



NF Clinic Network (NFCN) Application Form*

Clinic Name:

Mayo Clinic

Affiliated Hospital:

Rochester Methodist Hospital
St. Mary's Hospital

Affiliated University or Institution:

Mayo College of Medicine

Clinic Address:

Mayo Clinic
200 First Street, SW
Rochester, MN 55905

Clinic Director:

Dusica Babovic-Vuksanovic, MD

Clinic Coordinator Name:

Lama Eldahdah, MS
Kara Mensink, MS

**Note: Some non-public information has been removed from this application form.*



The Neurofibromatosis Clinic Network (NFCN)

FORM PART A: Affiliate Clinic Application

1. ABOUT YOUR NF CLINIC

a. Is your NF Clinic:

- Freestanding
- Hospital based
- In an academic center
- Other (please describe)

b. Describe overall your NF Clinic, when it meets and how it functions.

The goal of the Mayo Clinic Multidisciplinary Neurofibromatosis Clinic is to provide the highest quality coordinated care to our patients and their families. We offer a "clinic without walls" where physicians from a variety of specialties work collaboratively to ensure the best possible care for each patient.

Communication among providers during the episode of care is a key element, as evidenced by the summary letters and, often, face to face summary consults provided to patients at the end of their visit. Care is coordinated through the Department of Medical Genetics. Usually,

appointments can be arranged such that all specialist evaluations occur within a 1-2 day time frame.

A patient, of any age, can be scheduled at any time to be evaluated by our medical geneticist and genetic counselor who will then refer to the other specialties, as needed. Based on the clinical history available prior to the appointment, specialty appointments are scheduled in advance. These appointments can be canceled with no penalty to the patient should they be determined unnecessary after evaluation by the Medical Geneticist or other members of the Multidisciplinary team. The benefit of scheduling specialty appointments in advance ensures that the key players from our team will be available to meet with the patient during her/his visit to the clinic. While the patient is visiting the different specialties, all physicians communicate with each other, such that important information regarding the patient's condition is relayed to all team members. After the patient completes all tests, procedures, and consults, the summary of recommendations for treatment and follow up is provided to the patient, documented in the patient's clinical record, and forwarded to the multidisciplinary team. There is considerable opportunity for follow up and additional care.

2. CLINIC DIRECTOR and STAFF EXPERTISE

a. CLINIC DIRECTOR: Please describe:

i. Your experience to date with NF care

I have extensive experience in the diagnosis, management, and coordination of care for patients with NFI, NFII, and Schwannomatosis. I see on average at least 1-2 patients with neurofibromatosis per day.

ii. Your past and current association with NF clinical trials

I am, currently, the Principal Investigator of a clinical trial for the fourth time. [(Pirfenidone for adults (Phase II), Pirfenidone for children (Phase I and Phase II), AZD2172 for adults (Phase II)]

iii. Your past and current association with other clinical trials e.g. oncology trials

Our patient population is a large referral base for oncology trial participation. We refer patients to internal (Mayo) and external providers, dependent on patient's needs and availability of experimental trials.

b. CLINIC DIRECTOR: Please provide information on:

- i. Present and past funding you have received for NF research. Include funding source, date received, amount and project description.

Present Funding

- Phase I/Phase II Study of Pirfenidone in NF1 and Plexiform Neurofibromas. Funded by Food and Drug Administration. (R10 DAMD17-02-1-0641)
- Phase I/Phase II Study of Pirfenidone in NF1 and Plexiform Neurofibromas - PI Effort only. Funded by Department of Defense. (DAMD17-2-1-0641)
- A Phase 2 Study of AZD2171 in Adult Patients with Neurofibromatosis Type 1 and Extensive Plexiform and Paraspinal Neurofibromas (P7133). Funded by National Institutes of Health. (N01 P7133)

