information about patients with other researchers, **while still protecting your privacy**. This is done by hiding any information that could identify you (your name, address, etc.) from the researchers. The information that we share with researchers is “de-identified” because all personal identifiers have been removed. Your personal information such as your name, address, or other information that identifies you or your family will be labeled with a code number, stored in a secure place, and protected with a password. Only authorized people who work in the Registry will have access to this code and your protected information.

Your identifiable information will not be shared with anyone outside the Registry (unless you give your permission to share it). Approved scientists, researchers, and clinicians will be allowed to see and study only the de-identified information (information that has been removed of all identifiers). They can analyze this de-identified information to study the most common symptoms in DM and FSHD, learn how they progress over time, and other topics to better understand these rare diseases and to develop new treatments.

A subset of de-identified information collected from you may be shared with certain other databases. We may share de-identified information with other registries that collect information on many rare disease and registries specific for DM and FSHD in Germany, Italy, and Australia for example. We may share de-identified information with other databases in order to develop global knowledge of DM and FSHD that may lead to new research studies, clinical trials, and clinical treatments.

2.) Receive information about other studies and decide if you want to join

Another way the Registry supports research is by helping recruit patients who may be eligible to participate in other studies. These other studies may involve traveling to research centers across the US or completing questionnaires at home. Unaffected family members may be recruited to complete studies on quality of life or to serve as “healthy controls” to compare muscles strength or other things to people with DM or FSHD.

Approved researchers can recruit patients who look like a good match for their study. If you are a good match, you will be provided with a description of the study through mail, email, or social media and given information on how to contact the researchers (their name, phone number, etc.). It is up to you to choose whether or not to contact the researchers. The researcher cannot contact you directly.

3.) Receive newsletters and other updates

We provide newsletters and other updates through mail, email, or social media with exciting news in DM and FSHD research and clinical care. You can specify how you’d like to receive this information.

Who is conducting this study?

Dr. Rabi Tawil is the Principal Investigator. Drs. Mike McDermott and Charles Thornton are Co-Investigators.

This study is also guided by members of its Scientific Advisory Committee. Members of this

committee include scientists and researchers from all over the United States and Canada, who were instrumental to the development and design of the forms of the Registry and who provide ongoing support to review research applications submitted to the Registry. Researchers all over the world can use the Registry.

Is my information safe and confidential?

Yes! We follow stringent federal, state, and University guidelines to protect your privacy. Examples include the federal Health Insurance Portability and Accountability Act (HIPAA) which provides guidelines for maintaining privacy and the security of health information. All requests from other researchers or databases to use information from the Registry are reviewed by our Scientific Advisory Committee. Other safeguards are discussed on pages 5 and 6.

How do researchers apply to the Registry?

Researchers interested in using the Registry to analyze information or recruit patients submit a brief application and summary of their study. These studies are reviewed by the Registry's Scientific Advisory Committee. Studies are reviewed for safety, privacy, and scientific purpose. Upon approval, the Registry staff will work with the researcher to determine which members to recruit based on the number of subjects needed, the inclusion and exclusion criteria detailed in the study, geographical restrictions, etc. Eligible members will be sent an announcement through mail, email, or social media regarding the approved study and can volunteer to participate by contacting the researcher.

What types of studies from other researchers are available?

Some studies involve filling out questionnaires at home, for example, about quality of life and other important topics. Other studies may involve collecting blood or tissue samples, testing your muscles, or testing new treatments. Each study is voluntary and requires your agreement (consent).

DESCRIPTION OF PROCEDURES

The forms you have received will take about 20 minutes to read and complete. The following information is requested:

1. This **entire** consent form (pages 1-7) with your signature.
2. A Patient Information Form with your name, address and phone number, as well as information about your muscle strength, general health, and how your disease has affected your daily life. Unaffected family members will complete a shortened version of this form.
3. A Request for Medical Information. Please provide the complete name, address, and phone number of your doctor(s) on this form. This form gives us permission to request medical records about your disease and how it was diagnosed. This form permits your physician to send test results such as the results of muscle biopsy, genetic testing, heart tracing, electromyography (EMG), as well as records that pertain to your muscular dystrophy. We will only request this information from unaffected family members if they have received a genetic test or other exams that show you don't have muscular dystrophy.
4. If you would like to communicate with us via email you must sign an additional consent form, the *Patient Email Consent Form*.
 - Please mail all completed forms to us in the self-addressed and pre-stamped envelope.
 - Once we receive your application, we will review your forms and may contact you if additional information is needed.

