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Radiation Research Program
Division of Cancer Treatment and Diagnosis

Cancer Disparity Research Partnership (CDRP) Program

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Program Director

ASTRO Program Expert Committee Meeting

November 1, 2010

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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CDRP Program Highlights

- June 6, 2010 → Coastal Carolina Radiation Oncology (CCRO) receives ASCO 2010 Clinical Trials Participation Award
- June 18, 2010 → NOVA Research Co. submits Final U56 CDRP Evaluation Report to NCI
- June 30, 2010 → RRP sends CDRP PIs, EAC and Experts Final U56 CDRP Evaluation Report
- August 1, 2010 → U54 grantees issued year 2 awards
- Sept. 7, 2010 → NOVA Research Co. awarded 4-year U54 CDRP Evaluation contract
- Oct. 6, 2010 → RCRH partners with SD Dept. of Health to receive CDC grant for Patient Navigation project

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CDRP Program Reminders

- Nov. 1, 2010 → ASTRO-NCI Diversity Symposium and Reception at 5:30PM at Aqua Room 313
- Nov. 30, 2010 → U56 Final Progress Report due to NCI from UPMC McKeesport, 21st Century Oncology and New Hanover Regional Medical Center
- Jan. 13-16, 2011 → NO CDRP PSC meeting at RTOG; may schedule a teleconference call in March 2011
- June 1, 2011 → U54 Annual Progress Report due to NCI
- June 16-19, 2011 → CDRP PSC meeting at RTOG in Philadelphia where PI present program update

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CDRP U56 Accomplishments – # Trials Open

TABLE 2 – NUMBER OF CLINICAL TRIALS OPEN PER FISCAL YEAR (AS OF SEPTEMBER 30, 2009)

Grantee Sites	Number of Clinical Trials Open per Fiscal Year (%)					
	FY04	FY05	FY06	FY07	FY08	FY09
Rapid City	48 (75)	52 (63)	76 (55)	98 (48)	101 (42)	94 (40)
Laredo	4 (6)	5 (6)	5 (4)	N/A	N/A	N/A
Centinela Freeman	0 (0)	5 (6)	6 (4)	3 (1)	6[a] (2)	4 (2)
New Hanover	5 (8)	9 (11)	11 (8)	5 (2)	7 (3)	7 (3)
Singing River	0 (0)	1 (1)	20 (15)	40 (20)	39 (16)	61 (26)
UPMC McKeesport	7 (11)	10 (12)	19 (14)	57 (28)	89 (37)	69 (29)
Total[b,c,d]	64 (100)	82 (100)	137 (100)	203 (100[c])	242 (100)	235 (100)

N/A = Not applicable; Laredo's CDRP grant was relinquished in 2007.

[a] After closure of the radiation oncology center in January 2008, no new trials were open until August 2008 (see sections 3.3.2 and 3.7.2 for a description of events).

[b] Trials opened in a given year that remained active (i.e., open to patient accrual) in subsequent years were counted each year they remained open.

[c] Data do not include clinical trials that were opened for follow-up only.

[d] Column percents do not total 100% due to rounding.

2010 U54 Data**

89 - 91
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4 - 6
12 - 14
50
48 - 52
206-211

** 9 months 2010 data only

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Types of Clinical Trials Open by CDRP Site

TABLE 3 – TYPES OF CLINICAL TRIALS OPENED BY SITES (AS OF SEPTEMBER 30, 2009)

Grantee Sites	PI-Initiated	Mentor-Initiated	RTOG	Other Cooperative Groups[a]	Pharmaceutical/ Industry	Total (%)	2010 U54 Data**
Rapid City	8	1	30	174 (2 R; 22 CR; 118 M/S; 32 CC/P)	1	214 (47)	89 - 91
Laredo	1	1	2	3 (2 CC/P; 1 UNK)	1	8 (2)	---
Centinela Freeman	0	0	5	1 (1 UNK)	2	8 (2)	4 - 6
New Hanover	1	1	9	7 (7 R/CR)	0	18 (4)	12 - 14
Singing River	0	0	20	63 (5 R/CR; 58 M/S[b])	7	90 (20)	50
UPMC McKeesport	11[c]	0	22	53 (1 R, 11 CR, 41 M/S)	28	114 (25)	48 - 52
Total	21 13	3 4	88 46	301 131	39 14	452 (100[d]) 208	206-211

[a] Trial Category for Other Cooperative Groups: R = radiation only; CR = combined chemoradiation; M/S = medical and/or surgical; CC/P = cancer control and/or prevention; UNK = unknown category of trial.