Past Funding

- Principal Investigator
Volumetric Analysis of Neurofibromas in Patients Treated with Pirfenidone. Funded by Neurofibromatosis Inc - Minnesota. (NFIM-1) 08/2002 - 07/2004
- Principal Investigator
Toward the Application of New Therapeutics for Neurofibromatosis Type 1. Funded by Foundation 06/2003 - 05/2005
- Principal Investigator
A Phase II Clinical Trial of Pirfenidone Treatment of Patients with Neurofibromatosis. Funded by CR Programs. 01/2000 - 12/2003
- Co-Investigator
Optimal Technique for Buccal Smear Collection in Breast Feed Infants. Funded by CR Programs. 08/1997 - 07/1998

- ii. Your NF-related clinical and scientific publications. Include Journal, Citation and Title.

- Babovic-Vuksanovic D, Babovic S. Liposuction for Debulking Neurofibromas. In: Textbook of Liposuction: Principles and Practice. (in press). Shiffman, M, Di Giuseppe A. (Eds) 2005; 28: 568.
- Mensink KA, Ketterling RP, Flynn HC, Knudson RA, Lindor NM, Heese BA, Spinner RJ, Babovic-Vuksanovic D. Connective tissue dysplasia in five new patients with NF1 microdeletions: further

expansion of phenotype and review of the literature - art. no. e8. J Med Genet 2006 Feb; 43(2):E8.

- White JB, Scheithauer BW, Amrami KK, Babovic-Vuksanovic D, Spinner RJ. Contiguous conventional and plexiform schwannomas - Report of two cases. J Neurosurg 2006 Feb; 104(2):319-24.
- Park WC, White WA, Woog JJ, Garrity JA, Kim YD, Lane J, Witte R, Babovic-Vuksanovic D. The role of high-resolution computed tomography and magnetic resonance imaging in the evaluation of isolated orbital neurofibromas. Am J Ophthalmol 2006 Sep; 142(3):456-63.
- Babovic-Vuksanovic D, Ballman K, Michels V, McGrann P, Lindor N, King B, Camp J, Micic V, Babovic N, Carrero X, Spinner R, O'Neill B. Phase II trial of pirfenidone in adults with neurofibromatosis type 1. Neurology 2006 Nov 28; 67(10):1860-2.
- Spinner RJ, Endo T, Amrami KK, Dozois EJ, Babovic-Vuksanovic D, Sim FH. Resection of benign sciatic notch dumbbell-shaped tumors. J Neurosurg 2006 Dec; 105(6):873-80.
- Babovic-Vuksanovic D, Widemann B, Dombi E, Gillespie A, Wolters P, Toledo-Tamula M A, O'Neill B, Fox E, MadDonald T, Beck H, Packer R. Phase I Trial of Pirfenidone in Children with Neurofibromatosis Type 1 and Plexiform Neurofibromas. Pediatric Neurology 2007; 36:293-300.
- Krishnan S, Goble J, Frederick L, James C, Uhm J, Babovic-Vuksanovic D. Inhibitory effect of Pirfenidone on glioblastoma cell lines: Implications for treatment of neurofibromatosis-associated gliomas. Journal of Applied Research 2007; 7(1):58-68.
- Dombi E, Solomon J, Gillespie AJ, Fox E, Balis FM, Patronas N, Korf BR, Babovic-Vuksanovic D, Packer RJ, Belasco J, Goldman S, Jakacki R, Kieran M, Steinberg SM, Widemann BC. NF1 plexiform neurofibroma growth rate by volumetric MRI: relationship to age and body weight. Neurology 2007 Feb 27; 68(9):643-7.
- Babovic S, Babovic-Vuksanovic D. Liposuction in treatment of plexiform neurofibromas. In: Shiffman MA, Di Giuseppe A, editors. Liposuction: principles and practice. Berlin: Springer; 2006. p. 550-3.

c. Who are the key staff in your NF clinic facility?

Provide Name; Title; Degree/Qualifications; Role in Clinic.

- Dusica Babovic-Vuksanovic, M.D., F.A.A.P., F.A.C.M.G.
Chair, Department of Medical Genetics
Associate Professor of Medical Genetics and Pediatrics
DIRECTOR OF NF CLINIC
- Lama Eldahdah, M.S. (Genetic Counselor)
- Kara Mensink, M.S., C.G.C.