After joining the Registry

- Once you are enrolled into the Registry, we may contact you through mail, email, or social media about opportunities to participate in other studies. We will send you information about the studies for which you may be eligible, including the researchers' names and phone numbers.
- If you are interested, you can contact the researcher for more information about the study.
- **The Registry will not provide any information that could identify you to the researcher.** All research studies will have been reviewed and approved by the researcher's human subjects institutional review board and the Scientific Advisory Committee of this Registry.
- Once a year, Registry staff will send you a form through the mail, email, or social media to update your address, phone number, and information about your health and/or any symptoms of your muscle disease. The staff will also ask you about any studies in which you have participated. It should take about 15 minutes to review and complete this "annual update" form.
- We ask that you contact us if you move or change your phone number or email address so that we are able to update your contact information.
- Participation of family members is strongly encouraged. However, while family relationships may be recorded in the Registry, none of their names or identifying information will be collected. No information about you will be shared with members of your family. Each family member is encouraged to enter the Registry and to complete the forms themselves, if interested and able. Family members who are unable to enroll themselves may be enrolled by a parent or guardian.

NUMBER OF SUBJECTS

We expect 3,000 subjects or more to participate in this study.

BENEFITS OF PARTICIPATION

You might not benefit from being in this study. The potential benefit to you from being in the Registry is receiving information about other studies you may want to join. You will receive information about Registry activities and research advances in myotonic dystrophy, FSHD, and related diseases.

Researchers may benefit by using the Registry to study why individuals have different symptoms, learn about how certain treatments work and don't work, help medical professionals improve how they treat individuals with DM and FSHD, and advance research in DM and FSHD by collecting information that researchers can use.

RISKS OF PARTICIPATION

There is minimal risk in taking part in this study. It includes questions that can be sensitive and that you may feel uncomfortable. You do not have to share any information you do not want to. Another risk of participation is the possible loss of confidentiality due to unauthorized release of medical information.

SPONSOR SUPPORT

The University of Rochester is receiving payment from the National Institutes of Health (NIH) for conducting this study (grant #U54-NS048843 and contracts #N01-AR-5-2274 and #NO1-AR-0-2250).

COSTS

There will be no cost to you to participate in this study.

PAYMENTS

You will not be paid for participating in this study.

CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the researcher is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

CONFIDENTIALITY OF RECORDS AND HIPAA AUTHORIZATION

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we follow stringent federal, state, and University guidelines discussed above and below. For example, the University has sophisticated computer safeguards, such as firewalls, virus checking, network/workstation access passwords, and backup and disaster recovery. Paper forms are stored by unique Registry identification numbers, double locked, and maintained by other University safeguards.

While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use related information from your medical records, results of laboratory tests, and both clinical and research observations made while you take part in the research.

We will use your health information to conduct the study, to determine research results, and

possibly to develop new tests, procedures, and commercial products. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.

To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services; the University of Rochester; The National Institutes of Health.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others. For example, by Federal law, we must send study information to the FDA for drug and device studies it regulates. Information that may need to be reported to FDA cannot be removed from your research records.

As stated in the section on Voluntary Participation in the Consent Form, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above.

The information for this Registry is collected under the authority of Sections 435-442 of the PHS Act (285d-285d-7 of Title 42, USC). The data will be maintained in accordance with the Privacy Act 42 United States Code 241.

CONTACT PERSONS

For more information about this research study, please contact:

James Hilbert, MS or Elizabeth Luebbe, MS
University of Rochester, Department of Neurology
601 Elmwood Ave, Box 673
Rochester, NY 14642
Telephone: (888) 925-4302 or (585) 276-0004.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420315, Suite 1-250, Rochester, NY 14642-8315, Telephone (585) 273-4127 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

VOLUNTARY PARTICIPATION

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time,

for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

SIGNATURE/DATES

After reading and discussing the information in this consent form, you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

SUBJECT CONSENT

I have received two identical copies of this consent form (one to keep and one to return) and have read the contents. If I had any questions, I have called the study team and have received the answers to my questions. I agree to participate in this study.

After signing one copy of this consent form, I will **mail the entire form (pages 1-7)** to:

Health Project Coordinator
National Registry of DM and FSHD
University of Rochester, Department of Neurology
601 Elmwood Ave, Box 673
Rochester, NY 14642

REGISTRY PARTICIPANT PRINTED NAME: _____

REGISTRY PARTICIPANT SIGNATURE: _____

DATE: _____

GUARDIAN (Person legally responsible for applicant, if applicable) - Guardian must sign when applicant is mentally incapable of understanding the consent form.