[b] Some medical/surgical oncology trials (n=15) opened at this site are also considered cancer control/prevention trials.

[c] These patients are enrolled on UPMC PI-initiated trials via the University of Pittsburgh Cancer Institute (UPCI).

[d] Column percents do not total 100% due to rounding.

** 9 months 2010 data only

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U56 Yearly Accrual by CT Types

TABLE 7 – CUMULATIVE NUMBER OF PATIENTS ACCRUED IN EACH TYPE OF CLINICAL TRIAL, BY FISCAL YEAR (AS OF SEPTEMBER 30, 2009)

Type of Clinical Trial	FY03[a]	FY04	FY05	FY06	FY07	FY08	FY09	Total (%)	2010 U54 Data**
PI-Initiated	0	1	44	78	78	38	62	301 (18)	9
Mentor-Initiated	0	0	0	0	0	0	160	160 (10)	13
RTOG	10	7	17	26	34	24	50	168 (10)	18
Other Cooperative Groups[b]	271	349	39	75	84	98	82	998 (60)	66
Radiation Only	*1*	*0*	*4*	*20*	*9*	*0*	*3*	*37 (4)*	- -
Radiation/Combined Treatment[b]	*65*	*9*	*14*	*24*	*19*	*13*	*14*	*158 (16)*	- -
Medical/Surgical[b]	*140*	*25*	*24*	*27*	*55*	*79*	*57*	*407 (41)*	- -
Cancer Control/Prevention[b]	*75*	*316[c]*	*6*	*9*	*10*	*11*	*14*	*441 (44)*	- -
Pharmaceutical/Industry	0	0	5	1	8	6	31	51 (3)	49
Total	281[a]	357	105	180	204	166	385	1,678 (100[d])	155

[a] Rapid City had approximately 33 active clinical protocols opened during FY03 in which they accrued 281 patients onto the STAR trial and cooperative group trials (RTOG and NCCTG) (n=281).

[b] Rapid City data include patients who were enrolled onto both RTOG and other cooperative group trials. The database structure at this site did not allow segregating the different trial categories (e.g., radiation only, medical/surgical) by only cooperative group trials.

[c] Includes Laredo's accruals to NCI prevention trials, STAR (n=9) and SABOR (300).

[d] Column percents do not total 100% due to rounding.

** 9 months 2010 data only

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Accrual to Types of Clinical Trials

TABLE 6 – CUMULATIVE NUMBER OF PATIENTS ACCRUED AT EACH SITE BY TYPE OF CDRP CLINICAL TRIAL (AS OF SEPTEMBER 30, 2009)

Grantee Sites	PI-Initiated	Mentor-Initiated	RTOG	Other Cooperative Groups	Pharmaceutical / Industry	Total (%)
Rapid City	252	154	45	482	0	933[a] (56)
Laredo	0	0	6	313[b]	3	322 (19)
Centinela Freeman	0	0	17	16	30	63[c] (4)
New Hanover	39	6	50	23	0	118 (7)
Singing River	0	0	18	106	6	130[d] (8)
UPMC McKeesport	10[e]	0	32	58	12	112[f] (7)
Total	301 9	160 13	168 18	998 66	51 49	1,678[g] (100[h]) 155

[a] Rapid City accrued 927 patients; 6 patients were on more than one clinical trial and were counted twice. Data includes CDRP prior accrual onto the STAR and cooperative group trials (RTOG and NCCTG) (n= 281).

[b] Includes accruals on prevention trials, STAR (n=9) and SABOR (n=300).

[c] Centinela Freeman accrued 60 patients; 3 patients were on two different types of trials and were counted twice.

[d] Singing River accrued 107 patients; about 20 patients were on two to four different types of clinical trials and were counted every time they participated in a trial.

[e] These patients were enrolled on UPMC PI-initiated trials via the University of Pittsburgh Cancer Institute (UPCI).

[f] UPMC McKeesport accrued 110 patients, 2 patients were on two different types of trials and were counted twice.