- Brian Patrick O’Neill, M.D.
Professor of Neurology, Mayo College of Medicine
Director, Mayo SPORE in Brain Cancer, NIH NCI P50 CA108961
- Robert J. Spinner, M.D.
Department of Neurologic Surgery
Associate Professor of Neurologic Surgery,
Orthopedics, and Anatomy, Mayo Clinic College of Medicine
- Michael J. Link, M.D.
Associate Professor of Neurosurgery
Consultant, Departments of Neurologic Surgery and
Otorhinolaryngology
- Colin L.W. Driscoll, M.D.
Department of Otorhinolaryngology
Associate Professor of Otorhinolaryngology
Mayo Clinic College of Medicine
- Kimberly K. Amrami, M.D.
Associate Professor of Radiology

d. Who within this core staff currently coordinates NF patient services?
Describe this individual’s NF clinic related duties.

- Dusica Babovic-Vuksanovic, M.D., F.A.A.P., F.A.C.M.G.
- Lama Eldahdah, M.S.
- Kara Mensink, M.S., C.G.C.
- Mary Kelly, R.H.I.A.

e. Describe any areas of NF care in which your clinic has particular expertise (e.g. optic glioma, vestibular schwannoma, bone manifestations, learning disabilities etc.) and the clinic staff that provide this care.

- Paraspinal neurofibroma
 - Clinical trials, Dr. Dusica Babovic
 - Surgical, Dr. Fredric Meyer (neurosurgeon)
- Schwannomatosis treatment
 - Surgical, Dr. Robert Spinner (neurosurgeon)
- Vestibular Schwannoma
 - Dr. Link

3. PATIENT SCHEDULING and REFERRALS

a. Provide the details of the ‘typical’ timeframe in which patients receive a response to a request for scheduling, are actually scheduled for an appointment, how patients are prioritized, etc.

Patients are responded to immediately and appointments are scheduled in 4-6 weeks at which point the patient can meet with individuals from the departments of genetics, neurology, audiology, ophthalmology,

orthopedics and other specialists as needed, during the same visit. More urgent cases are seen within one week of the request.

- b. Provide details of those specialists to whom (either within or outside our own clinic facility) your clinic refers NF patients for the following specialty care. **These should individuals familiar and experienced with consensus guidelines for care of individuals with NF** (Please provide information for PEDIATRIC CARE referrals in the first table and ADULT CARE in the second table).

PEDIATRIC CARE

| SPECIALTY | DOCTOR | CLINIC ADDRESS | PHONE | EMAIL (if available) |
|--|---------------------|---|--------------|------------------------------|
| Genetics | Dr. Dusica Babovic | 200 First St.SW Rochester, MN 55905 | 507 284-3215 | dbabovic@mayo.edu |
| Neurology | Dr. Suresh Kotagal | Same | 507 266-0774 | Kotagal.suresh@mayo.edu |
| Orthopedics | Dr. Anthony Stans | Same | 507 266-5225 | stans.anthony@mayo.edu |
| | Dr. Wm Shaughnessy | Same | 507 284-3660 | shaughnessy.william@mayo.edu |
| Developmental pediatrics/learning disabilities | Dr. Wm Barbaresi | Same | 507 284-1703 | wbarbaresi@mayo.edu |
| | Dr. Robert Voigt | Same | 507-284-1703 | voigt.robert@mayo.edu |
| Ophthalmology | Dr. Brian Mohney | Same | 507 284-2233 | mohney@mayo.edu |
| Neurosurgery | Dr. Corey Raffel | Same | 507 284-8167 | raffle.corey@mayo.edu |
| Plastic surgery | Dr. Uldis Bite | Same | 507 284-3214 | bite.uldیس@mayo.edu |
| Neurooncology | Dr. Cynthia Wetmore | Same | 507 284-8640 | wetmore.cynthia@mayo.edu |
| Medical Oncology/Radiation Oncology | Dr. Carola Arndt | Same | 507 284-2652 | carndt@mayo.edu |
| Endocrinology | Dr. Aida Lteif | Same | 507 284-3442 | lteif.aida@mayo.edu |
| Audiology/ENT | Dr. Colin Driscoll | Same | 507 284-4065 | driscoll.colin@mayo.edu |
| Radiology/ Neuroradiology | Dr. Jane Matsumoto | Same | 507 284-0046 | matsumoto.jane@mayo.edu |
| General Surgery/Surgical Oncology | Dr. Christoher Moir | Same | 507 284-2623 | moir.christopher@mayo.edu |
| Dermatology | Dr. Jennifer Hand | Same | 507 284-3736 | hand.jennifer@mayo.edu |
| Cardiovascular Disease | Dr. David Driscoll | Same | 507 284-9969 | driscoll.david@mayo.edu |
| Oral and Maxillofacial Surgery | Dr. Eugene Keller | Same | 507 284-3193 | keller.eugene@mayo.edu |
| Behavioral Issues | Dr. Michael Mellon | Same | 507 284-4431 | Melon.michael@mayo.edu |