GUARDIAN'S PRINTED NAME: _____

GUARDIAN'S SIGNATURE: _____

DATE: _____

PERSON OBTAINING CONSENT

The subject has been given adequate opportunity to read the consent before signing and has been provided with a copy of the consent form for their records.

REGISTRY COORDINATOR PRINTED NAME: _____

REGISTRY COORDINATOR'S SIGNATURE: _____

DATE: _____



University of Rochester Department of Neurology
National Registry for DM and FSHD
601 Elmwood Ave, Box 673
Rochester, NY 14642
Telephone: (888) 925-4302 Fax: (585-276-2494)

& Affiliates

SH 48 Authorization for Release/Disclosure of Medical and/or Behavioral Health Information

PLEASE PRINT.

Patient name: _____ Date of Birth: _____
Address: _____ Patient's phone#: _____
City/State/Zip: _____

This Authorization allows URMC & Affiliates to: (check one or both)

- ☐ **SEND** copies of your record to (or discuss your information with) the provider/person/facility bel^o""
☐ **RECEIVE** copies of your record from (or discuss your information with) the provider/person/facility bel^o""

Name of Provider/ Person/Facility _____ Address _____
City, State, Zip Code _____ Phone #/Fax# include area code _____

PURPOSE FOR THIS REQUEST: ☐ Healthcare or Appointment (date) _____ ☐ Insurance ☐ Other

TYPE OF RECORDS or INFORMATION REQUESTED: Check all that apply:

The records requested are to include: ☐ Mental Health Treatment Records ☐ Alcohol/Drug Treatment Records
(Release/disclosure of HIV-related information requires additional authorization on form NYS DOH2557 or OCA 960)

☐ **Inpatient admission(s)/date(s):**

(Check only one of the following 3 choices if requesting inpatient records)

- ☐ Treatment summary (includes discharge summary, history/physical, laboratory tests, x-ray reports, operative reports, pathology)
☐ Specific information or reports (describe): _____
☐ Other (describe): _____

☐ **Outpatient/Office visits--date(s):** _____ **and/or specific illness/injury:** _____
(Check type of outpatient visit to be released)

- ☐ Clinic/doctor/dental visit ☐ Ambulatory Surgery visit ☐ Emergency Department Record
☐ Radiology report(s) ☐ Laboratory test results ☐ Immunizations ☐ Physical/occupational therapy record(s)
☐ Other (describe): _____

AUTHORIZATION VALID FOR: (If nothing is checked below, this authorization is valid for this request only.)

- ☐ This request only
☐ One year from the date of this authorization **OR** _____ (insert date) This authorization applies to the records of the treatment received on or prior to the date of this authorization.
☐ **This request and for medical records of any future treatment of the type described above until:** _____ (insert date)

I understand that:

- My right to healthcare treatment is not conditioned on this authorization, except in very limited circumstances (e.g. non-emergent mental health or chemical dependency treatment).
- I may cancel this authorization at any time by submitting a written request to the address provided at the top of this form, except where a disclosure has already been made in reliance on my prior authorization.
- If the person or facility receiving this information is not a health care or medical insurance provider covered by privacy regulations, the information stated above could be redisclosed, except that chemical dependency treatment records protected by Federal Confidentiality Rules 42C FR Part 2 may not be disclosed without my written authorization unless otherwise provided for in the regulations.
- There may be a charge for the requested records.
- The medical records requested above may be faxed in cases of medical necessity.

Signature of Patient or Representative _____ Date _____

Relationship to Patient (e.g., parent, child, spouse, etc.) _____

**National Registry of Myotonic Dystrophy and Facioscapulohumeral Muscular
Dystrophy Patients and Family Members**

Patient Information Form *for Unaffected Blood Relatives of Individuals with
Facioscapulohumeral Muscular Dystrophy (FSHD)*

The purpose of this form is to collect information from individuals who are unaffected blood relatives of individuals who have FSHD. **Please return this form within three weeks if at all possible.** If you have any questions about this form, please call Local: (585) 506-0004 in Rochester NY or Toll Free: (888) 925-4302 for assistance. You may reach us by Fax at: (585) 273-1255 or by mail at: 601 Elmwood Avenue, Box 673, Rochester, NY 14642-8673.

Date: _____

NAME: _____
First Middle (Maiden) Last

ADDRESS: _____
Street

City State Zip Code

TELEPHONE: Home: (____) _____ Work: (____) _____
Area Code Number Area Code Number

EMAIL ADDRESS: _____

Date of Birth: ____/____/____ Sex: ☐ Male ☐ Female
Mo Day Year

The information for this Registry is collected under the authority of Sections 435-442 of the PHS Act (285d-285d-7 of Title 42, USC). The data will be maintained in accordance with the Privacy Act 42 United States Code 241.