[g] This total includes about 30 patients that were counted more than once because they participated in more than one clinical trial. The total number of unduplicated patients accrued was 1,644 (see Table 5).

[h] Column and row percents do not total 100% due to rounding.

168/1678 = 10.0% RTOG accrual; 998/1678 = 59.5% Coop. Group accrual

2010 U54 Data**

42

- -

- -

72

28

13

155

** 9 months 2010 data only

18/155 = 11.6% RTOG

66/155 = 42.6% Coop. Group

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Total Patients Accrued by Race

TABLE 5 – CUMULATIVE NUMBER OF PATIENTS ACCRUED TO CLINICAL TRIALS BY RACE/ETHNICITY FOR ALL SITES (AS OF SEPTEMBER 30, 2009)

Race/Ethnicity	Total Number of Patients Accrued to CDRP Clinical Trials (%)		2010 U54 Data**
American Indian/Alaska Native	138	(8)	2
Asian	2	(0)	1
Native Hawaiian or Pacific Islander	1	(0)	0
Non-Hispanic Black or African American	100	(6)	17
Non-Hispanic White	1,071	(65)	130
Hispanic/Latino	331	(20)	0
Unknown	1	(0)	0
Total #	1,644[a]	(100[b])	150

[a] Includes patient accruals to clinical trials opened prior to CDRP: Laredo's accruals to SABOR (n-300) and STAR trials (n = 9) and Rapid City accruals to STAR and cooperative group trials (RTOG and NCCTG) (n=281).

[b] Column percents do not total 100% due to rounding.

** 9 months 2010 data only

572/1644 = 34.8% U56 minority accrual rate

20/150 = 13.3% U54 minority accrual rate

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Eligibility Rates for Screened Pts

TABLE 8 - NUMBER OF PATIENTS SCREENED (SCR) AND ELIGIBLE (ELIG) FOR CANCER CLINICAL TRIALS, BY FISCAL YEAR (AS OF SEPTEMBER 30, 2009)

*U54 Data – 9 months

Grantee Sites[a]	Patients Screened (FY07Q4 - FY09)		Patients Eligible (FY07Q4 - FY09)		Eligibility Rate[b] (%)	
Rapid City	1,601	579	457	94	29	16
Centinela Freeman	28	0	28	0	100[c]	0
New Hanover	228	256	84	116	37	45
Singing River	982	287	166	47	17	16
UPMC McKeesport	637	205	84	13	13[d]	6
Total	3,476	1,327	819	270	24	20

[a] Data were not available for Laredo.

[b] Eligibility rate is based on the number of patients eligible divided by the number of patients screened.

[c] Centinela Freeman did not screen all patients.

[d] Only includes data on the UPMC McKeesport site out of a total of five participating hospital at this CDRP site.

Accrual Rates for Eligible Pts

TABLE 10 –PATIENT CLINICAL TRIAL ACCRUAL RATES BY SITE (AS OF SEPTEMBER 30, 2009)

Grantee Sites[a]	Eligible Patients (FY07Q4 - FY09)		Patients Accrued (FY07Q4 - FY09)		Patient Accrual Rate[b] (%)	
Rapid City	457	94	343	42	75	45
Centinela Freeman	28	0	28	0	100	0
New Hanover	84	116	74	72	88	62
Singing River	166	47	87	23	52	49
UPMC McKeesport	84	13	68	3	81[c]	23
Total	819	270	600	140	73	52

[a] Data were not available for Laredo.

[b] Accrual rate is based on the number of patients enrolled onto clinical trials divided by the number of patients eligible for clinical trials.

[c] Only includes data on the UPMC McKeesport site out of five participating UPMC hospital sites.

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U56 Planning Phase Findings

U56 Phase Identified:

-- **Eligibility barriers:** shortage of trials, restrictive enrollment criteria; co-morbidities; advanced stage of disease; etc.

-- **Accrual barriers:** insurance, performance status, age, transportationstandard treatment preference; etc.