ADULT CARE

| SPECIALTY | DOCTOR | CLINIC ADDRESS | PHONE | EMAIL (if available) |
|--|---|---|------------------------------|---|
| Genetics | Dr. Dusica Babovic | 200 First St SW Rochester, MN 55905 | 507 284-3215 | dbabovic@mayo.edu |
| Neurology | Dr. Brian O'Neill | Same | 507 284-8431 | boneill@mayo.edu |
| Orthopedics | Dr. Mark Dekutoski | Same | 507 284-3658 | dekutoski.mark@mayo.edu |
| Developmental pediatrics/learning disabilities | N/A | | | |
| Ophthalmology | Dr. Brian Younge Dr. Jaqueline Leavitt | Same Same | 507 284-4567 507 284-3726 | byounge@mayo.edu leavitt.jacqueline@mayo.edu |
| Neurosurgery | Dr. Robert Spinner Dr. Fredric Meyer | Same Same | 507 284-2376 507 284-5317 | spinner.robert@mayo.edu meyer.fredric@mayo.edu |
| Plastic surgery | Dr. Uldis Bite | Same | 507 284-3214 | bite.uldیس@mayo.edu |
| Neurooncology | Dr. Scott Okuno | Same | 507 284-4849 | okuno.scott@mayo.edu |
| Medical Oncology/Radiation Oncology | Dr. Paula Schomberg | Same | 507 284-3551 | pschomberg@mayo.edu |
| Endocrinology | Dr. Wm F. Young | Same | 507 284-2191 | wyoung@mayo.edu |
| Audiology/ENT | Dr. Colin Driscoll | Same | 507 284-4065 | driscoll.colin@mayo.edu |
| Radiology/ Neuroradiology | Dr. Kimberly Amrami | Same | 507 284-1728 | amrami.kimberly@mayo.edu |
| General Surgery/Surgical Oncology | Dr. Eric Dozois | Same | 507 284-2218 | dozois.eric@may.edu |
| Dermatology | Dr. Jennifer Hand | Same | 507 284-3736 | Hand.jennifer@mayo.edu |
| Cardiovascular Disease | Dr. Sabrina Phillips | Same | 507 284-2129 | phillipslsabrina@mayo.edu |
| Oral and Maxillofacial Surgery | Dr. Eugene Keller | Same | 507 284-3193 | keller,Eugene@mayo.edu |
| Behavioral Issues | Dr. Sencan Unal | Same | 507 255-5307 | solay@mayo.edu |

4. NUMBER OF NF PATIENTS YOUR CLINIC SEES

- a. How many NF PATIENTS did you see in the past 12 months?
- b. How many of these were **NEW** patients to your clinic?