This project has been funded in whole or in part by the National Institutes of Health (grant #U54-NS048843 and contracts #N01-AR-5-2274 and #N01-AR-0-2250).

1. Indicate how many family members are affected:

	YES	NO	If "Yes," how many are affected?
Brothers and sisters			
Children (Are any affected children under the age of 18? <input type="checkbox"/> yes <input type="checkbox"/> no)			
Spouse			
Mother			
Father			
Grandparents			
Aunts or uncles			
Cousins or other relatives			

2. Are any other members of your family in the Registry?

☐ Yes ☐ No ☐ Not sure

3. Please indicate which of the following statements best represents you:

_____ I do not have any symptoms of FSHD but I have not been examined by a neurologist.

_____ I do not have any symptoms of FSHD and a neurologist has examined me and confirmed that I am not affected.

_____ I had DNA testing that confirmed that I am not affected.

ETHNICITY/RACE

Are you Hispanic or Latino?

☐ Yes ☐ No

How would you describe your race? Select one or more of the following categories:

☐ American Indian or Alaskan Native

☐ Asian

☐ Black or African American

☐ White

☐ Native Hawaiian or other Pacific Islander

Please provide the name, address, and telephone number of a family member or friend we can contact in case you move or change your phone number.

Name: _____ Relationship: _____

Address: _____

Phone Number: _____

IMPORTANT: Please read, sign and return the attached Consent Form. Without it we cannot consider you for entry into the Registry.

Thank you for your support of the National Registry.



Research Subject E-mail Consent Form

Subject name:
Subject #:
Subject e-mail:
Researcher: Dr. Rabi Tawil
Researcher e-mail: dystrophy_registry@urmc.rochester.edu
Authorized representative:
Name: _____
Relationship: _____
E-Mail: _____

1. RISK OF USING E-MAIL

Transmitting subject information by e-mail has a number of risks that subjects should consider. These include, but are not limited to, the following:

- a) E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
- b) E-mail senders can easily misaddress an e-mail.
- c) Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
- d) Employers and on-line services have a right to inspect e-mail transmitted through their systems.
- e) E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
- f) E-mail can be used to introduce viruses into computer systems.

2. CONDITIONS FOR THE USE OF E-MAIL

The researcher cannot guarantee but will use reasonable means to maintain security and confidentiality of e-mail information sent and received. The subject and researcher must consent to the following conditions:

- a) E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
- b) E-mail must be concise. The subject should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
- c) E-mail communications between subject and researcher will be filed in the subject's research record.
- d) The subject's messages may also be delegated to any member of the study team for response.
- e) The researcher will not forward subject-identifiable e-mails outside of URM and Affiliates without the subject's prior written consent, except as authorized or required by law.

- f) The subject should not use e-mail for communication regarding sensitive medical information.
- g) It is the subject's responsibility to follow up and/or schedule an appointment if warranted.
- h) Recommended uses of subject-to-researcher e-mail should be limited to:
 - a. Appointment requests
 - b. Prescription refills
 - c. Requests for information
 - d. Updates to information or exchange of non-critical information such as laboratory values.

3. INSTRUCTIONS

To communicate by e-mail, the subject shall:

- a) Avoid use of his/her employer's computer.
- b) Put the subject's name in the body of the e-mail.
- c) Put the topic (e.g., study question) in the subject line.
- d) Inform the researcher of changes in the subject's e-mail address.
- e) Take precautions to preserve the confidentiality of e-mail.
- f) Contact the researcher's office via conventional communication methods (phone, fax, etc.) if the subject does not receive a reply within a reasonable period of time.

4. SUBJECT ACKNOWLEDGMENT AND AGREEMENT

I acknowledge that I have read and fully understand this consent form. I understand the risks associated with the communication of e-mail between the researcher and me. I consent to the conditions and instructions outlined here, as well as any other instructions that the researcher may impose to communicate with me by e-mail. I agree to use only the pre-designated e-mail address specified above. Any questions I may have had were answered.

Subject or Authorized Representative signature

Date

Researcher signature

Date



BUSINESS REPLY LABEL

FIRST-CLASS MAIL PERMIT NO. 137 ROCHESTER NY

POSTAGE WILL BE PAID BY ADDRESSEE

University of Rochester
University of Rochester Medical Center
National Registry, Box 673
PO Box 23029
Rochester NY 14692-6971

NO POSTAGE
NECESSARY
IF MAILED IN THE
UNITED STATES