Therefore, new strategies and disparity appropriate protocols must be designed for minority/underserved populations

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U56 Planning Phase (2002 - 2009)

- Establish clinical research infrastructure at community hospitals
- Create community educational and outreach program
- Establish individual patient navigation program to address minority and underserved population needs
- Use Telesynergy® to facilitate mentoring, training and collaborations
- Increase presentations and publications on various aspects and components of CDRP program
- CDRP heightened awareness of cancer disparities in RTOG and establish annual NCI ASTRO Diversity Symposium

U54 Implementation Phase (2009 - 2013)

- Limited Competition RFA issued October 2008
- Five applications rec'd 12/08, reviewed 3/09
- Awards made August/September 2009

Goals:

- Expand minority/underserved patient accrual into all types of NCI clinical trials
- Develop strategies to address U56 identified barriers to accrual
- Disseminate best practices via publications and presentations at national meetings
- Continue efforts toward future program sustainability by securing non-NIH funding

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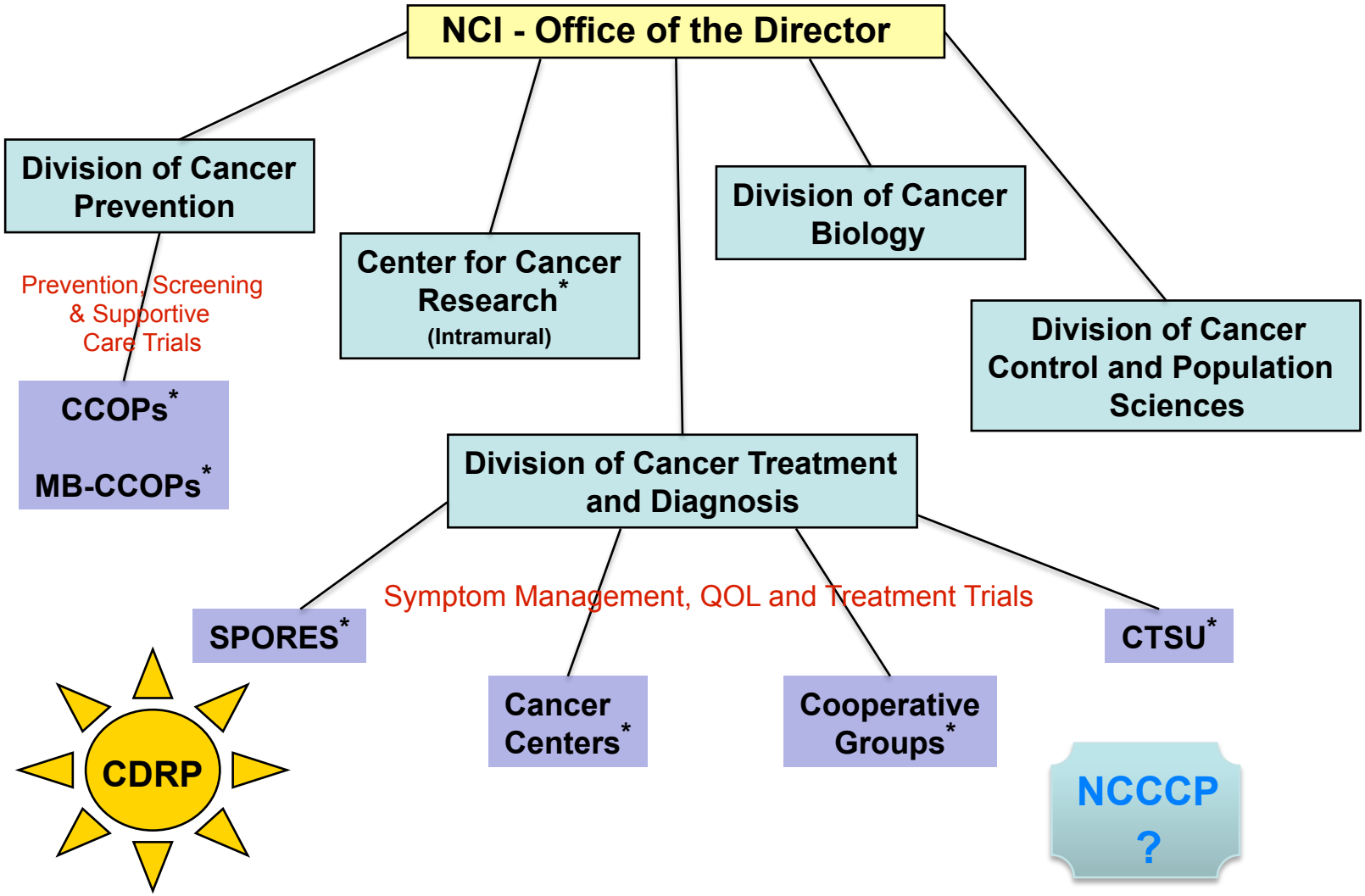
CDRP grantees will require new home after pilot program ends in 2013