Insert numbers below

| | NF1 | NF2 | SCHWANNOMATOSIS | OTHER |
|--|-----|-----|-----------------|-------|
| NUMBER OF PATIENTS SEEN IN PAST 12 MONTHS | 96 | 7 | 5 | 0 |
| NUMBER OF <u>NEW</u> PATIENTS SEEN IN PAST 12 MONTHS | 31 | 12 | 2 | 10 |
| TOTAL | 124 | 19 | 7 | 10 |

c. Overall what proportion of patients seen in the past year were (give finite numbers if these are available, or estimate percentage):

Under 18 _____ 18+ _____ (give numbers - if data available)

OR estimate

Under 18 (%) 50 18+ (%) 50

5. TRANSITIONING PEDIATRIC TO ADULT NF CARE

How does your clinic facilitate continuity of care for patients transiting from pediatric to adult care?

There is close communication and proximity between pediatric and adult care providers. Mayo has permanent electronic records, which allows access to previous medical care to new providers.

Explain how continuity of care is accomplished. Describe those partnering clinics with which you coordinate services, and explain any limitations:

Coordination of transition is performed by one, central department (Medical Genetics) who will see a patient during any time of his/her life (infancy through adulthood).

6. INTERNAL CONFERENCES

Provide details on internal conferences in your institution which are related to NF patient care in your clinic (e.g. NF Clinic case management conference, etc.)

As the patient meets with different specialties during their one visit, providers discuss progress (including test results and patient needs), through telecommunicative methods. Additionally, a bi-monthly research forum gives rise to opportunity for lectures focused on research by different specialties, including neurofibromatosis.

7. CLINICAL TRIALS

Our clinic is willing and able to provide our NF patients with information on, and to facilitate their participation in, clinical trials for which NF patients are eligible (check box)

Yes No

If 'no', briefly describe why.

Do you currently refer patients to clinical trials?

Yes No

If 'yes', provide details of current clinical trial protocols in which you currently or have had patients involved in the past 5 years.

- Phase I/Phase II Study of Pirfenidone in NF1 and Plexiform Neurofibromas. Funded by Food and Drug Administration. (R10 DAMD17-02-1-0641)
- A Phase 2 Study of AZD2171 in Adult Patients with Neurofibromatosis Type 1 and Extensive Plexiform and Paraspinal Neurofibromas (P7133). Funded by National Institutes of Health. (N01 P7133)

8. PATIENT REGISTRY

Do you currently have an NF specific patient database/registry?

Yes No

Due to lack of resources, there is no person responsible or systematic fashion for recording phenotype information/progress (although blood samples have been collected, after consent, on many patients).

If 'yes', please describe.

Would you be willing to transfer this data to a centralized CTF NF Database?

Yes No (Once we obtain resources to establish a database)

If 'no', explain your limitations.

9. PUBLICATIONS and RESEARCH (IF APPLICABLE)

a. Please list any relevant NF publications from your clinic in the past 5 years. Include Journal, Citation and Title.

- Babovic-Vuksanovic D, Babovic S. Liposuction for Debulking Neurofibromas. In: Textbook of Liposuction: Principles and Practice. (in press). Shiffman, M, Di Giuseppe A. (Eds) 2005; 28: 568.
- Mensink KA, Ketterling RP, Flynn HC, Knudson RA, Lindor NM, Heese BA, Spinner RJ, Babovic-Vuksanovic D. Connective tissue dysplasia in five new patients with NF1 microdeletions: further expansion of phenotype and review of the literature - art. no. e8. J Med Genet 2006 Feb; 43(2):E8.
- White JB, Scheithauer BW, Amrami KK, Babovic-Vuksanovic D, Spinner RJ. Contiguous conventional and plexiform schwannomas - Report of two cases. J Neurosurg 2006 Feb; 104(2):319-24.
- Park WC, White WA, Woog JJ, Garrity JA, Kim YD, Lane J, Witte R, Babovic-Vuksanovic D. The role of high-resolution computed tomography and magnetic resonance imaging in the evaluation of isolated orbital neurofibromas. Am J Ophthalmol 2006 Sep; 142(3):456-63.
- Babovic-Vuksanovic D, Ballman K, Michels V, McGrann P, Lindor N, King B, Camp J, Micic V, Babovic N, Carrero X, Spinner R, O'Neill B. Phase II trial of pirfenidone in adults with neurofibromatosis type 1. Neurology 2006 Nov 28; 67(10):1860-2.
- Spinner RJ, Endo T, Amrami KK, Dozois EJ, Babovic-Vuksanovic D, Sim FH. Resection of benign sciatic notch dumbbell-shaped tumors. J Neurosurg 2006 Dec; 105(6):873-80.
- Babovic-Vuksanovic D, Widemann B, Dombi E, Gillespie A, Wolters P, Toledo-Tamula M A, O'Neill B, Fox E, MadDonald T, Beck H, Packer R. Phase I Trial of Pirfenidone in Children with Neurofibromatosis Type 1 and Plexiform Neurofibromas. Pediatric Neurology 2007; 36:293-300.
- Krishnan S, Goble J, Frederick L, James C, Uhm J, Babovic-Vuksanovic D. Inhibitory effect of Pirfenidone on glioblastoma cell lines: Implications for treatment of neurofibromatosis-associated gliomas. Journal of Applied Research 2007; 7(1):58-68.
- Dombi E, Solomon J, Gillespie AJ, Fox E, Balis FM, Patronas N, Korf BR, Babovic-Vuksanovic D, Packer RJ, Belasco J, Goldman S, Jakacki R, Kieran M, Steinberg SM, Widemann BC. NF1 plexiform neurofibroma growth rate by volumetric MRI: relationship to age and body weight. Neurology 2007 Feb 27; 68(9):643-7.
- Babovic S, Babovic-Vuksanovic D. Liposuction in treatment of plexiform neurofibromas. In: Shiffman MA, Di Giuseppe A,

editors. Liposuction: principles and practice. Berlin: Springer; 2006. p. 550-3.

- De Ruitter G.C.W., Scheithauer, B.W., Amrami, K.K., Spinner, R.J.: Benign metastasizing leiomyoma with compression of the brachial plexus mimicking neurofibromatosis. *Clin neuropath* **25**:282-287, 2006.
- Spinner, R.J., Endo, T., Amrami, K.K., Dozois, E.J., Sim, F.H.: The application of high resolution MRI to tumor respectability in patients with sciatic notch dumbbell tumors. *J neurosurg* **105**:873-880, 2006.
- Spinner, R.J., Scheithauer, B.W., Perry, A., Amrami, K.K., Emmett, R., Gutmann, D.: Co-localized cellular schwannoma and plexiform neurofibroma in the absence of neurofibromatosis. In print, *J neurosurg*, July 2007.

b. Please provide information on NF-related research ongoing in your clinic or performed by personnel affiliated with your clinic.

- Phase II Clinical Trial of AZD2171 in Adult Patients with Neurofibromatosis Type I and Extensive Paraspinal Neurofibroma (Dusica Babovic-Vuksanovic)
- Effects of hormone therapy on human schwannoma xenografts in SCID mice (Dusica Babovic-Vuksanovic)
- Vestibular schwannoma xenografts in SCID mice (Dr. B. Neff)

10. PATIENT SUPPORT

Do you have an NF patient support group that meets in association with your NF Clinic?

No. However, we are involved in facilitating the formation of one (see attached documents that are provided to all applicable patients).

If 'yes' provide details.

If 'no', are you interested in starting such a group? Yes.

What resources would help you to do this?

- Database of patients
- Resource to allow communication among participants (e-mail, mailing, telephone)
- Location to have meetings

11. OTHER INFORMATION

Please provide any additional information that is pertinent to your request to join the CTF NF Clinic Network.

In addition to all the clinical services that can be found in a major medical center, we offer additional resources:

- Pain clinic for children
- Pain clinic for adults
- Innovative surgical treatment for painful manifestation of NF1, NF2, Schwannomatosis