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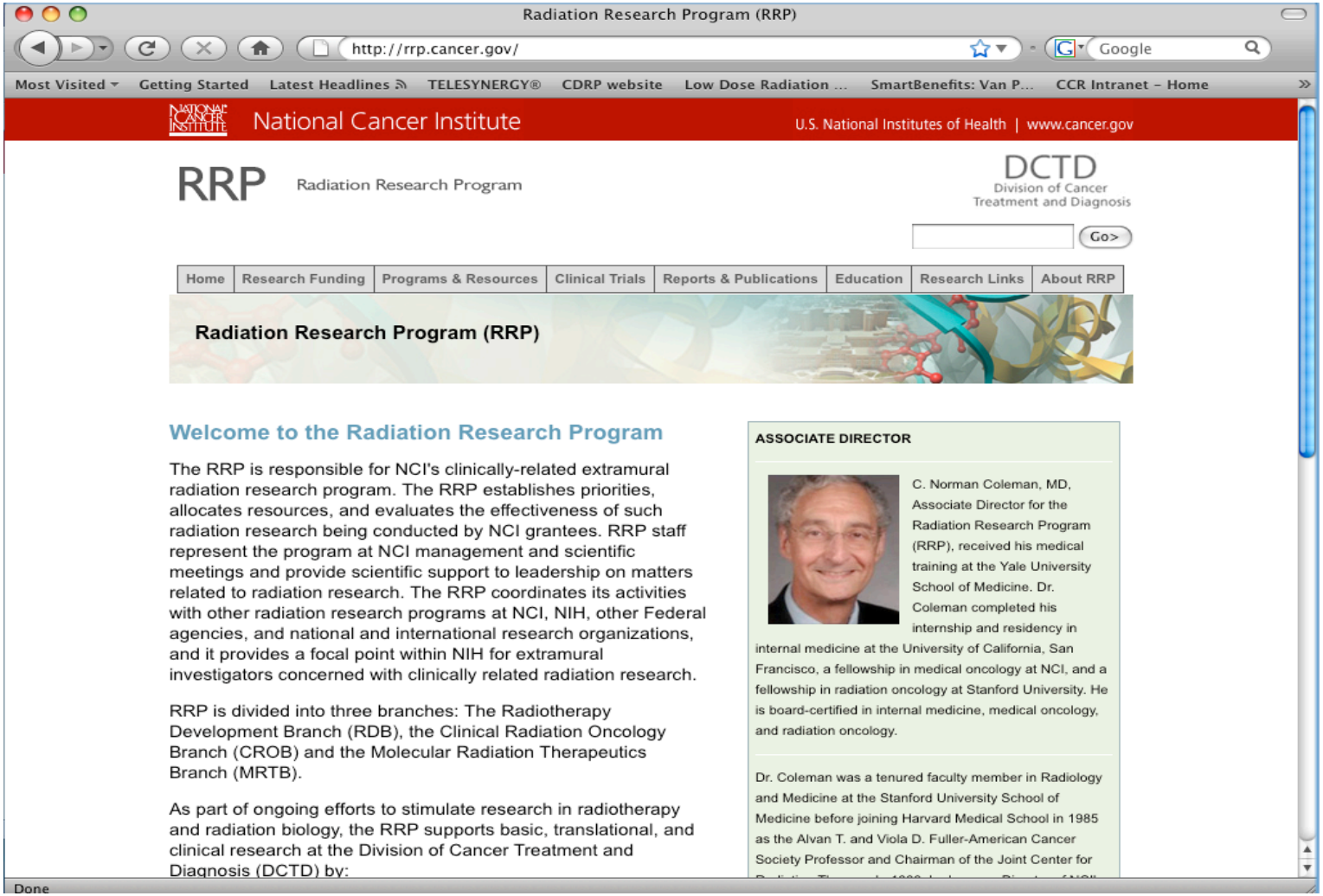
Updated Radiation Research Program Website

(http://rrp.cancer.gov)



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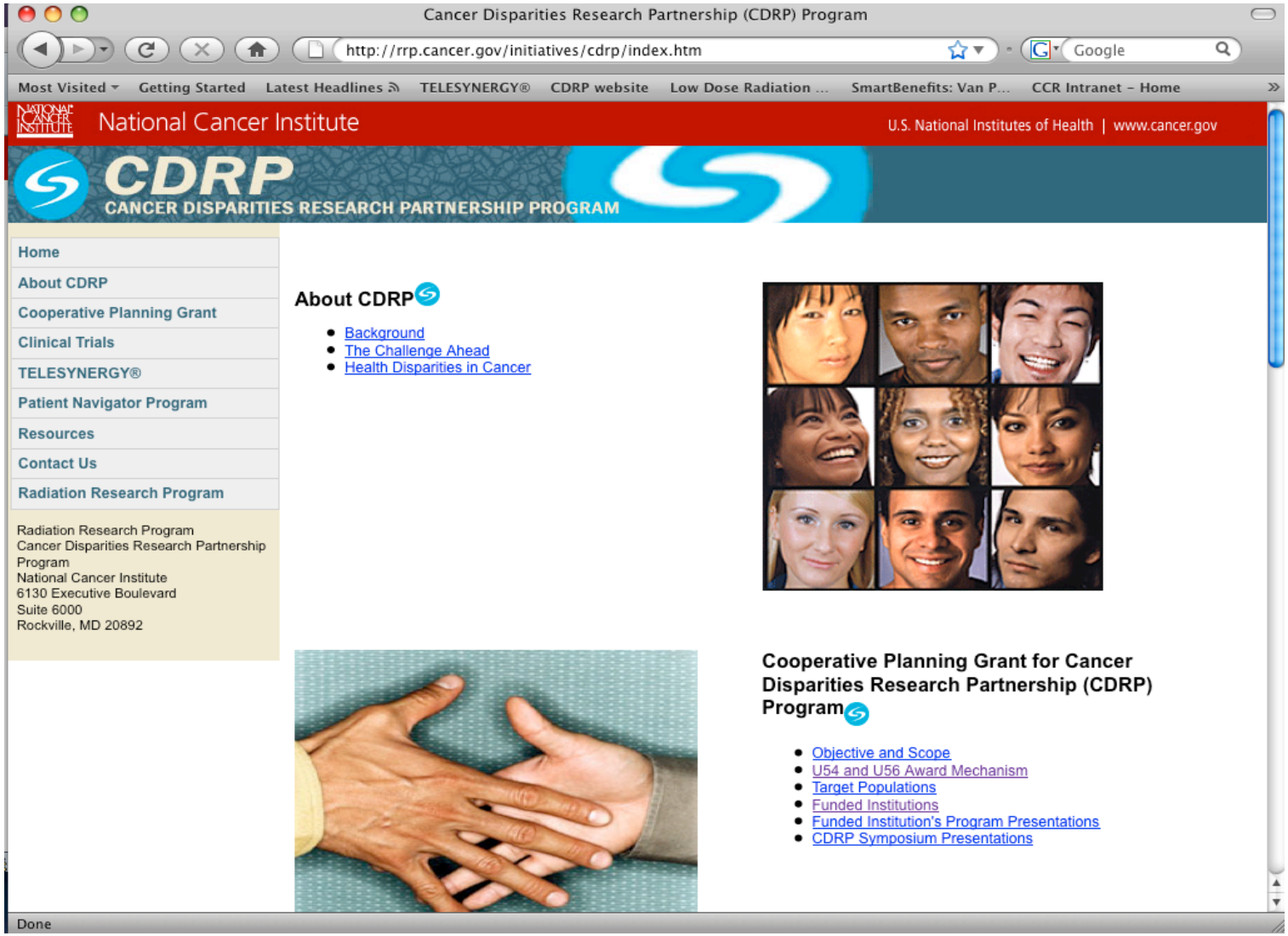
CDRP Website Within RRP Website

http://rrp.cancer.gov/initiatives/cdrp/index.htm



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